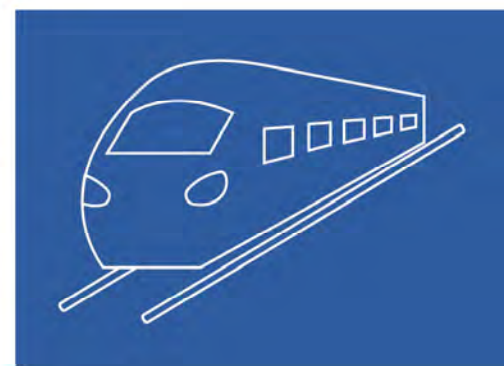
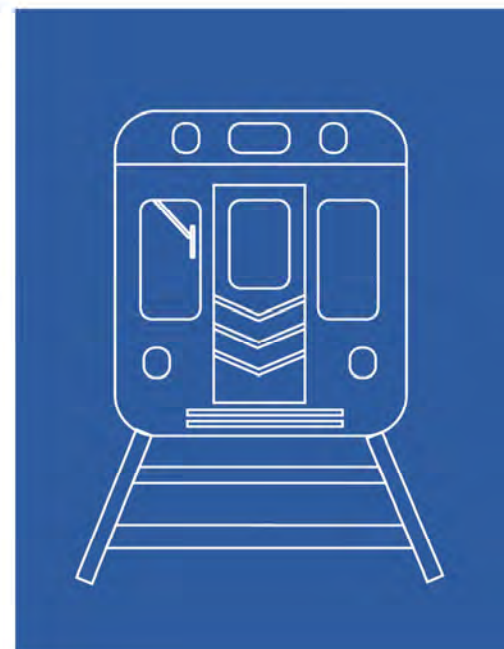
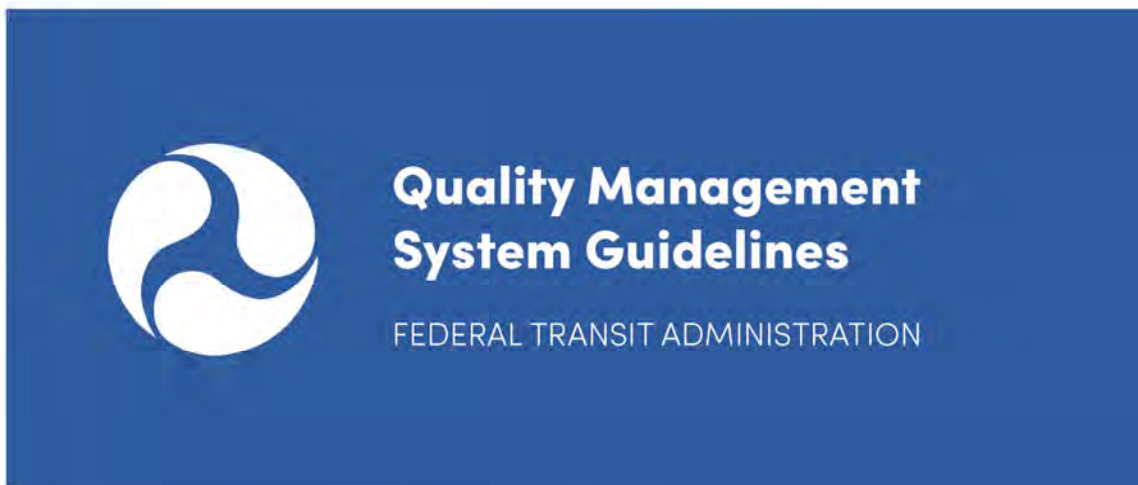
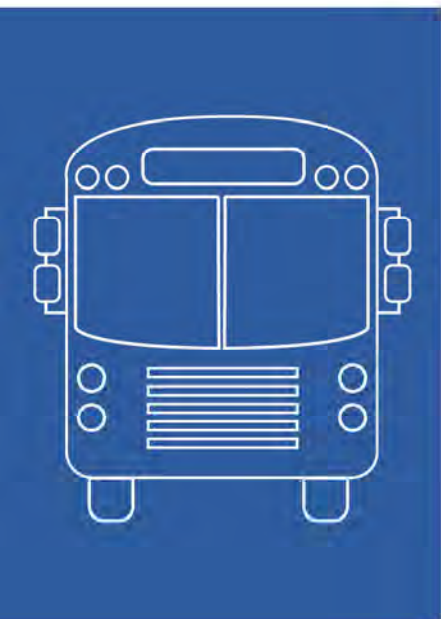




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List of Acronyms

AA	Alternatives Analysis
A2LA	American Association for Laboratory Accreditation
ACI	American Concrete Institute
ANSI	American National Standards Institute
AQL	Acceptable Quality Level
ASQ	American Society for Quality
ASCE	American Society of Civil Engineers
ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
AWS	American Welding Society
BLE	Blue Line Extension
BRT	Bus Rapid Transit
CA	Corrective Action
CAR	Corrective Action Report
CATS	Charlotte Area Transit System
CLRL	Central Light Rail Line
CM	Construction Manager
CM/GC	Construction Manager/General Contractor
CMC	Construction Management Consultant
CMQ/OE	ASQ Certified Manager of Quality/Organizational Excellence
CNYRTA	Central New York Regional Transportation Authority
CQA	ASQ Certified Quality Auditor

CQCS	Contractor Quality Control System
CQE	ASQ Certified Quality Engineer
CQI	Certified Quality Inspector
CSQE	ASQ Certified Software Quality Engineer
CTA	Chicago Transit Authority
DART	Dallas Area Rapid Transit
DB	Design-Build
DBOM	Design-Build-Operate-Maintain
DCD	Design and Construction Division
DOD	Department of Defense
DTCG	Denver Transit Construction Group
ESA	East Side Access
FD	Final Design
FFGA	Full Funding Grant Agreement
FHWA	Federal Highway Administration
FRA	Federal Railroad Administration
FTA	Federal Transit Administration
FTC	Franklin Transportation Center
GC	General Contractor
GEC	General Engineering Consultant
IEC	International Electrotechnical Commission
IFB	Invitation For Bid
ILAC	International Laboratory Accreditation Cooperation
IPS	Integrated Project Schedule

ISO	International Organization for Standardization
ITP	Inspection and Test Plan
LAP	Laboratory Accreditation Program
LRT	Light Rail Transit
MCP	Major Capital Project
MDMTA	Maryland Mass Transit Administration
MDT	Miami-Dade Transit
MRA	Mutual Recognition Arrangement
MTA	Maryland Transit Administration
MTACC	Metropolitan Transportation Authority Capital Construction
NCR	Nonconformance Report
NIST	National Institute of Standards and Technology
NVLAP	National Voluntary Laboratory Accreditation Program
NYCT	New York City Transit
OEM	Original Equipment Manufacturer
OP	Oversight Procedure
O&M	Operations and Maintenance
PE	Preliminary Engineering
PCGA	Project Construction Grant Agreement
PMO	Project Management Oversight
PMOC	Project Management Oversight Contractor
PMC	Project Management Consultant
PMP	Project Management Plan
PM	Project Manager (or Program Manager)

QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
RACI	Responsible, Accountable, Consult, Inform
REE	Rail Equipment Engineering
RFP	Request For Proposal
RTD	Regional Transportation District of Denver
SAS	Second Avenue Subway
SEPTA	Southeastern Pennsylvania Transportation Authority
SFRTA	South Florida Regional Transportation Authority
SPC	Statistical Process Control
SQA	Software Quality Assurance
SSGA	Small Starts Grant Agreement
SSMP	Safety and Security Management Plan
TCRC	Tri-County Commuter Rail
TRIMET	Tri-County Metropolitan Transportation District of Oregon
UPRR	Union Pacific Railroad
USACE	U.S. Army Corps of Engineers
VQS	Vendor's Quality System
VSDP	Vendor's Software Development Process
WMATA	Washington Metropolitan Area Transit Authority

Bibliography

ABS Consulting, *Root Cause Analysis Handbook, Third Edition*, Rothstein Associates Inc, Brookfield CT. 2014.

Aikens, C. Harold, *Quality Inspired Management: The Key to Sustainability*, Prentice Hall, Englewood Cliffs, NJ. 2010.

Andersen, Bjørn and Fagerhaug, Tom, *Root Cause Analysis – Simplified Tools and Techniques*, Second Edition, ASQ Quality Press, Milwaukee, WI, 2006.

ANSI/NCSL Z540. 3-2006, *Requirements for the Calibration of Measuring and Test Equipment*, National Conference of Standards Laboratories, Boulder, CO 2006.

American Society of Civil Engineers (ASCE), *Quality in the Constructed Project: A Guide for Owners, Designers, and Constructors*, Third Edition, ASCE, Reston, VA, 2011.

Arter, Dennis R., *Quality Audits for Improved Performance*, ASQ Quality Press, Milwaukee, WI, 2002

Association of American Railroads (AAR), *Manual of Standards and Recommended Practices – Section J - Quality Assurance M-1003*, Association of American Railroads, Washington, DC, 2019.

Blazey, Mark L., *Insights to Performance Excellence 2017-2018: Using the Baldrige Framework and other Integrated Management Systems*, ASQ Quality Press, Milwaukee, WI, 2017.

Bucher, Jay L., *The Quality Calibration Handbook – Developing and Managing a Calibration Program*, ASQ Quality Press, Milwaukee, WI, 2006.

Burke, Sarah E., Silvestrini, Rachel T., *The Certified Quality Engineer Handbook*, Fourth Edition, ASQ Quality Press, Milwaukee, WI, 2017.

Cianfrani, Charles A., Tsiakals, Joseph J., and West, John E., *ISO 9001:2015 Explained*, Fourth Edition, ASQ Quality Press, Milwaukee, WI, 2015.

Construction Management Association of America (CMAA), *Construction Management Standards of Practice*, Construction Management Association of America, McLean, VA, 2015.

Construction Management Association of America (CMAA), *Quality Management Guidelines*, Construction Management Association of America, McLean, VA, 2017.

Construction Project Management Handbook, Federal Transit Administration Report No. 0015, Washington, DC, 2012.

Cretu, Ovidiu, Stewart, Robert B., and Berends, Terry, *Risk Management for Design and Construction*, RS Means, Rockland, MA, 2011. Crosby, Phillip B., *Quality is Free: The Art of Making Quality Certain*, [Paperback], New American Library, New York, 1980.

Coleman Sr., Lance B., *Advanced Quality Auditing – An Auditor’s Review of Risk Management, Lean Improvement, and Data Analysis*, ASQ Quality Press, Milwaukee, WI, 2015.

Crosby, Phillip B., *Quality is Still Free: Making Quality Certain in Uncertain Times*, McGraw Hill, New York, 1995.

Crosby, Phillip B., *Quality Without Tears: The Art of Hassle-Free Management*, [Paperback], McGraw Hill, New York, 1995.

Crossley, Mark L., *The Desk Reference of Statistical Quality Methods*, Second Edition, ASQ Quality Press, Milwaukee, WI, 2007.

De Feo, Joseph A., Juran's Quality Handbook: The Complete Guide to Performance Excellence, Seventh Edition, McGraw-Hill, New York, 2016.

De Feo, Joseph A., Juran's Quality Essentials For Leaders, McGraw-Hill, New York, 2014.

Deming, W. Edwards, Out of the Crisis, [Paperback], The MIT Press Cambridge, MA, 2000.

Duffy, Grace L., and Westcott, Russell T. (editors), The Certified Quality Improvement Associate Handbook, Third Edition, ASQ Quality Press, Milwaukee, WI, 2015.

Duffy, Grace, The ASQ Quality Improvement Pocket Guide – Basic History, Concepts, Tools, and Relationships, ASQ Quality Press, Milwaukee, WI, 2013

Evans, James R. and Lindsay, William M., Managing for Quality and Performance Excellence, Tenth Edition, Cengage Learning, Boston, MA 2017.

Feigenbaum, Armand V., Total Quality Control, Fourth Edition, Revised, McGraw-Hill, New York, 2004.

Hutchins, Greg, Risk Based Thinking – CERM Academy Series on Enterprise Risk Management, Second Edition, 2018

ISO 10012:2003(E), Measurement management systems – Requirements for measurement processes and measuring equipment, American National Standards Institute, New York, NY 2003.

ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, American National Standards Institute, New York, NY 2017.

ISO 9001:2015, Quality Management Systems - Requirements, American National Standards Institute, New York, NY 2015.

ISO 9004:2018, Quality management -- Quality of an organization -- Guidance to achieve sustained success, American National Standards Institute, New York, NY, 2018.

Juran, Joseph M., Juran on Quality by Design: The New Steps for Planning Quality into Goods and Services, The Free Press, New York, NY, 1992.

Keller, Paul, Statistical Process Control Demystified, McGraw-Hill, New York, 2011.

Kubiak, T.M. and Benbow, Donald W., The Certified Six Sigma Black Belt Handbook, Third Edition, ASQ Quality Press, Milwaukee, WI, 2016.

National Cooperative Highway Research Program, NCHRP Project 20-68A, Scan 07-01: Best Practices in Project Delivery Management, Arora and Associates, P.C., Lawrenceville, NJ, 2009.

National Cooperative Highway Research Program, NCHRP Report 808: Guidebook on Alternative Quality Management Systems for Highway Construction, Transportation Research Board, Hapeville, GA, 2015.

Okes, Duke, Root Cause Analysis, Second Edition – The Core of Problem Solving and Corrective Action, ASQ Quality Press, Milwaukee, WI, 2019.

Orsini, Joyce Nilsson, The Essential Deming – Leadership Principles from the Father of Quality, , McGraw-Hill, New York, 2012.

Ott, Ellis R., Neubauer, Dean V., and Schilling, Edward G., Process Quality Control – Troubleshooting and Interpretation of Data, Fourth Edition, ASQ Quality Press, Milwaukee, WI, 2005.

Palmquist, Brian, An Architect's Guide to Construction – Tales from the Trenches Book 1, Quality-by-Design Software Ltd., Vancouver, BC Canada, 2015.

Phillips, Ann W., ISO 9001:2015 Internal Audits Made Easy: Tools, Techniques, and Step-By-Step Guidelines for Successful Internal Audits, Fourth Edition, ASQ Quality Press, Milwaukee, WI, 2015.

Project and Construction Management Guidelines, Federal Transit Administration, Washington, DC, 2016

Project Management Institute, A Guide to the Project Management Body of Knowledge (PMBOK Guide) - Sixth Edition, 2017.

Pyzdek, Thomas and Keller, Paul, The Handbook for Quality Management – A Complete Guide to Operational Excellence, Second Edition, McGraw-Hill, New York, 2012

Quantitative Risk Management and Decision Making in Construction, ASCE Press, 2017.

Robitaille, Denise, ISO 9001:2015 for Small and Medium-Sized Businesses, Third Edition, ASQ Quality Press, Milwaukee, WI, 2016.

Rumane, Abdul, Quality Management in Construction Projects, Second Edition, CRC Press, Boca Raton, FL, 2018.

Russell, J.P. (editor), The ASQ Auditing Handbook, Fourth Edition, ASQ Quality Press, Milwaukee, WI, 2012.

Russell, J.P., Pocket Guide to ISO 9001:2015, Fourth Edition, ASQ Quality Press, Milwaukee, WI, 2016.

Tague, Nancy R., The Quality Toolbox, Second Edition, ASQ Quality Press, Milwaukee, WI, 2010.

Third Party Contracting Guidance, FTA Circular 4220.1F, Federal Transit Administration, Washington, DC, 2013.

Transportation Research Board, Circular E-C090: Design-Build A Quality Process, Transportation Research Board, 2006.

Transportation Research Board (TRB), Special Report 179: Glossary of Urban Public Transportation Terms, Transportation Research Board, 1978.

Walton, Mary, The Deming Management Method, G.P. Putnam's Sons, New York, NY, 1988.

Westcott, Russell T. (editor), The Certified Manager of Quality/Organizational Excellence Handbook, Fourth Edition, ASQ Quality Press, Milwaukee, WI, 2013.

Wood, Douglas C. (editor), Principles of Quality Costs – Financial Measures for Strategic Implementation of Quality Management, Fourth Edition, ASQ Quality Press, Milwaukee, WI, 2013.

(Bolded items are suggested readings)



The Quality Management System Guidelines were originally developed in 1992 and updated in 2002 (then called the *Quality Assurance and Quality Control Guidelines*) and later in 2012. These *Guidelines* are for Federal Transit Administration (FTA) project sponsors that are undertaking design, construction, or equipment acquisition programs. They may also be used as a guideline for transit agencies in establishing a Quality Management System (QMS) related to their Operations and Maintenance (O&M) programs.

FTA requires transit agencies undertaking major capital programs (these are typically referred to as “project sponsors” [formerly called “grantees”] when applying for or working under FTA grants) to prepare a Project Management Plan (PMP), which includes a Quality Plan. The Quality Plan should be developed in concert with the PMP. Even for smaller projects, a Quality Plan can be a useful management tool for developing and specifying activities to ensure project quality.

For sponsors undertaking multiple projects, the development of a Project Quality Plan should be an outgrowth of a functioning QMS. A comprehensive QMS is comprised of a written quality policy, objectives, quality plan, written procedures, and support from both management personnel and other staff.

Chapter 1 provides an introduction to quality including relating these *Guidelines* to ISO 9001 standards, guideline objectives, definitions, and an overview of various other quality topics as they may relate to transit projects. Chapter 1 also includes a brief historical overview of quality, a description of quality as it relates to the project lifecycle, a description of quality costs and quality tools, and possible barriers to the successful implementation of a quality program.

Chapter 2 contains a description of FTA’s 15 essential elements of a QMS. The elements should be taken into consideration when developing a Quality Plan, Manual, or any related procedure. The 15 elements, originally derived from the 20 elements of the ISO 9001:1987 standard, are as follows:

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

This update to the 2012 *Guidelines* has placed additional focus on both internal and external organizational context (including stakeholders), as well as the review of risks and opportunities and resulting actions. It is important to note that the exact numbers and names of the 15 elements have been retained in this revision since many agencies and contractors have developed their Quality Plans that contain 15 sections or chapters with the same titles as the 15 elements.

Although it may be helpful to structure the quality manual or procedures in accordance with these elements as many agencies and contractors have done, organization of the quality functions for the organization or project should be tailored to the organizational needs and management structure of the transit agency itself. It is not mandatory that a Quality Plan be structured corresponding to the 15 elements, only that the Quality Plan incorporate the concepts of the 15 elements. Plans may also be structured in accordance with the ISO 9001:2015 standard.

Chapter 3 discusses alternative approaches to organizational structures for different types of projects. No matter what organizational structure is utilized on a project, or what consultants or contractors may be involved, the project sponsor has overall responsibility for the QMS and must maintain oversight and/or a Quality Assurance (QA) function on the project. It is important that quality personnel remain objective and independent from other project functions. Chapter 3 also includes an overview of the use of Independent Assurance Programs and sections on Test Lab Accreditation and Software Quality Assurance.

Chapter 4 discusses the development of a Project Quality Plan. Initially developed along with the PMP during the project planning phase, the Project Quality Plan is a living document, which evolves over the project lifecycle, going into appropriate levels of detail at each stage. Chapter 4 includes specific information on what the Project Quality Plan should cover during each of the following phases of the project lifecycle:

- Project Development and/or Requesting Entry into Engineering;
- Engineering and/or Requesting FFGA/SSGA;
- Bid/Award and/or Construction;
- Startup and Safety Certification.

When developing project-specific forms, procedures, or plans, it should be noted that existing agency quality documents can be tailored to fit the needs of the project through minor changes. This approach is often quicker than starting from scratch, and can also be more advantageous as it provides a better uniformity and more traceability to other organizational documents.

Several appendices provide more information that may be of help to transit agencies:

Appendix A provides examples of FTA's 15 essential QMS elements as contained in various agency quality manuals and/or procedures. These examples accompany text explaining why they were included. Each of the 15 examples is provided to illustrate how various agencies relate their quality documentation to the FTA elements. Sometimes, the text from these examples may not cover all aspects of that element as written in Chapter 2 of these *Guidelines*. However, they still meet the basic intent of that element.

Appendix B outlines the 15 elements as they may apply to an agency's Operations and Maintenance (O&M) program. Some agencies simply compartmentalize Operations and Maintenance from a project standpoint and only concern themselves with quality when the funding dictates it. Others are more progressive and staff quality from the agency level, which engages all executives.

Appendix C provides several case studies which stress the importance of quality in transit projects and can also serve as lessons learned for future projects.

It is important to remember that quality improvement need not stem from action taken to correct issues as they arise. Using the quality tools outlined in these *Guidelines*, transit agencies can work to continually improve their capital projects throughout the project lifecycle.



1.1 Objectives and Background

These Guidelines were first published in 1992, and subsequently updated in 2002, as the Quality Assurance and Quality Control Guidelines. In 2012, the Quality Management System Guidelines were published as the third update, with these 2019 Quality Management System Guidelines serving as the fourth and most recent update. The *Guidelines* have been developed and maintained under the Federal Transit Administration (FTA) sponsorship to assist each transit agency in developing its Quality Management System (QMS) and plans for its FTA-funded transit capital improvement projects. For this reason, these Guidelines are focused on quality management as it applies to capital projects, though it does cover many other aspects of quality in transit agencies. FTA regulations require each FTA funded major capital program to submit a Program Management Plan (PMP) for FTA approval. These regulations also stipulate that a Quality Plan must be referenced or included as part of the PMP.

FTA maintains oversight for the grants that it awards, but assigns the grant administration and management responsibility to the grant recipients, called project sponsors. FTA's Office of Program Management delegates the responsibility for oversight of nearly all capital grants to the appropriate FTA Regional Office.

The *Quality Management System Guidelines* is one of several initiatives undertaken by FTA to enhance the management of the projects that it funds. The initiatives have included guidance to transit agencies on topics such as insurance and risk management; the continued development of the *Construction and Project Management Guidelines*, and assignment of Project Management Oversight Contractors (PMOC) to perform oversight and provide input to FTA. Project Management Oversight means the monitoring of a major capital project's progress to determine whether a project is on time, within budget, in conformance with design criteria, constructed to approved plans and specifications and is efficiently and effectively implemented. The roles and responsibilities of the PMOC are defined in the FTA's Project Management Oversight Procedures (OPs).

The *Construction and Project Management Guidelines* and the *Construction Project Management Handbook* each include a brief description of Quality Assurance (QA) and Quality Control (QC) as a part of a management control system. They describe some aspects of both QA and QC as they apply to a Quality Program in engineering, as well as construction quality management.

This *Quality Management System Guidelines* document expands upon the Quality Program guidance contained in other documents. Its major purpose is to promote the development of a transit agency's QMS or FTA-funded project QMS consistent with contemporary FTA practices, to affect successful implementation of projects.

Before undertaking the original 1992 *Guidelines*, effort, information was gathered through the PMOCs to determine the state of Quality Programs for FTA funded capital improvement projects. Today, many of the larger transit agencies have mature Quality Programs and staffs both dedicated to and familiar with quality requirements and activities. In 2012, the title of the *Guidelines* was changed to refer to the QMS rather than QA and QC, because guidance is not only offered for these activities, but for the system as a whole, including how it is integrated with the management of the project itself in capital projects.

This chapter defines a number of quality concepts, gives a historic overview of their development and their relationship, and discusses quality in the context of project and construction management. This chapter also includes a description of what makes up an effective QMS; perspectives on quality from the standpoint of the service provider and user; a description of the inter-relationships and balances among quality, cost, and schedule; an overview of the barriers to quality; and suggested resolutions; and directions for using these *Guidelines*.

1.2 Quality Definitions

Following are definitions of various terms used in the quality field:

Table 1-1: Quality Term Definitions

Quality Policy	The overall quality intentions and direction of an organization with regard to quality, determined by top management. The ISO 9001:2015 quality standard specifies that a Quality Policy will be appropriate to the purpose of the organization, provide a framework for establishing quality objectives, and be communicated and understood within the organization.
Quality Objectives	Objectives or goals, related to quality. ISO 9001:2015 specifies that objectives should be measureable and consistent with the Quality Policy.
Quality Management System (QMS)	The American Society for Quality (ASQ) defines the QMS as “A formalized system that documents the structure, responsibilities and procedures required to achieve effective quality management.”
Quality Management	ASQ defines Quality Management as “The application of a quality management system in managing a process to achieve maximum customer satisfaction at the lowest overall cost to the organization while continuing to improve the process.”
Quality Procedures	Written instructions for implementing various components of the QMS. Procedures should identify what is to be done; who should do it; and how, where, and when it should be done.

Quality Plan	The typical form of the main document used in developing and implementing a QMS. The Quality Plan should contain the Quality Policy, objectives, and written procedures. In larger properties, there can be more than one Quality Plan. For example, there could be a corporate quality plan, divisional quality plans, and specialized quality plans for design, procurement, construction, operations, and maintenance activities, with each prepared by those responsible for the work.
Quality Program	The coordinated execution of applicable Quality Plans and activities for a project.
Quality Control (QC)	Techniques that are used to assure that a product or service meets requirements and that the work meets the product or service goals. Generally, QC refers to the act of taking measurements, testing, and inspecting a process or product to assure that it meets specification. It also includes actions by those performing the work to control the quality of the work. Products may be design drawings/calculations or specifications, manufactured equipment, or constructed items. QC also refers to the process of witnessing or attesting to, and documenting such actions.
Quality Assurance (QA)	QA involves all those planned and systematic actions necessary to provide adequate confidence to the management that a product or service will satisfy given requirements for quality. It emphasizes planned and systematic actions and are necessary to provide adequate confidence that preventive/continual improvement actions at a management level will result in a product or service that meets requirements. QA includes ensuring the project requirements are developed to meet the needs of all relevant internal and external agencies, planning the processes needed to assure quality of the project, ensuring that equipment and staffing is capable of performing tasks related to project quality, ensuring that contractors are capable of meeting and carrying out quality requirements, and documenting the quality efforts.
Quality Oversight	Oversight can be defined as watchful care or general supervision. Quality oversight can range from an informal process of keeping in touch with the QA organization to a second layer of QA activities, depending upon the circumstances. Quality oversight verifies the execution of the Quality Program.
Quality Audit	A documented activity performed in accordance with written procedures or checklists to verify, by examination and evaluation of objective evidence, that applicable elements of the QMS have been developed, documented, and effectively implemented in accordance with specified requirements. An audit should not be confused with an inspection or QC check. It is a primarily QA activity that involves some QC.

Major Capital Project (MCP)	A Project that: 1. Involves the construction of a new fixed guideway or extension of an existing fixed guideway; 2. Involves the rehabilitation or modernization of an existing fixed guideway with a total project cost in excess of \$100 million; or 3. The Administrator determines it to be an MCP because the project management oversight program may benefit the project sponsor. Typically, this means a project that involved the following: i. Generally is expected to have a total project cost in excess of \$100 million or more to construction; ii. Is not exclusively for the routine acquisition, maintenance, or rehabilitation of vehicles or other rolling stock; iii. Involves new technology; iv. Is of a unique nature for the sponsor and/or involves a sponsor whose experience indicates that the implementing agency may benefit from the oversight or technical assistance of a project management oversight contractor.
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1.3 A Historical Overview of Quality

Dating back to the early crafts, product quality was a very personal product characteristic. Craftsmen earned their reputation by producing quality goods for each customer. With the Industrial Revolution and mass production, the one-to-one relationship between craftsmen and customer was gone. Specifications or standards for how to produce a product became the substitute for the craftsman's personal touch. QC was the function of inspecting the end product to determine if it met the specification or standard.

Standards became important not just to ensure that pieces fit together, but also to ensure the safety of the final product. As early as 1914, the American Society of Mechanical Engineers (ASME) developed codes for boilers and pressure vessels. Use of these standards for boilers resulted in fewer failures, even as performance improved.

Quality standards began to be applied to the nuclear industry in the late 1940's, and in 1954, the ASME published ASME NQA-1, *Quality Assurance Program Requirements for Nuclear Facilities*. This publication listed eighteen criteria for a QA program. In the nuclear industry, QA refers to the entire quality process.

In the 1950's, the Japanese adapted the statistical QC procedures promoted by W. Edwards Deming, and the managerial performance approach advocated by Joseph M. Juran. These concepts combined with a highly educated Japanese work force, and with the Japanese approach to continual quality improvement, led to Japan establishing itself as the leader in quality in the electronics and automobile industries. The real push for Quality Programs in the United States came in the 1960's, when Secretary of Defense Robert McNamara introduced the concept in the Department of Defense (DOD). The idea eventually spread to the construction sector of DOD and the Corps of Engineers instituted its own program in the late 1960's.

The Japanese went beyond concepts of QC and reliance on inspection and testing, to the point where high quality work is expected from the start. Japanese corporations expect an extremely high level of quality from their suppliers, and long-term relationships are built with those suppliers that can meet quality expectations. The Japanese use management techniques to involve the entire work force in quality improvement efforts. They make a continuing effort to understand the desires of the customers to ensure

that they are “building the right thing as well as building it right”. The Japanese now have a program that encompasses a total QMS.

In the past several decades, many large companies have implemented other quality approaches, such as ISO 9001 and Six Sigma, a more statistical-based approach, which has additional focus on controlling quality through continual improvement. The FTA and these *Guidelines* refer to quality as an overarching system which includes aspects of both QA and QC, along with management focus on achieving objectives through continual improvement of its systems.

1.4 Quality in the Context of Project and Construction Management

The function of project and construction management is to assure acceptable quality while executing the project on time and on budget. For an FTA project sponsor, acceptable quality has several definitions, one of which is meeting the needs of the FTA, other stakeholders, and the public, as well as satisfying all of the regulatory and operational requirements outside and within the sponsor’s agency.

The major reason for emphasizing the need for a Quality Plan/Objectives, in addition to the PMP requirement, is to explicitly recognize the importance of quality, while keeping it both objective and separate from (while still integral to) other project management functions. The job of project management is to manage scope, schedule, budget, quality, risk, resources, stakeholders, and safety of a project. However, since quality measures are often best made from a separate, objective viewpoint, it helps to have a management structure that retains this objectivity. Some examples of management structures for various project types are shown in Chapter 3.

1.5 Quality Management System (QMS)

Transit projects can involve many processes that vary in nature: planning, engineering design, systems design, software development, construction, and manufacturing. The manufacturing industry, which generally utilizes processes that are repetitive in nature, can more easily make use of quality programs that are based on statistical QC techniques. The statistical nature of these types of quality programs facilitates process improvements through continual efforts.

Planning, engineering design, and construction, on the other hand, often involve “one of a kind” projects where a QMS that emphasizes effective management practices is more appropriate. Similarly, software development and systems design are related processes that each requires their own unique QMS and specialized quality tools and procedures.

1.5.1 Characteristics of a QMS

An effective QMS is not just one where good products and services are delivered; rather, it is one that continuously seeks to improve the products and services being delivered and the corresponding delivery processes used by the organization. In order to establish an effective QMS, the following characteristics are required:

- Leadership – Adopting a Quality Policy, instilling a culture that values quality, involving all levels of management in quality initiatives, identifying a Quality Manager (QM), providing resources and personnel to accomplish quality objectives, delivering products and services that always meet customer expectations.
- Design Quality and Prevention – Developing products and services that meet customer expectations and reduce life cycle cost.
- Strategic Quality Planning – Establishing a vision for the future of where and what the organization wants to be and developing a Plan to arrive at that destination.

- Focus on Customer Satisfaction – Clearly identifying internal and external customers, their requirements, and making decisions that support the commitment to meet those requirements.
- Continual Improvement – Identifying key areas for improvement, whether they are products and services or processes.
- Teamwork and Employee Participation – All employees participate to the best of their ability and within the bounds of their areas of expertise to deliver products and services that meet requirements for performance, cost, and schedule.
- Training and Development – All persons at all levels within the organization receive basic and advanced quality training relative to their functional and managerial responsibilities within the organization.



Figure 1-1: Quality and the Project Lifecycle

Quality should be involved in all stages of a project, including being an integral member of the transit agency's management organization, separate from projects themselves. It is important to note that individual elements and subcomponents of a QMS are introduced into projects at different stages, so quality does not start nor does it stop with the projects themselves. [Figure 1-1](#) illustrates the project lifecycle. Quality, along with safety, remains at the core of any project phase during the lifecycle, including project development/planning. Quality does not start/stop before and after design and construction, it is a constant.

1.5.2 Involvement

The goal of a QMS is to be pervasive throughout the transit agency. As a result, every person within the organization must participate to the extent that his or her job responsibilities dictate. This includes members of agency senior management, functional management, and project management; functional and office staff; and shop and field personnel. In addition, all consultants, contractors, and suppliers must adhere to the QMS. Some, such as testing labs and manufacturers, may have their own Quality Plan or certification, which must conform to that of the transit organization. Others may choose to adopt the agency's Quality Plan in some respects, or submit their own quality system to conform. In all of these cases, the consultant/contractor/supplier becomes an extension of the agency's QMS.

1.5.3 Implementation Process

In order to implement an effective QMS, the following general steps should be followed:

- Senior management must commit to the development of a QMS. All personnel should receive introductory and advanced training, as applicable, on general and specific quality topics.
- Interested parties/stakeholders should be identified and appropriately managed.
- Organizational objectives must be defined and followed.
- Customer expectations and requirements must be defined.
- Data related to the products, services, and the delivery processes must be gathered and analyzed. The results of the analyses must be used to improve services.
- Feedback must be provided to the responsible managerial and functional areas for further process improvement.

1.5.4 Tools

There are many tools available to Project Managers (PMs), Program Managers, project controls staff, and quality personnel to solve problems, control processes, improve products and services, and assure project success. A summary of those tools may be grouped into two broad categories:

1. Statistical Quality and Process Control Tools:
 - Cause and Effect Diagrams (also known as Fishbone/Ishikawa Diagrams)
 - Flowcharts
 - Checksheets
 - Pareto Diagrams
 - Histograms
 - Control Charts
 - Scatter Diagrams
 - Affinity Diagrams
 - Prioritization Matrices
 - Activity Network Diagrams
 - Acceptance Sampling
2. Project-related Tools
 - Stakeholder Register
 - RACI Chart
 - Pre-Activity and Coordination Meetings
 - Progress Meetings
 - Quality Meetings
 - Meeting Minutes and Action Item Lists
 - Partnering
 - Constructability Reviews
 - Design Discipline Reviews
 - Interdisciplinary Coordination Reviews
 - Value Engineering
 - Risk Assessment
 - Probability Distributions
 - Tornado Diagrams
 - Status Reports

- Inspections
- Nonconformance Reports
- Corrective and Preventive Actions
- Brainstorming
- Benchmarking
- Peer Reviews
- Quality Audits/Oversights

1.5.5 Root Cause Analysis

Many of the tools identified in Section 1.5.4 will assist the PM or project management team in identifying quality and other problems. Once a problem is identified, it is necessary to determine the cause of that problem. Sometimes the cause is not so obvious and the PM or quality staff must look further to determine the actual cause. It is important to note that there are often cases where a direct “cause” is apparent, but the actual cause is an issue that stems from the same root cause. For that reason, this process is known as Root Cause Analysis.

Root Cause Analysis is the concept of analyzing a problem beyond the obvious symptoms manifested by the problem, and identifying the actual cause of the problem. A piece of equipment that is not able to produce product to the specified tolerance, at first glance, may appear to require adjusting, or replacement. However, the root cause of the problem could very well be operator error, design errors and/or omissions, unrealistic requirement(s), incorrect material(s), factory conditions, or some combination of all of these (sometimes there may be more than one root cause). Fixing the most obvious condition may not solve the actual problem and could result in further complications or delays. Consequently, all possible conditions and combinations must be explored before a problem can truly be eliminated. Note that this is true whether the problem involves a piece of equipment, a process, a system, or an individual.

One useful technique for determining root cause is the “5 Whys”, used in many organizations and originally developed by Japanese industrialist, Sakichi Toyoda. This technique suggests that one should continue to ask “why” in order to properly identify an issue’s root cause. Although the technique suggests that one should ask this question five times to determine root cause, the question may be asked more or fewer times in practice, depending on the issue. The point of the technique is to remind the user of the depth that cause-effect relationships can have, and how that depth may not always be apparent. The actual root cause, when discovered, will often point towards a process or system issue. A tool often used in root cause analysis is the Cause and Effect Diagram (also known as the Fishbone or Ishikawa Diagram).

1.6 Quality from Service Provider and User Perspectives

It is important to take into account differing perspectives with regard to quality in the transit industry, specifically that of the service provider (see Section 1.6.3) and the user (see Section 1.6.4). Depending on what a person sees or values in a product, or process, or project, the definition of quality can vary vastly. It is virtually impossible for all parties to agree on one definition that satisfies everyone, due to their different places in the organization and their focus in the project. Given the inherent “subjective” nature of the definition of quality, it is often important to identify specifications for acceptance, or Acceptable Quality Levels (AQLs).

Quality objectives are more often met (or exceeded) when agencies employ detailed performance specifications in their procurement documents. By focusing on the functional elements of the end product, rather than the detailed characteristics of each subcomponent, the owner agency provides the

contractor/manufacturer with the needed flexibility to utilize its expertise in delivering a quality product that will not only meet the owner agency's expectations, but do so in a cost effective manner.

1.6.1 Product Characteristics

Every project has its own unique objectives and product characteristics or design features, even in those cases where the project involves similar product deliveries, such as buses or rail vehicles. A quality project or product is one that delivers to the project sponsor all of these features in a timely, cost effective manner. Not only must the product contain the requisite features, but also these features must effectively integrate and operate within the surrounding infrastructure in which the product will be used. As a result, the quality of the system or product should be evaluated, not as a stand-alone unit, but as an integrated system. Additionally, the delivered project or product should be evaluated in light of its associated support materials, such as documentation, training, test equipment, and spare parts. Although the user and service provider will view most of the product characteristics similarly on the surface, the underlying product characteristics and support material will not be viewed at all by the user. Individual product characteristics are too numerous to list, but may be broadly described as features related to the product's design and its associated support materials.

1.6.2 Service Characteristics

In addition to product characteristics, each transit capital project will require its own unique service characteristics. These service characteristics, when viewed by the service provider, will differ from those that will be expected by the user of the system. They differ in the sense that they represent the service delivered by the consultants, contractors, suppliers, etc. on the project. The user, on the other hand, views service characteristics by how well the service provider performs. Although some of the language that describes quality may be the same, e.g., on-time performance, the deliverer of the service will differ. Essentially, in one case the project sponsor is the recipient of the service and in the other case the sponsor is the deliverer of the service. Some of the service characteristics are:

- Reliability
- Dependability
- Availability
- Responsiveness
- Competence
- Courtesy
- Credibility
- Cost
- Security
- Accessibility

1.6.3 The Service Provider

The service provider is generally the transit agency or port authority that provides transit services to the public. The project sponsor and transit agency are generally one and the same. However, within the transit agency is a broad range of functional and administrative departments, all of which are typically customers and service providers to one another. For example, the construction management and engineering departments are typically involved in the procurement of systems and equipment that will be used by the operations department to deliver service to the riding public. Thus, the construction management and engineering departments are providing a service to the operations department that is providing a service to the public. Reversing the process, the operations department must provide their

operating requirements to the construction management and engineering departments so that they can be translated into contract specifications.

At the opposite end of this cycle is the maintenance department that also provides a service to the operations department. Each of these departments, along with all those departments not explicitly mentioned, report to or provide a service to the administration of the transit agency. Thus, it is safe to assume that every individual in the transit agency is a “service provider” in some capacity – operations, engineering, construction, maintenance, procurement, etc. A department that receives a service from another department is an internal customer.

1.6.4 The User

The user of the system is the public. In most cases, the public has the option to use or not use the services offered by the transit agency. Thus, the transit agency is competing for the dollars that will be spent by the public on transportation. These dollars are vital to the long-term success of the transit agency and thus, the user is a necessary component to that success. The public is one of several external customers.

1.6.5 Benefits to the Service Provider

When transit projects are successfully accomplished in a quality fashion, they offer the following benefits to the service provider:

- Successful, within-budget, on-time projects
- Reliable, safe, dependable equipment
- Effective, easy-to-use support materials
- Lower life cycle costs for materials, maintenance, etc.
- Involved, interested, satisfied work force
- Increased ridership
- Opportunities for growth
- Increased funding
- Improved image
- Transit-supporting public

1.6.6 Benefits to the User

When transit projects are successfully accomplished, they offer the following benefits to the user:

- Transportation that is accessible, easy-to-use, reasonably priced, reliable, safe, and dependable
- Transit alternatives that offer less stress and more peace of mind

1.7 Inter-relationships and Balances among Quality, Cost, and Schedule

1.7.1 Quality Attributes or Dimensions

As noted in Section 1.6 above, the definition of quality varies depending on who is doing the defining, be it the project sponsor, customer, consultant, contractor, or supplier. Nevertheless, it is imperative that the sponsor clearly identify the “attributes or dimensions of quality” in its contract specification and purchase orders. By so doing, the project sponsor can make clear to its consultant, contractor, or supplier its quality expectations and that it will maximize the probability that the product or project that it is procuring will satisfy its needs. Examples of quality attributes that can and should be specified include:

- **Performance** – A project’s main operating or functional characteristics
- **Conformance** – How the project will be measured as meeting the contract specification

- **Reliability** – The mean time or distance between failures
- **Maintainability** – The mean time to repair
- **Availability** – The percent of time the system is available for service
- **Aesthetics** – Appearance, color, etc.
- **Features** – Functionality, beyond the main operating or functional characteristics
- **Durability** – Ability to adapt to ambient conditions
- **Safety** – Freedom from hazards
- **Warranty** – Guarantee of freedom from defects for a specified period of time
- **Service Life** – Expected time prior to major overhaul of the system

In addition to specifying these quality attributes, it is imperative to specify the support materials that will allow the service provider to cost effectively maintain the system in a manner that will assure continued delivery of quality service to the user of the system. Examples include:

- **Documentation** – Drawings, procedures, maintenance and operator manuals
- **Training** – Maintenance (primary and secondary) and operator
- **Test equipment** – Primary and secondary
- **Recommended** staffing levels
- **Spare parts**

1.7.2 Quality Costs

Quality costs fall into two major categories: the price of conformance and the price of non-conformance. The price of conformance is also known as the cost of detection and can be further divided into prevention costs and appraisal costs. The price of non-conformance is also known as the cost of lesser quality and can be further divided into internal failure costs and external failure costs. [Table 1-2](#) and [Table 1-3](#) identify examples of each of these categories.

As shown in Tables 1-2 and 1-3, quality costs cover a wide spectrum and occur during all phases of the project. Although many nonconformance costs are borne by the contractor, the project sponsor may also experience unwanted costs as a result of non-conformance, such as loss of revenue, project personnel cost increases due to longer project duration, and extra costs associated with work performed by the sponsor's own personnel (force account) supporting the contractor. In addition, overall life cycle costs for such items as maintenance and spares will typically be higher for the project sponsor as a result of non-conformance issues that could not be resolved.

Costs associated with conformance quality activities include design, process and document control, inspection and testing, and audits and training.

Table 1-2: Quality Costs - Price of Conformance/Cost of Detection

Prevention Costs (Associated with assuring the product or project meets requirements)	Early establishment of objectives Stakeholder engagement Design analysis & reviews Constructability reviews Training Prototyping Systems analysis Planning activities Value Engineering Preparation of: • Project Management Plan (PMP) • Quality Plan • Risk and Contingency Management Plan • Safety and Security Management Plan (SSMP) • Real Estate Acquisition Management Plan
Appraisal Costs (Associated with determining the degree of product or project conformance)	Audits Design checking (disciplinary, interdisciplinary, and constructability) Supplier inspection Incoming inspection In-Process Inspection Final Inspection Field inspection Testing Reliability/maintainability/safety analysis & testing

Table 1-3: Quality Costs - Price of Nonconformance/Cost of Lesser Quality

Internal Cost of Defects or Failures (Associated with problems discovered prior to product or project delivery)	Assessment costs Scrap Repair Rework Downtime Schedule delays Cost of extended financing
External Cost of Defects or Failures (Associated with problems discovered after product or project delivery)	Warranty repair costs Product recalls Customer complaints Product liability costs Transportation costs Labor, equipment, and materials Decrease in ridership

1.7.3 Balancing Quality, Costs, and Schedules

It is evident from [Table 1-2](#) that the conformance activities are not just related to quality, but also fall into the category of good project management practices. Thus, it is difficult to clearly define how much is being spent on quality activities. Nevertheless, industry studies have shown that preventing defects avoids or reduces unwanted project costs and improves delivery performance. One rule of thumb is that every dollar spent on prevention saves ten dollars in appraisal and failure costs. Further, quality expert Philip Crosby, in his 1979 landmark book, *Quality is Free*, espoused the philosophy that the cost of poor quality is greater than the cost of preventing it. Thus, he concluded that quality improvement efforts will more than pay for themselves.

Project sponsors are generally both consumers and providers of products and services. If the sponsor accepts a poor design or approves nonconforming workmanship that does not satisfy its own requirements, it can be certain that the resulting product or service will not meet the requirements of its customers, the public. This can have serious consequences resulting in the loss of ridership, the potential for liability, the loss of productivity, and an increase in life cycle costs.

Quality-related efforts are beneficial to the success, overall cost, and delivery performance of the project; therefore, PMs must demonstrate diligence when making decisions that affect the quality-related efforts outlined in the 15 quality elements.

1.8 Barriers to Quality and Suggested Resolutions

1.8.1 Management Awareness

Managers have the responsibility for guiding the organization. They set the direction for the organization, establish the goals, and inspire the attitudes that drive their individual teams toward accomplishing the organization's mission. Most employees will focus on issues that they believe are of primary concern to their managers. This attitude moves up and down the chain of command. There is no doubt that management is interested in providing quality products and services to their clients; however, the degree of interest is directly proportional to the actions of management. Simply put, actions speak louder than words and merely saying that a manager is interested in quality is not enough. Rather, managers must:

- Establish a Quality Policy, quality objectives, Quality Plans and quality procedures/work instructions
- Provide leadership of, and actively participate in, business/quality initiatives
- Provide the necessary resources to accomplish project/quality objectives
- Install an infrastructure that assures contractual/quality requirements are accomplished
- Make decisions that support an emphasis on quality and long-term goals

1.8.2 Cost and Schedule Concerns

At the project level, PMs are still faced with day-to-day decisions that must balance their short-term requirements with the agency's long-term goals. Furthermore, although Section 1.7 purports that the long-term benefits of quality far exceed the short-term costs, PMs are generally evaluated annually on their short-term performance. This may tend to impact their decision-making. The following **suggestions** may help to mitigate this concern:

- Senior management should be educated as to the wisdom of focusing on quality and the need to keep encouraging it;
- Life cycle costing should be used to evaluate decisions in lieu of simply using project costs;

- Senior management should support decisions that favor long-term cost considerations rather than short-term project costs;
- PMs should be evaluated on the long-term implications of their decision-making;
- Project quality management should be organized so that decision-making is reported to, and can be supported by, transit agency quality management;
- Project objectives should be clearly established, and decision-making, when possible, should be directed toward meeting these overarching objectives.

1.8.3 Resistance to Change

Many people and organizations are apprehensive of change and consequently are slow to change. It is usually when the negative consequences of not changing outweigh the consequences of changing that change takes place. In fact, it was only after the Japanese auto industry successfully applied quality improvement concepts and posed serious competition to the American auto industry that quality began to make serious strides in the United States. Thirty years later the FTA required project sponsors to incorporate quality concepts in their projects and the result has been the successful application of these concepts and improved project performance. Thus, we can see how slowly change can take place.

Even though significant strides have occurred, there is still room for improvement in the transit industry. Some of the rules suggested by quality guru Joseph Juran to avoid resistance to change include:

- Select the right time to start
- Work with the recognized cultural leadership
- Start with small quality-related initiatives
- Provide participation in quality-related activities at all levels within the organization
- Provide enough time for change to take affect
- Avoid surprises that can negatively affect the outcome
- Treat people with respect and dignity
- Deal directly with the resistance

1.8.4 Lack of Training

An effective QMS involves all personnel at all levels within the organization and even personnel outside the organization, especially those entities that supply funding. Everyone within the organization should be trained in order to know what role he or she plays in implementing an effective system. Training should start with senior management and work its way down into the organization. The quality department should receive parallel training in order to be in a position to help implement initiatives and provide additional levels of leadership and further training within the organization. At the project level, the entire project team should be trained regarding the unique quality requirements of the project. As the project evolves, training should be expanded to include consultants, contractors, and suppliers, as required. Inspectors and other personnel may require specialty training or certification when performing critical functions, such as welding or inspecting pressure containers, etc. Finally, training is not a one-time event. Rather, it is an on-going process that helps to assure that all members of the organization, in general, and the project team, in particular, can successfully implement and assure the success of the organization's or project's quality goals and requirements.

1.9 How to Use These Guidelines

Transit agencies should use these *Guidelines* to develop their Quality Plans. In order to develop an effective Quality Plan an agency should:

1. Read these *Guidelines* in order to understand what constitutes a Quality Plan.
2. Seek advice and counsel from the regional FTA representative and personnel from other agencies about the development of a Quality Plan.
3. Collect source material that may be useful and applicable.
4. Determine which of the fifteen elements apply to federally-funded project(s).
5. Review the examples provided in the Appendices.
6. Begin to establish the Quality Plan following the direction of these *Guidelines* and the applicable elements.

Agencies should develop unique Quality Plans and quality procedures that satisfy their individual needs. The FTA recommends seeking the advice and counsel of other agencies who have developed successful Quality Plans in order to learn from their experiences. However, it is important to note that the examples in these *Guidelines* and other sources should only be used as reference material and should not be copied directly.

Throughout the *Guidelines*, the words “should” and “may” are used with respect to the individual elements and subcomponents thereof. This is because this document provides guidance rather than requirements. However, sponsors of FTA-funded projects should note that the project quality plan functions as a part of the overarching PMP, which is approved by the FTA. For this reason, project sponsors should be aware that any use of the word “should” in these *Guidelines* may be deemed as a requirement by the FTA in evaluating those project quality plans or assessing the adequacy of the project or organizational QMS, commensurate with the size and complexity of the project.



CHAPTER 2: ESSENTIAL ELEMENTS OF A QUALITY MANAGEMENT SYSTEM

This chapter discusses the fifteen elements that are the basis for FTA's guidance regarding Quality involving design, procurement, manufacturing, and 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 recommended in order to determine which elements are applicable and warrant procedures.

FTA's guidance regarding Quality involving operations and maintenance is covered in Appendix B of these *Guidelines*.

Section 2.1, Background, describes the origin of the fifteen elements, other efforts to develop construction-oriented Quality 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 a Quality Plan and detailed quality procedures for each element:

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

The description of each element begins with text describing the core principles of that element in **bold**. Detailed guidelines for the element follow the bold text. The element description ends with an **example**, which presents a successful implementation of either some or all of the requirements in that element.

2.1 Background

The fifteen elements were originally adapted from the 1987 version of the American National Standards Institute Guidelines (ANSI/ASQC Q90 through Q94). The International Organization for Standardization's standards (ISO 9000 through 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 9000:1987** standard, which contained the twenty elements from which the FTA's fifteen quality elements are derived, has gone through four revisions:

- **ISO 9000:1994** emphasized quality assurance via preventive actions, instead of just checking final product, and continued to require evidence of compliance with documented procedures.
- **ISO 9001:2000** combined the three standards (9001, 9002, and 9003) into one, and was named ISO 9001:2000. Design and development procedures were required only if a company engaged in the creation of new products. The 2000 version sought to make a radical change in thinking by emphasizing the concept of process management. The Year 2000 version also demanded involvement by upper management, in order to integrate quality into the business system. This update also involved focus on continual improvement and data analysis and changed the numbering system from the 1987 and 1994 versions.
- **ISO 9001:2008** used the same numbering system as ISO 9001:2000 to organize the standard. As a result, the new ISO 9001:2008 standard looked very much like the ISO 9001:2000 standard. No new requirements were added. However, some important clarifications and modifications were made. More emphasis was placed on purchasing and documentation.
- **ISO 9001:2015** uses a new numbering system from ISO 9001:2008: This version addresses risks and opportunities associated with its contexts and objectives. There is more emphasis on service industries and less on manufacturing. ISO 9001:2015 uses the phrase "goods and services" instead of the term "product". There is a greater focus on management commitment and on the customer. Risk-based thinking is emphasized throughout the standard. Although Documented Information replaces Document Control and Records, it is still necessary to maintain document control and record keeping systems.

Table 2-1 shows the relationship of ISO 9001:1994 and the 2000/2008/2015 versions to the FTA's 15 elements. This table is an ideal cross-reference for the FTA, transit agencies, and companies who use the latest ISO standard's documentation format. They can be used as an aid in indicating that all of the required elements of these *Guidelines* have been properly addressed. ANSI and ISO Standards represent sound quality management practice. Evidence of the acceptance of these standards by industry is the proliferation of companies that have become ISO certified over the past twenty years. At the end of 2000, fewer than one-half million companies were certified to ISO 9000. By the end of 2018, more than one million companies from over 170 countries were certified to ISO 9001:2015.

The update to these *Quality Management System Guidelines* incorporates improvements from the revisions to the ISO standard since 1987, while retaining the elemental structure of the initial 1987 and 1994 revisions. The FTA has retained this structure as it has been proven to work well in the design and construction environment, and many agencies, consultants, and contractors have developed plans following this structure that do not require structural changes to conform to the revised ISO 9001

standards. It is not necessary that a Quality Plan contain the 15 elements by title as long as the Plan incorporates the content that is described in these *Quality Management System Guidelines*.

The fifteen quality elements are seen as good management practice to ensure quality of design, manufacturing, and construction services, as well as other transit agency functions such as operations and maintenance. They are applicable not only for quality programs of FTA-funded project sponsors, but also for organizations providing goods and services to them. In fact, many consultants and construction contractors have developed their Quality Plans based on the fifteen quality elements. The Second Avenue Subway (SAS) Project in New York City required each of their construction contractors to prepare their Quality Plan based on the fifteen quality elements. This provided a benefit of maintaining a consistent Quality Management System for a multi-billion dollar project.

Table 2-1: Comparison of FTA 15 Elements with ISO 9000

FTA-PA-27-5194- 12.1 Element Number	Title	ISO 9001- 1994 No.	ISO 9001- 2000/2008 No.	ISO 9001- 2015 No.
1.	Management Responsibility	4.1	5.1	5.1
2.	Documented Quality Management System	4.2	4.2.2	4.3
3.	Design Control	4.4	7.3	8.3
4.	Document Control	4.5	4.2.3	7.5
5.	Purchasing	4.6	7.4	8.4
6.	Product Identification and Traceability	4.8	7.5.3	8.5.2
7.	Process Control	4.9	7.5.1, 7.5.2	8.1
8.	Inspection and Testing	4.10	8.2.4	8.5.1
9.	Inspection, Measuring, & Test Equipment	4.11	7.6	7.1.5
10.	Inspection and Test Status	4.12	7.4.3	8.6
11.	Nonconformance	4.13	8.3	8.7
12.	Corrective Action	4.14	8.5.2, 8.5.3	10.2
13.	Quality Records	4.16	4.2.4	7.5.3
14.	Quality Audits	4.17	8.2.2	9.2
15.	Training	4.18	6.2.2	7.3

The American Society for Quality (ASQ) has been a leader in emphasizing quality throughout the design and construction community. ASQ's Construction Technical Committee, which was established in 1982, evolved into the Engineering, Architectural, and Construction Division in the early 1990's and then into the Design and Construction Division (DCD) in the mid-1990's. Currently, DCD membership includes many quality professionals from agency, consultant, and contractor organizations throughout the United States, Canada, and internationally.

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

The elements sometimes refer to generic organizational entities that could be the transit agency (or sponsor), the consultant, or the construction contractor. The following [Table 2-2](#), lists some of the generic organizational entities referenced in the quality elements:

Table 2-2: Organizational Entities in a QMS

Management	The subset of the organization responsible for managing the agency or project at the highest level (executive and/or project managers included). This is usually the project sponsor, but may also be a consultant to the project sponsor at the highest level.
Designer	The organization responsible for developing the design or design standards. This includes the sponsor itself when designs or design standards are developed in-house, and typically a consultant providing architectural/engineering services.
Purchaser	The sponsor or other organization responsible for specifying, contracting, and accepting requirements for goods or services.
Supplier or Vendor	Any organization providing services, products, or materials for agency capital projects. The supplier could be a product manufacturer, or a provider of raw materials.
Contractor or Consultant	Any organization providing services or products to a transit agency under direct contractual agreement. The contractor could be part of the project sponsor's organization in the case of force account work. For large contracts, the contractor/consultant will often consist of a joint venture with two or more contractors/consultants.
Subcontractor or Subconsultant	Any organization supplying services or products under contract to a contractor or consultant. The subcontractor/subconsultant would not contract directly with the transit agency, but with a contractor/consultant or another subcontractor/subconsultant.
Construction Management	An organization providing oversight of contractors. This may consist of individuals from the transit agency or consultant personnel.

2.2 The Fifteen Elements of a Quality Program

2.2.1 Element 1: Management Responsibility

The transit agency should establish and document a Quality Policy and a Quality Management System (QMS) that includes commitment, framework, and requirements for setting and achieving quality objectives for the organization and for each specific project. The organization should communicate, implement, and maintain the Policy at all levels of its organization. Management should designate a representative who will have independent authority and responsibility for ensuring that the Quality Policy and QMS is developed, implemented, maintained, and continually being evaluated and improved to sustain Quality. Management should also ensure resources needed for the QMS are available, identify those persons responsible for the quality assurance function

and should define in writing the responsibility, authority, and interrelation of those persons. There should be an established Quality Plan for the organization, as well as a project-specific plan on any FTA-funded project. Organizational and project-specific interested parties or stakeholders should be identified and managed at a level commensurate with their involvement and interest.

The responsibility for and commitment to the Quality Policy and the Quality Plan belongs to the highest level of management (see “Top Management” as defined in ISO 9000). Management should therefore declare and document its commitment to quality. Management should ensure that the Quality Policy and Quality Plan are understood, implemented, and maintained throughout the organization, and that they address continual improvement. *Note: If the Quality Program remains constant, it may stagnate; however, when continual improvement is part of the culture, quality remains an active part of the project.*

A management representative should be designated, who has the responsibility and independent authority to ensure that management's Quality Policy, objectives, and plan(s) is/are implemented and maintained and that the requirements and expectations of the *FTA's Quality Management System Guidelines* are achieved. This position should report to the highest position on the project sponsor or project organization chart to assure that quality is implemented properly and being managed organizationally and functionally independent of those having direct responsibility for the work being performed. Maintenance includes documented review of the Quality Policy and Quality Plan at regular intervals to ensure that they remain suitable, effective, and conform to the current version of these *Guidelines*.

The Quality Plan should set objectives and be developed based on these *Guidelines* and the organization's Quality Policy, which will be reviewed by top management and evaluated based upon available data and records, as well as against these *QMS Guidelines*. Large and/or complex projects may require a project-specific quality plan, and such a plan should be developed for any FTA-funded projects. *Note: For relatively small or simple FTA-funded projects, the quality plan may be included as a part of the PMP rather than a separate document.* Project-specific quality plans should also include project-specific quality objectives and document how the FTA's quality requirements and expectations for the project will be achieved and implemented.

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. *Note: the quality organization chart is separate from the overall project organization chart. The project chart includes staff that do not have responsibility for quality, and often will not go to the same level of depth for QC personnel that the quality organization chart will.* The chart should identify the Quality personnel 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 Quality personnel responsible for assuring quality must be organizationally and functionally independent of those having direct responsibility for the work being performed. This can best be accomplished when those ensuring or controlling quality report to the highest level of management.

Each organization involved in a transit capital project should be responsible for achieving its own quality. While consultants or contractors to the project sponsor can assume some responsibility for QA, this responsibility must not be completely delegated. The project sponsor should maintain a QA oversight capability to ensure that the QMS and supporting plans/procedures are working and being implemented accordingly at the agency itself and within the supplier and contractor organizations.

Many people, groups, or organizations have the ability to impact an organization/project or are notably impacted by that organization/project. These stakeholders are often critical to the successful operation

of the QMS. For this reason, it is important for management to identify stakeholders, analyze their expectations and their potential impacts, and develop management strategies to engage them effectively over time. This often involves proactive and continual communication and managing conflicting interests, among other considerations. Due to the impact that stakeholders can have on the success of a project, they should be identified during Project Development and managed through Project Startup.

Example:

In some quality programs that are considered a successful model for construction projects, the project sponsor maintains the independence of the contractors' quality processes as much as possible. The contractors maintain primary QC responsibility, as well as a QA responsibility of their own as part of their Quality Management System (QMS), but the project sponsor (or their PM/CM consultant) provides an independent oversight of the entire process, making them primarily responsible for QA.

2.2.2 Element 2: Documented Quality Management System

The transit agency should establish and maintain a documented QMS to ensure project quality objectives and plans are implemented and maintained and that the requirements and expectations of the FTA's Quality Management System Guidelines are satisfied. The QMS requirements should extend to the agency's consultants, contractors, and suppliers as appropriate. The scope of the QMS should be established by considering the boundaries and applicability of the QMS. The project sponsor should consider external and internal issues of the organization; requirements of the organization stakeholders; products and services of the organization.

Written Quality plans, procedures, and instructions should be developed and regularly reviewed/updated for activities affecting quality in design, procurement, manufacturing, and construction as applicable to the work performed. Quality procedures and instructions should also be developed for control of processes including design, interface coordination, inspection; testing; nondestructive examination; inspection, measuring, and test equipment; disposition of nonconforming product; corrective and preventive actions; risk analysis/mitigation; maintenance of quality records; quality audits; and training to assure requirements and expectations of the FTA's Quality Management System Guidelines are achieved. The quality procedures and instructions should contain examples of the quality records needed to demonstrate that documentation requirements are understood and that the procedures and instructions are being followed accordingly.

The plans, procedures, and instructions should contain a statement of their purpose and scope, and should contain any references to appropriate codes, standards, or specifications. Consideration should be given to the end user in developing the documents, whether they be internal or external to the organization. In developing the quality procedures and instructions, 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 design, construction or manufacturing, adequate time should be allowed to develop appropriate quality procedures and instructions for the new techniques and to train the personnel who will be using these new techniques.

Example:

Many successful projects have a top-tier Quality Plan which ties together the various elements, processes, and forms. This Plan is then updated over time to tailor the Quality Plan to the design, procurement, manufacturing, and construction aspects of the transit capital construction project as it progresses. Each transit agency determines which procedures and instructions are applicable to its specific capital

project(s) at any given time, and this is a helpful way to facilitate this determination throughout the lifecycle of the project(s).

2.2.3 Element 3: Design Control

During the identification of the project's applicable design criteria and development of the design quality requirements/design quality plan, the designer should include QA/QC provisions and references within the design quality plan. Furthermore, the designer should establish and maintain procedures in the agency or project's quality plan to control, verify and document that the design criteria, other specified requirements, and requirements of the client, stakeholders, and any other relevant regulatory agencies are met. Design Control includes associated quality control and assurance procedures to demonstrate and ensure that the design requirements and criteria are understood and met; planning and scheduling the disciplinary, interdisciplinary, and constructability design review activities and review comment resolution process; executing the design quality checking activities; and controlling design changes through project completion including planning, preliminary engineering/final design, and construction phases with associated quality procedures prior to implementing change of requirements.

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. Note that input requirements include those at federal, state, and local levels, as well as the project sponsor's design standards, stakeholder expectations/requirements, and any project objectives or requirements established during the project development phase.

Each group (e.g., discipline, consultant, etc.) responsible for the design of a defined element of the project scope should provide its own written quality control procedures. These should include the checking of drawings, calculations, specifications, and any applicable reports or software application code against design standards; the peer review of drawings; review for constructability and interdisciplinary coordination of the established design; and the documentation of such activities. Quality activities should be performed to verify compliance with established procedures and to determine the effectiveness of the procedures in meeting quality objectives and requirements.

The designer should prepare a design quality plan, which may be included in the quality plan or established as a separate document. The designer must also identify design QA/QC activities in the project schedule as distinct activities with realistic durations. These activities should roll up into an Integrated Project Schedule (IPS), when applicable. The design quality plan should identify who has professional responsibility for the different design elements, and who has the QC responsibility for each design element, including those individuals who are responsible for the review, verification, and approval of design documents and changes. The design quality plan should also identify the various organizational interfaces required among different groups producing and commenting on the design with an associated comment resolution process. It should specify the information to be documented, transmitted, and regularly reviewed. The design quality plan should specify how the operations and maintenance departments of the transit agency will interface with those producing the design. The development of this design quality plan and the design schedule are both quality functions which are carried out by the designer and are further described by the FTA in other documents. However, both the design quality plan and overarching IPS are to be developed and reviewed/updated in such a manner that ensures proper integration and should be subject to review by quality staff.

The design quality plan should also include provisions for QC checks of the integration of various elements of the design performed by subconsultants and QA oversight of the subconsultant's design QC process. Integration QC, completed before each submittal, should be specified in the design quality plan, with a requirement for record documentation indicating that integration coordination review has been completed for the subcontractors' design in addition to (or as a part of) the overarching interdisciplinary design review. Note that subcontractor and interdisciplinary coordination may not be a separate formalized review in all cases. It is also common for these reviews to be performed through ongoing coordination meetings attended by design discipline leads or subconsultant leads. In these cases, meeting records should be maintained as evidence of interdisciplinary coordination review.

The design quality plan and/or IPS should reference/include important design milestones that impact the overall project schedule. The milestones should be established with project objectives and FTA expectations having been taken into consideration. Any agency or stakeholder reviews of the designs at milestone submissions should document comments and resolutions by each reviewer. The records of these reviews should be maintained.

Design output should be checked and documented to demonstrate it meets the input design requirements, including acceptance criteria and appropriate regulatory requirements whether or not these have been stated in the design input requirements, and identify those aspects of the design that are crucial to the safe and proper functioning of the final product or system.

The designer should assign sufficient qualified personnel to verify the type and number of QC activities required to attain the quality of the design. Design audits should be undertaken to verify that the personnel assigned to perform design quality control activities are implementing the QC activities properly.

Quality Assurance procedures should be established for the identification, documentation, review, and approval of all changes and modifications to the design requirements through project completion including planning, preliminary engineering/final design, and construction phases prior to implementing change of requirements. Impacts of changes on other project elements should be assessed and accepted before any change is made. Procedures should ensure that all relevant personnel are notified of changes and understand resulting impacts. Additionally, procedures should be established to incorporate construction phase generated as-built information into the end-of-project design documentation. End-of-project documentation should be appropriately labeled and maintained by the sponsor for future use.

Example:

The project is typically baselined at the completion of the Preliminary Engineering (PE) Phase to allow accurate and comprehensive monitoring of any and all changes that follow and to establish the basis on which the project cost estimate is determined. In the case of Major Capital Projects (MCPs), the baseline for the project definition will be established during the initial Final Design phase activities but prior to the FTA considering a Full Funding Grant Agreement (FFGA), as it is those details (in drawings, specifications, contract packaging and scheduling) that must be carried forward and implemented. A similar approach is taken by the FTA with regard to Project Construction Grant Agreements (PCGAs) for non-MCP projects. The FTA's 2016 *Project and Construction Management Guidelines* state the following:

In an effective configuration management program, drawings are uniquely numbered and otherwise identified. Specifications follow a standard format and each [section, subsection and] paragraph is identified. Complete drawing lists are established and the total number of drawings, the titles of the drawings, the revision status, and the dates on which the drawings were approved are recorded. Procedures are established and changes to approved drawings or specifications should only be made

in accordance with [these approved procedures]. Permanent files are maintained of all contract documents that include historical information relating to all project changes. As the project is implemented, configuration management evolves to include the documentation of the completed improvement in terms of as-built drawings. Configuration management ensures that the correct, approved status of the evolving design is known or is available to all project personnel using that information. If done properly, configuration management ensures that replacement equipment or components capable of meeting the original equipment requirements can be procured at a later date.

2.2.4 Element 4: Document Control

Procedures for control of project documents should be established and maintained. The document control measures should ensure that all relevant documented information is current and readily available to all users who require them. Electronic document distribution and management should be managed in the same manner as hard copy distribution and management.

Document Control is more than maintaining a project's files. It includes controlling a master list of the latest project documents by a management group. Once a baseline set of documents is established by project management, any change to the baseline set is reviewed and accepted/rejected by the group and the documents are changed under the group's control. Controlled sets of documents are distributed to the members of the project team that requires them and a list of those holding the documents is maintained. The distribution, storage and retrieval of these documents, the elimination of obsolete documents, and control of changes to the documents is the function of this group. A document repository and/or distribution software may be utilized to assist in meeting these guidelines, but the agency should retain control of the software and/or documents in all cases (using contractor or consultant-controlled repositories is not advised).

Copies of the documents should be distributed so that they will be available at all locations that need them for effective functioning of the QMS. Distribution should be controlled in a way that approved documents are accessible in a timely manner, noting their revision and/or date information. Obsolete documents should be promptly eliminated from each work location or prominently identified that they are obsolete/have been superseded. All document changes should be reviewed and revised by the responsible parties. The project sponsor should verify that the change has been made.

When possible, the same authorized personnel who reviewed and approved the original documents should review changes to the documents and data, unless the control procedures specifically allow otherwise. Changes should be promptly distributed to all locations, in addition to the prompt update of the master list, enumerating the current revision of each document. Personnel in the field should have means of verifying that they have the most up-to-date versions of documents, either through the master list or other means. Often the master list is updated and maintained electronically in a document control software application or on a server with "read only" permission provided to authorized individuals. Access rights should be defined to prevent unauthorized access or alterations to the master list or any other controlled documents.

Following are examples of the types of documents requiring control:

- Drawings
- Specifications
- Inspection procedures
- Test procedures

- Calibration procedures
- Special work instructions
- Operational procedures
- Maintenance procedures
- Project Management Plans
- Risk and Contingency Management Plans
- Real Estate Acquisition Management Plans
- Quality Assurance Plans
- Rail and Bus Fleet Management Plans
- Safety and Security Management Plans

The agency should have standard naming conventions for drawings and specifications which apply to all projects that they undertake. These conventions should be provided to designers as inputs to their design. Other documents (plans, reports, etc.) may have methods of identification and control that vary by project, but they should be controlled in such a way that the revision or date can be used to identify the current version of the document in all cases.

Example:

A useful tool for keeping track of project documents is a software package that lists every document developed for the execution of the project. Examples of software packages include:

- | | |
|---------------|-----------------|
| • Documate | • Docuware |
| • DOORS | • Efilecabinet |
| • FileCenter | • MasterControl |
| • ProjectWise | • QualityOne |
| • SharePoint | • Templafy |

2.2.5 Element 5: Purchasing

The purchaser should ensure that the purchased service or product conforms to the purchaser's specified requirements that includes, as required, personnel competence and required qualifications of a supplier's, consultant's or contractor's personnel. The purchaser should require supplier quality programs appropriate to the work being performed and in accordance with these Guidelines and the purchaser's own quality requirements.

Purchasing requirements apply to all contractors, consultants, and suppliers, including construction contractors, and manufacturers. The purpose of this element is to ensure that purchasing requirements are clear and complete, that the contractor, consultant, or 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.

Contractor Quality Management efforts should be spelled out in the contract, either as a specification or as a section in the scope of work. Requirements should include, as a minimum:

- A Contractor Quality Plan that complies with these Guidelines
- A Contractor Quality Manager who is independent of production
- Contractor Quality Staff who can supplement the Quality Manager in inspecting and documenting the quality of the work
- An Inspection and Test plan
- Hold points or witness points, to halt the work at key milestones so that inspection and testing can occur before subsequent work makes inspection/testing more difficult or impossible
- Inspection and test status (see Element 10)
- Nonconformance procedures (see Element 11)
- Corrective/Preventive action procedures (see Element 12)
- Records of inspection and test results showing conformity with acceptance criteria (see Element 13)

The level of acceptable quality level specified in the contract will depend upon the complexity and importance of the service or product, and not all 15 elements of these Guidelines will necessarily apply. The contractor, consultant, or supplier may be allowed to use only its existing quality programs or standards or other quality standards if specified by the transit agency or any stakeholders. In addition, FTA Circular 4220.1F, *Third Party Contracting Guidance*, provides contracting guidance to assist project sponsors in procuring third-party services on capital projects receiving federal funding.

The purchaser may establish a documented list of acceptable suppliers, consultants, and contractors for the desired service or product. Established lists should be consistent with applicable procurement requirements and conscious of any applicable Suspension or Debarment lists. The purchaser should select suppliers, consultants, and contractors based on their ability to meet contract requirements, including quality and timeliness requirements. As such, the purchaser should have a systematic process in place to review the suppliers', consultants', or contractors' ability to meet these requirements (e.g., due diligence by the purchaser) either prior to, or immediately after the completion of the solicitation, but always prior to awarding a purchase order or contract.

The contract or purchasing requirements should clearly specify the requirements and expectations of the purchaser, including relevant standards, drawings, specifications, milestones, processes, procedures, tests, inspections, documentation, and approval criteria and personnel for all deliverables. The purchaser of services or products should ensure that the selected supplier/consultant/contractor fully understands and agrees to the contract terms and conditions and has the capacity to perform as required. For after-market purchases from an Original Equipment Manufacturer (OEM) where proprietary parts or systems are required, or in the case of sole source requirements, the purchaser should determine and define the salient characteristics of the product, and make sure that the supplier/consultant/contractor has quality standards and systems in place to meet these characteristics.

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

Where equipment procurement is involved, the purchaser should define, as appropriate, the means and methods for handling, storage, packaging, and delivery of the equipment and any timelines associated with such. The purchaser should establish procedures to receive, inspect, accept, store, and maintain equipment procured. All equipment that is damaged or is otherwise deemed unsuited for use prior to acceptance by the purchaser, should be documented and reported to the supplier or contractor immediately upon discovery. These quality standards should also be placed on the purchase of small parts from catalogue suppliers or distributors, with the responsibility for compliance and periodic testing shared by both the supplier and purchaser.

For all proprietary purchased equipment, software, materials, or similar, the purchasing requirements should specify that services or materials needed for the continual operation and maintenance of the purchased product will be available over the expected life of the system (e.g., in the case that a hardware or software supplier discontinues a product or service, information should be released to the purchaser which allows them to alternatively service the system to maintain a state of good repair).

Example:

One exemplary purchasing system has the agency's procurement department keeping an ongoing index of all suppliers', contractors', and consultants' compliance with the terms, conditions, and delivery of quality products or services, consistent with the requirements of awarded contracts or purchase orders.

All deviations or poor performance is recorded and maintained and becomes the basis for responsibility checks and requests for remedial action of the contractor, consultant, or supplier in future procurements. Further, for large capital construction and manufacturing procurements, the agency regularly conducts industry forums several months prior to advertising procurements, in order to go over contractual terms and conditions, and technical elements that might present problems to the contracting community and that may dissuade competition for or interest in the procurement. During these sessions, the agency lets the contracting community know how it plans to procure and manage the project, so that there are no surprises and all rules and expectations are clearly understood.

By taking proactive measures such as recording deviations and poor performance, and performing regularly scheduled audits of the procurement packages, the agency is able to continually review and update its policies, procedures, and template purchasing documents in order to maximize competition and foster collaborative relationships with the contracting community, which leads to better pricing, timely performance, and quality deliverables.

2.2.6 Element 6: Product Identification and Traceability

Measures should be established and maintained for identifying and controlling items of production, such as 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.

Product identification should be maintained to track materials, parts and components during fabrication. Acceptable techniques include:

- Stamping
- Tagging
- Physical Separation

Traceability involves connecting raw materials and final products to a specific test report, purchase order, or warranty. Product identification and traceability are best implemented during all production phases: from receipt of raw materials, through the manufacturing process and the delivery of final products to the buyer.

Raw materials should be traceable back to a specific batch number, shipment number, product data, purchase order, or packing slip. Storeroom or inventory tracking procedures should allow for items to be traceable back to a particular order number, batch number, test lot, or other pertinent source. Final assemblies should be marked with specific project numbers, model numbers, serial numbers, bar codes, or other acceptable markings. All pertinent product information related to each assembly should be accessible and retrievable.

Example:

Mill certificates supplied for rail must include the heat number that was stamped into the web of the rail it is intended to represent. Rail cannot be incorporated into the work until the specified mill certificates for that heat have been received, reviewed and accepted. Rail lacking the specified documentation and corresponding stamp would be considered nonconforming and could not be incorporated into the work until resolution is approved.

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. Transit agencies should also ensure that any activities related to the expectations of the FTA or other involved agencies are carefully monitored and controlled by identifying any necessary specifications and determining a method to verify that they are met.

To achieve accuracy and consistency in production, installation, and testing processes, the Quality Program should provide for:

- Documented work instructions, including acceptance criteria, where such are needed to ensure quality; use of suitable production, installation, and testing equipment; a suitable working environment; personnel qualifications and certifications; and conformance with referenced standards/codes and quality plans/procedures.
- Monitoring and controlling of processes and documenting product characteristics during production, installation, and testing.
- When required, changes to processes must be controlled.

Continuous monitoring and/or conformance with documented procedures is required during special processes, such as welding, nondestructive testing, and heat treatment, where the results of the processes will affect quality of the final product and cannot be verified at a later stage of the process.

Example:

A major issue in process control is to ensure that work is performed in the proper sequence. Documented work instructions can help with sequence control where there is complex work or when there are multi-disciplined interfaces.

For example, documented work instructions can be utilized in the control of the epoxy grouting of rebar into a concrete deck. The rebar would be used to hold poured concrete plinths upon which track is affixed. Two other related examples are the process of epoxy coating rebar at the fabricator's shop, usually before bending, and the repair in the shop before shipment to any damage to the coating that occurred during

the bending process. A related example is the process of epoxy coating in the field to rebar damaged in transit or during field bending or installation. For the epoxy coating to be effective, the application processes need to be monitored and performed in strict accordance with manufacturer's procedures.

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. Where appropriate, testing should be included in the specifications, including references to testing procedures, frequency and location, requirements for witnessing of tests, and where factory inspection and/or testing is recommended prior to shipping.

One decision that project sponsors must make is who should conduct inspection and testing. Will it be the project sponsor, an independent third party, the contractor, or some combination? The degree to which a project sponsor relies upon inspection and testing results conducted by the contractor may be driven by the following risk factors:

- **Form of contract:** Was the contractor selected through a Best Value procurement such as Design-Build or CM/GC, whereby Quality Management was part of the criteria, or was it a traditional low-bid procurement?
- **Size of the contract:** Are the bidders likely to be larger, sophisticated contractors with mature Quality Management Systems, or smaller bidders that are newer or have limited experience as a prime contractor?
- **Complexity of the project:** Is the work a straightforward project with few specifications, or a multi-discipline project with many types of specifications?
- **Type of Work:** Does the contract involve specialty or high risk work?

Regardless of the answer to these questions, project sponsors should consider placing some level of responsibility for inspection and testing upon the contractor, since they have the most access to and control over the work, backed up by a project sponsor-managed verification process that focuses on both the end-product and the contractor's quality management processes (see Element 5) for further discussion of procurement approaches and organization).

When products are delivered to the purchaser, it is the responsibility of the purchaser to establish measures to verify that the products 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 history 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 construction documents, Quality Plan, documented procedures, or referenced industry standard 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. Additionally, consideration should be given to ensuring that the entity conducting the inspection and/or testing has the proper credentials. For example, testing of construction materials such as concrete, backfill, welded metals, etc. generally requires a properly accredited lab, certified technicians, and thorough understanding of the testing standards.

Records of the various inspections and tests performed by the contractor, project sponsor, and third parties must be maintained to provide evidence that the product has passed inspection and/or test with defined acceptance criteria prior to installation.

Example:

Given that everything cannot be inspected, the project sponsor should consider a risk-informed process for priority planning of inspection/testing resources based on risk – the likelihood of failure and the seriousness should a failure occur. The following criteria are offered as guidance for what to emphasize in an effective inspection and testing program:

- Items or work affecting safety
- Items that will be covered or otherwise hidden from the view of maintenance personnel
- 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 and documented in the quality plan or other project documentation. A schedule of testing equipment that needs periodic and regularly scheduled recalibration should be required of the contractor(s) and be checked by the transit agency's QA personnel. Requests for Proposal (RFPs), Invitations For Bid (IFBs), and other procurement documents should require that all contractors' testing equipment have identified calibration intervals before they are utilized on the project.

Inspection, measuring, and test equipment used should meet the standards of accuracy for the measurements that are required. The equipment should be calibrated according to national standards or the equipment manufacturer's specifications when available/specified, and to other documented standards where neither are defined. The equipment should be recalibrated at regular intervals, and the recalibration properly documented. A record of the equipment calibration status should be maintained, including calibration date and due date. When feasible, a sticker should be secured to the equipment identifying calibration status. If this is not possible, then the calibration record should be traceable to the equipment through other means of identification. The record of calibration should be maintained and show the incoming and outgoing calibration metrics in order to determine the equipment's fitness for use prior to calibration.

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.

Example:

ISO 10012:2003, *Measurement Management Systems - Requirements for measurement processes and measuring equipment*, is the ISO standard that specifies generic requirements and provides guidance for the management of measurement processes and metrological confirmation of measuring equipment used to support and demonstrate compliance with metrological requirements.

Some examples of construction test equipment that require regular calibration follow:

- Devices that test for the tightness of structural bolts
- Concrete entrained air and slump measuring devices
- Soil density and plasticity, and gradation measuring devices
- Loading frames for soils, aggregates, and bituminous testing
- Coating thickness measuring devices
- Meggering devices that test resistivity to ground
- Ohm meters for testing resistivity
- Distance measuring equipment for surveying
- Pressure testing gauges for testing pressure capacity of piping systems

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, inspection records, test software, physical location, or other suitable means. The status identification indicates the conformance or nonconformance with regard to inspections and tests performed.

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. Photographic records of nonconformances can be useful.

Example:

While some operations may be easily tagged in the field as to their inspection status, it is good practice to keep a record set of drawings in the construction manager's or resident engineer's office with traceability through daily inspection reports, status reports, and payment documents. On major capital projects, the quality organization should keep test records to include conformances and nonconformances. It can be beneficial to maintain these records in a database for analysis and trending to help identify the root cause of nonconformances.

2.2.11 Element 11: Nonconformance

Procedures should be established and maintained for the immediate identification and control of nonconformances in order to prevent the unintended use or delivery of nonconformances that do not conform to their requirements. Appropriate action should be taken based on the nature of the nonconformance and its effect on the conformity of products and services. This should also apply to nonconformances detected after delivery of products and during or after the provision of services. Nonconformances should be identified, segregated/contained, documented, and evaluated to determine appropriate disposition. Disposition should be taken to address the instances of nonconformances detected, separate from the corrective actions taken to prevent recurrence.

At a minimum, nonconformances should be controlled through immediate identification and segregation/containment. Once these actions are taken, the nonconformance itself should be documented, along with any immediate actions taken. When segregation is not possible, nonconforming items should be clearly identified as such. Nonconforming conditions should be documented in such a way to describe the nonconformance itself, any immediate segregation/containment actions taken, the disposition, and any concessions obtained. The document should identify the authority responsible to make decisions and act with respect to the nonconformance. This documentation should be traceable to any corrective action to prevent recurrence (described in *Element 12*).

Those activities affected by the nonconformance should be notified. The responsibility for review and authority for the disposition of nonconformances should be defined in documented procedures.

Disposition of nonconformances will typically be defined as follows:

- **Use-As-Is:** accepting the nonconformance without repair, rework, or replacement
- **Repair:** modifying the nonconformance to better meet the requirements
- **Rework:** modifying the nonconformance in such a way that it meets the original requirements without exception
- **Scrap:** removing (and disposing) of the nonconformance

A disposition of use-as-is or repair should be undertaken only after obtaining the documented concurrence of the engineer of record that includes a technical justification. All nonconformances should be resolved in cooperation with project management and quality personnel. A disposition of repair or rework should be followed by a re-inspection of the nonconformance to assess conformance, in accordance with the original documented procedures. Disposition of nonconformances should be determined by appropriate personnel and documented for the record.

Example:

The project sponsor should require the contractor to keep a log of nonconformances and continually review their status. Assigning due dates to specific personnel can help to expedite their resolution. Transit agency quality management can use this tool to work through issues with the contractor and monitor progress, as well as assist with analysis and trending.

When evaluating the resolution of a nonconformance, one should determine if repeated or recurring nonconformances should be elevated to corrective action status. The corrective action to prevent recurrence is usually an action at a management level that determines the root cause and eliminates the condition that led to the nonconformance and prevent further nonconformances. The determination of corrective action is independent of the disposition of the nonconformance.

2.2.12 Element 12: Corrective Action

Corrective action procedures should be established, documented, and maintained. These include procedures for investigation of the root cause of nonconforming work and the corrective action needed to prevent recurrence. QA personnel should verify that the corrective action has been accomplished. The agency should also analyze risks and otherwise establish processes to detect potential nonconformances, as well as determine preventive action to eliminate the causes thereof in order to prevent their occurrence. This element also includes implementing and recording changes resulting from preventive action, corrective action, and continual improvement initiatives. ISO 9001:2015 does not address preventive action; however procedures that address preventive action are still recommended.

When a nonconforming condition occurs, including any arising from complaints, the following actions should be implemented:

- Taking action to control and correct the nonconformance
- Investigating the root cause(s) of the nonconformance to determine why it occurred, and whether further nonconformances could potentially occur
- Determining the corrective action(s) to address the root cause(s) and assigning it to a specific authority or individual for implementation
- Implementing the action(s)
- Verifying the effectiveness of the action(s) taken
- If applicable, updating the register of risks and opportunities to reflect the above, as well as any other relevant plans or procedures
- Retaining documentation as evidence of the nature of the nonconformities and any subsequent actions taken, and the results of the corrective action

Where the nonconformance is common to most projects, it is recommended that the corrective action should be memorialized in a Lessons Learned format and disseminated throughout the agency.

Potential risks and/or opportunities should be identified early and continually throughout the life of a project. The need for action should be evaluated. If actions are taken, the results of these actions should likewise be recorded.

Preventive action procedures should be established to address risks and opportunities alike, including:

- Determining potential nonconformances and their causes
- Evaluating the need for improvements to prevent occurrence of nonconformances including analyzing processes to detect and eliminate potential causes of nonconformances
- Evaluating opportunities for improvement to processes based on best practices or lessons learned
- Reviewing the effectiveness of any actions taken or improvements made
- Implementing and recording changes in processes resulting from actions and improvements

Example:

Elements 11 and 12 deal with a similar subject matter and are often conflated. Typically, agencies will utilize a Nonconformance Report (NCR) to document the initial nonconformance, the disposition, the root cause analysis, and the corrective action taken to prevent recurrence. This way, guidance from Elements 11 and 12 of these *Guidelines* is addressed by the same NCR, simplifying traceability. Many agencies also have a separate Corrective Action Report (CAR). The CAR is used to document any instances where issues are repetitive or systemic throughout the organization or project(s). The CAR will then document a more

detailed analysis of the repetitive/systemic issue and document both the root cause analysis and action taken to address the concern. The CAR is used less often to signify importance and elevate the concern(s).

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, retention periods, and disposition of quality records.

Quality records should be maintained to show achievement of quality objectives and appropriate functioning of the QMS. Supplier, consultant, contractor, and subcontractor quality records should be included when pertinent. There should be a controlled version of each quality record. Different versions of quality records should be identifiable and traceable, so there is no confusion when referencing these records.

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 (if possible, reference required retention periods in purchasing documents). Wherever possible, testing results, delivery slips, and certifications for material should be kept together to show test results for specific material.

Additionally, any electronic data should be regularly backed up, and backups should be stored offsite in a manner to ensure their safety from deterioration and/or damage.

FTA has specific requirements for maintenance of all project records (including safety and other non-quality records) beyond the successful completion of the project. For example, all project documents related to issues in litigation must be available until the litigation is settled. Safety related documents must be maintained for the operational life of the transit system. Therefore, it is in an agency's best interest to provide continuity in the maintenance of the files for a project by having the agency's personnel take possession of the files prior to the departure of the design and construction consultants/contractors. The ability to readily retrieve documents for review and use by the project is also critical. This function should be tested periodically and should allow the agency better success at producing records when needed, such as in response to public requests.

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

The following are examples of the types of quality records requiring control:

- Approved quality plans and procedures
- Design review records and submittals
- Inspection reports
- Test data
- Qualification records (e.g., welding, special inspections, etc.)
- Calibration records
- Nonconformance reports
- Corrective actions
- Audit reports
- Training records
- As-Built system information

Example:

A useful tool for keeping track of quality records is a Quality Records List, usually generated from an existing list of documents. 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 suppliers, consultants, contractors and subcontractors. Similarly, applicable contract documents should be tracked and controlled in accordance with the transit agency's retention policies.

2.2.14 Element 14: Quality Audits

Quality audits are not the same as financial audits. A quality audit program should be established to ensure that the QMS is implemented and maintained in a way that conforms to the organization's requirements. Findings from audits should be documented in a report, as well as integrated into the existing nonconformance, risks, and opportunities logs whenever practical. A schedule should be developed for both internal and external audits.

Each internal and external audit should be identified on an audit schedule, when possible. A checklist or other indicator of scope should be prepared in advance of the audit and shared with the auditee prior to the audit. The frequency should depend upon the importance of the process concerned, changes affecting the organization, results from previous audits, or with other consideration based on organizational/project size and complexity. 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 for the area being audited. These documents should be maintained as quality records. Responsible management personnel should take timely action to respond to audit findings. A follow-up audit to verify the corrections were made or are in process is recommended in some cases.

Audit findings may be considered inputs for corrective action, preventive action, or continual improvement. Findings should be classified as deficiencies, which require corrective action, or recommendations, which suggest action be taken to make improvements. Deficiencies may be further classified in the following manner:

- Major Nonconformance – A repetitive or systemic deficiency
- Minor Nonconformance – A failure to adhere to plans or requirements

Recommendations may be further classified as follows:

- Observations – Conditions which may result in deficiencies if no action is taken (i.e., risks)
- Opportunities for Improvement – Conditions which will not likely result in a deficiency if no action is taken, but should be considered for the purposes of continual improvement
- Best Practices - Noteworthy process or performance which may benefit other aspects of the project, program, or organization if captured as a lessons learned and distributed

Quality audits should be independent and performed to applicable requirements or standards (checklists should reference these, whenever practical). Qualified quality personnel should conduct the quality audit to ensure that it provides substantive results. As part of the audit, an entrance meeting and an exit meeting should be held. A final report that identifies the results of the audit should be generated, distributed, and tracked for completion of actions. Audit findings should be incorporated into the organization or project's primary tracking system or log for nonconformances, risks, and opportunities.

Example:

Successful quality programs usually audit in a systematic manner which ensures each element is audited at least once a year, with several elements being audited each quarter. Audit frequency may also coincide

with any incentive programs established for the project or significant project milestones. Regardless of approach, the document control function should be visited frequently, as this area can breakdown in a short time if not rigidly maintained. Auditing all elements at once can become time consuming, so auditing several elements each quarter allows for more frequent, shorter audits of contractor activities.

2.2.15 Element 15: Training

Transit agencies should establish minimum position requirements for internal personnel and for consultant/contractor personnel who affect quality on Major Capital Projects. They should also establish and maintain procedures for identifying the training needs of 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 (including certifications) should be maintained. Upon personnel reassignment within the organization or project team, the need for training should be reassessed based upon the new position.

Training needs should be identified for transit agency and project personnel. It is also encouraged that effectiveness of training be evaluated. Records of the training and evaluations, qualifications, and quality-related certifications should be maintained.

Example:

- Applicable actions can include the provision of training to, the mentoring of, the reassignment of currently employed persons, or the hiring or contracting of competent persons.
- A training matrix can be used as an effective tool for determining which personnel require what training. The training matrix lists the relevant personnel within the agency or within project consultants and contractors versus various quality related procedures. [Table 2-3](#), below, is an example of a training matrix, and the information that should be contained in one:

Table 2-3: Example of a Training Matrix

	Procedure Number							
	1	2	3	4	5	6	7	8
CEO /Other Executives	CR		RA					
Project Manager	CR	RA	RA	RA	RA	RA	CR	RA
Project Engineer	CR	RA	RA	RA	RA	RA	CR	
Staff Engineers		RA	RA					
Purchasing Manager	CR	RA	RA			RA	CR	RA
Resident Engineer	CR	CR	RA	RA				
Inspectors		CR		RA	RA			RA
Safety Manager	CR	RA	RA				CR	RA
QA Personnel	RA	RA	CR	RA	RA	RA	RA	RA

Key

CR: Classroom

RA: Read and Acknowledge



CHAPTER 3: ORGANIZATION OF A QUALITY MANAGEMENT SYSTEM

FTA project sponsors use many different organizational structures for carrying out capital projects. All work, including design, procurement, construction management, construction, and start-up and testing may be done in-house or by outside suppliers, consultants, or contractors. All of the applicable Quality Management System (QMS) elements should be incorporated into the activities of the organizational entities involved in the project, regardless of its structure. The implementation of quality management activities should mitigate the disruption to continuing project sponsor operations, while remaining both separate/objective and integral to those operations.

3.1 General Principles

In Chapter 2, the quality element *Management Responsibility* states that a person should be designated as a representative of management who has the responsibility and authority to ensure that the management's Quality Policy plans, and procedures are implemented and maintained. Those responsible for verifying that quality activities are performed in accordance with established requirements and procedures should be independent of those directly responsible for the work. For example, the Quality Manager (QM) on a construction project should report to the project sponsor's management at a level above the Project Manager (PM).

The fulfillment of management's responsibility for quality requires that:

- A Quality Policy be adopted by the project sponsor's senior manager (e.g., General Manager or CEO) and accepted by all members of management.
- The Quality Policy complements the organization's Mission Statement.
- Quality Objectives and Quality Plan be established, based on this Quality Policy, and progress toward these objectives be tracked.

- There be a prevailing attitude that all members of the organization are responsible for the fulfillment of the Quality Policy and achievement of these objectives, and that management examines all elements of the organization for assurance that quality is being attended to.
- There be a person designated by and reporting to the senior manager to oversee the established QMS and advise the senior manager of the effectiveness in meeting project quality objectives.
- Those responsible for ensuring quality report at least one level higher than the activity for which they have oversight responsibility.

It is important to distinguish between responsibility for Quality Policy/Objectives and responsibility for quality of a project or activity. Each person responsible for a project or an activity is also responsible for achieving quality of that project or activity. On the other hand, the Quality Assurance (QA) staff is responsible for participating in the quality processes to ensure that these processes are working. If the processes are working properly within a project, there is more certainty that the project quality objectives will be achieved.

The QA staff should be seen by the PM as part of the team. The QA staff and the Quality Control (QC) activities should be seen as helpful in preventing errors which could lead to significant problems and increased cost. The PM and his/her organizational structure should reinforce the concept that the QA staff is part of the project team.

An appropriate approach to carrying out the *Management Responsibility* element is for the project sponsor to have a person in charge of Quality reporting to senior management. Where the QA role is focused on capital projects, the person in charge of Quality should report to the senior manager responsible for the implementation of all capital projects or to another senior member of the project sponsor. The advantages of such a structure are:

- The responsible management for the project sponsor can be confident that appropriate attention is being paid to quality and that FTA and other funds are being used wisely.
- Quality is highly visible within capital projects of the project sponsor.
- QA activities are coordinated so that duplicate planning, training, and oversight activities are eliminated.

The person in charge of Quality should be responsible for verifying the implementation and maintenance of the project sponsor's Quality Policy and detailed Quality Procedures. The person in charge of Quality should provide oversight of all quality activities, assistance to the PMs in the development of Project Quality Plans, prevention and resolution of quality problems, oversight of contractor quality programs, QA training programs, QA oversight, and QA audits.

As stated previously, the FTA requires that major capital projects have a Project Management Plan (PMP) that includes or references a Quality Plan for the project. Responsibility for achieving quality within a capital project and for the Quality Plan should rest with the PM for that project. Although the person in charge of Quality should report independently to a senior manager, inspectors on a project who are performing QC activities generally report to the PM or resident engineer. The PM should have access to quality personnel to assist with project quality activities. A concerted effort to comply with quality requirements by those performing the work can further prevent errors which could lead to significant problems and increased cost.

The matrix organization for project management provides a mechanism for the PM to have access to QA staff assistance, and for quality oversight to be provided at a management level higher than the PM. The QA personnel work in partnership with representatives of engineering, procurement, construction, and

start-up and testing on various projects. This structure allows the QA representatives to be partners in the QMS, rather than outsiders who are there to find fault.

Some project sponsors divide the QA responsibilities and assign them to functional areas such as engineering, procurement, construction, and start-up and testing. This approach recognizes the specialty skills that are appropriate for QA in these various areas. Indeed, in larger project sponsor organizations, it makes sense to have functionally specific Quality Plans. Although it is less desirable to split the QA organization because it results in multiple Quality Programs and procedures within the agency and a less visible program overall, such a program can still provide adequate quality at the project level.

There are situations where a project sponsor may not have a permanent QA staff. One example is where a project sponsor undertakes a one-time capital project where the quality function is a discrete activity developed solely as a part of the project. In general, lack of dedicated QA staff can cause a problem if the project faces budget or time pressures. Lack of a dedicated QA staff has often resulted in weakened Quality Programs.

3.2 Project Management Plan

The FTA requires its project sponsors undertaking a major capital project to submit a Project Management Plan (PMP) for FTA's review and approval, both initially and as changes are made throughout the project. Although FTA has some discretion in determining which capital projects are considered major, they generally include projects like construction of a new fixed guideway segment, extension of an existing fixed guideway, modernization of an existing fixed guideway, and vehicles such as light rail and busses, pursuant to a Full Funding Grant Agreement (FFGA). As part of the PMP, FTA requires that the project sponsor include a Quality Plan and define quality responsibility for design, construction, procurement, system installation, and integration of system components.

While PMPs are required only for major capital projects, they are encouraged for all projects because they are a very useful project management tool. Similarly, significant benefits can be derived from a Quality Plan even where the project is not considered major and a Quality Plan is not required.

The PMP should be produced during the Project Planning phase of the project. The timing is essential for the Quality Plan as well, since the requirements for quality in design should be specified at the time of the design procurement. The PM's expectations for a project QMS must be made known in the procurement documents. These requirements should be a detailed extension of the PMP's established quality requirements.

The PMP should be updated as the project progresses through final design, procurement, construction, testing, and start-up. Likewise, the Quality Plan and Objectives should be adjusted to reflect the organization and particular requirements to be instituted at each of these phases. Chapter 4 of these *Guidelines* discusses the development of the Quality Plan for a project.

When a project sponsor has an existing Quality Plan, Quality Policy, and/or written procedures, a project Specific Quality Plan can adopt any of those elements that are appropriate for the specific project or project phase under consideration. Responsibility for preparing the Specific Quality Plan could rest with the person in charge of Quality or with quality staff assigned to the project. The PM must approve the Specific Quality Plan because the PM is ultimately responsible for the quality of the project.

3.3 Alternative Organizational Structures

Sections 3.4 and 3.5 describe alternative ways of organizing a QMS given different project organizations and objectives:

3.4 Quality Program for Construction with a Project/Construction Management Consultant

One alternative for organizing a major capital project is to use a Project or Construction Management Consultant (PMC or CMC) to manage outside construction contractors. This type of project management organization is one of several that have been successful in implementing quality programs.

There may be a number of reasons for the success of this approach. First, a project can be a discrete activity organized to minimize disruption to the project sponsor's established internal relationships. Second, many experienced PMCs and CMCs have adopted QA programs and have considerable experience in applying such programs for design and construction projects. It is important that a PMC or CMC tailor their Quality Program to the project that they are managing.

When a project sponsor uses a PMC/CMC to undertake the QA role for a project, the project sponsor still needs assurance that the project quality objectives are satisfied. The project sponsor cannot delegate this responsibility. Therefore, the project sponsor's oversight of the quality process must be maintained to assure that it functions effectively.

Figure 3-1 shows an organization chart for the project management and the quality organization for a project with a PMC/CMC. As can be seen from this figure, the construction contractor is responsible for QC. The PMC/CMC provides the QA, and in this scenario, the project sponsor provides QA oversight for the project.

In order for the structure shown in **Figure 3-1** to be successful, all parties must understand their responsibilities and Quality Plan requirements from the beginning. The contract documents for the construction contractors must specify the role of the PMC/CMC in providing QA for the project as well as the contractor's responsibility for QC, including the development of PMC/CMC and contractor's Quality Program Plans. Contract documents must specify that the construction contractor must provide the PMC/CMC with appropriate access for observation and inspection, as well as access to quality records. In most cases, project sponsors have found it difficult to achieve effective contractor Quality Programs when the PMC's/CMC's QA role has not been adequately defined in the contract documents.

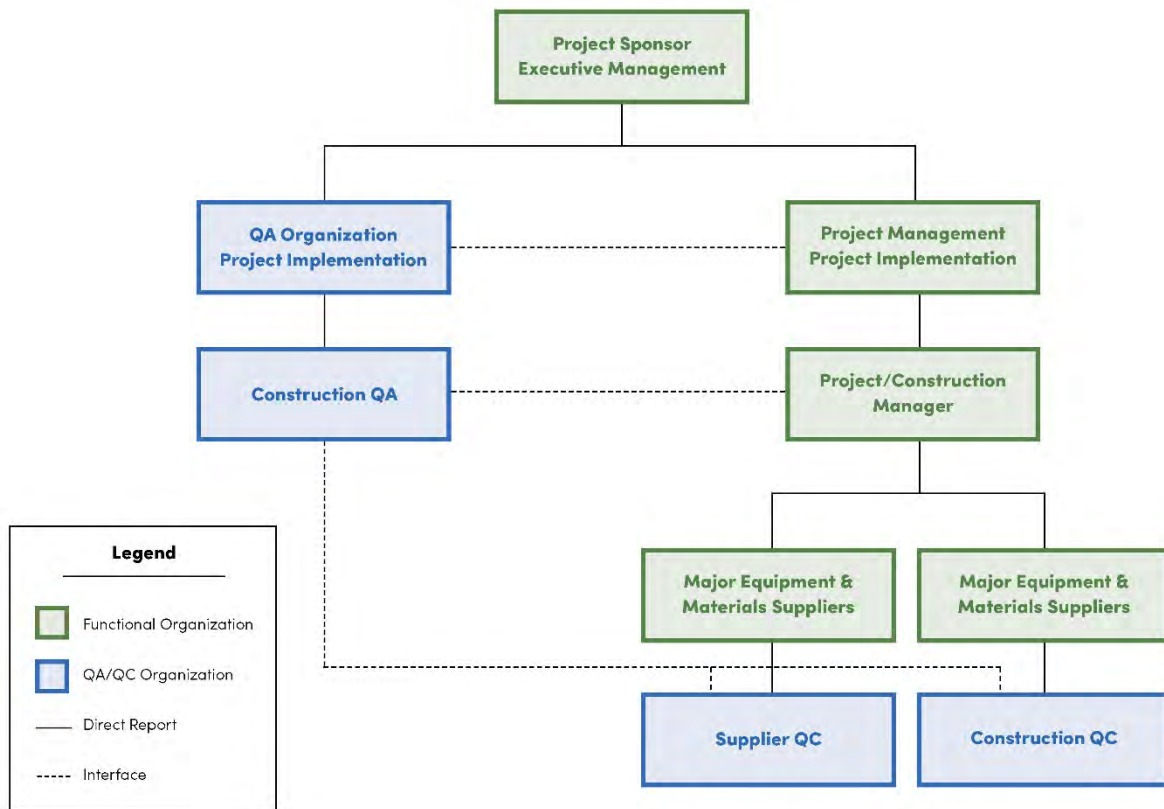


Figure 3-1: Example of a Project Quality Organization with a PMC/CMC

Likewise, the PMC/CMC must understand the project sponsor's role in quality oversight of the project. That role needs to be spelled out in the request for qualifications and the contract documents with the PMC/CMC in order to clearly indicate the approach the project sponsor will take to assure that the PMC's/CMC's QMS requirements are satisfied.

3.4.1 Quality Program with In-house Construction Management

Another alternative for organizing a large capital construction project is to use internal staff for construction management. Construction is done either by outside construction contractors or by inside force account staff. Often this option follows the use of PMCs/CMCs on long, multi-stage projects. Agency staff assumes more and more of the responsibilities of the PMC/CMC, and finally takes over all construction management functions.

The project sponsor's construction management team should be responsible for QA for the project and should have appropriate staff available for undertaking the QA role. The person designated to provide QA oversight for the project should verify to the project sponsor's senior manager that the established QMS is being appropriately implemented and followed. This oversight activity is especially important where the project scope does not justify a separate QA staff for the project, and where the PM/PMC/CMC staff assumes QA responsibilities. Without oversight, this latter arrangement often leads to a weakened QA program.

Typically, where there is an outside construction contractor; that contractor is responsible for the QC system to be applied to the work performed. Often the construction contractor has its own Quality

Program that can be utilized when acceptable to the project sponsor. An exception in transit construction projects occurs where the project sponsor or a third party takes responsibility for materials testing, thus assuming a QC activity. Contract documents must clearly specify the responsibilities of each organization.

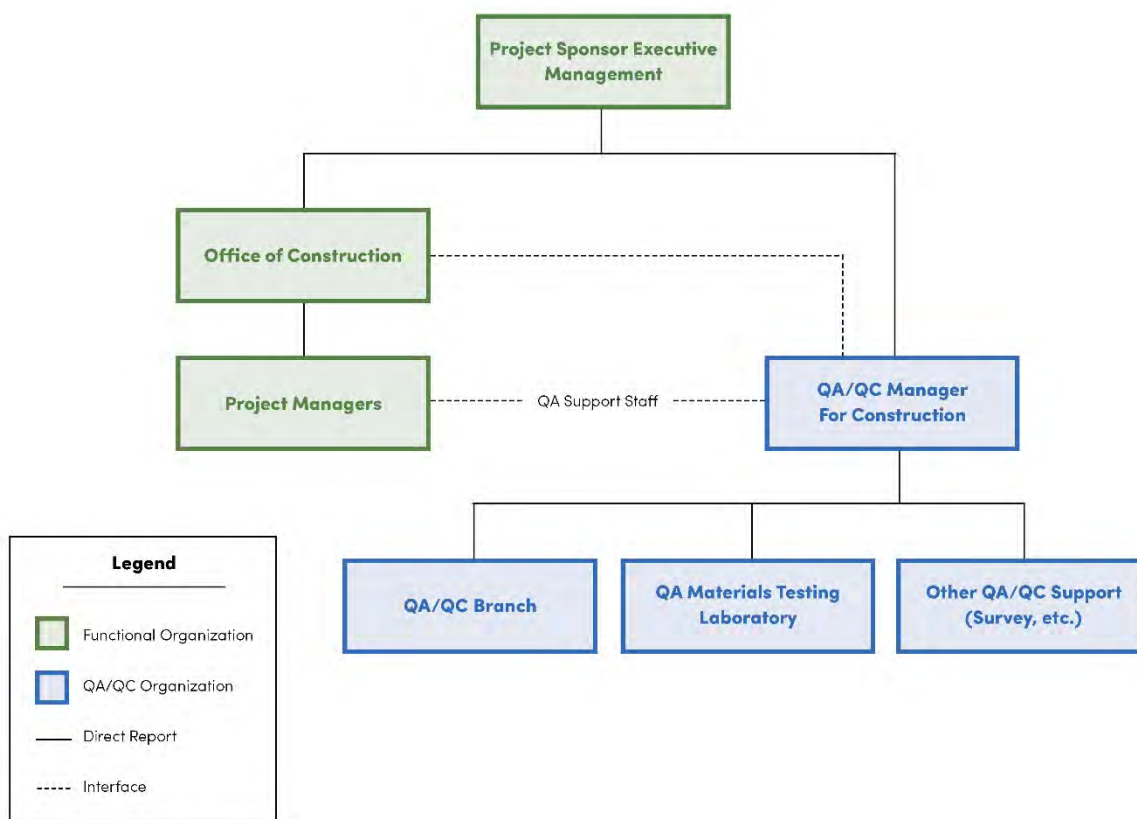


Figure 3-2: Example of a Quality Program with In-house Construction Management

A similar approach for quality should be followed where construction is performed by force account staff. The internal construction manager should be responsible for undertaking the QA role, while the force account staff should be responsible for QC. There should also be an independent person from the project sponsor's staff designated to provide QA oversight to verify to the project sponsor's senior manager that the established QMS is being appropriately applied. This latter role is important, especially if the construction manager is not familiar with QA responsibilities and the QMS.

Some project sponsors have evolved from using a CMC to doing their own construction management, employing outside construction contractors. Such organizations should have a QM for transit development activities. The QM may require staff for providing quality support to the PMs, depending on the scope of the department/organization and its projects. It may also have a materials testing laboratory or additional QC resources to provide some QC for contractor work. Construction contractors are still responsible for the QC, so the project sponsor should develop specifications for the contractor's QC program. It is extremely important that contract documents clearly specify responsibilities of each organization. **Figure 3-2** shows an organization for a Quality Program with In-house Construction Management.

3.4.2 Quality in Design

As with construction, there are many different ways for a project sponsor to organize its design activities. The project sponsor may use a General Engineering Consultant (GEC) for design and outside Architecture and Engineering (A&E) firms to produce the design. The project sponsor may handle design management in-house and contract the design to an A&E firm. The project sponsor could handle both management and design in-house.

Quality Programs in design can vary to accommodate the management organization for design. Typically, the organization doing the design is responsible for QC of design.

The organization providing design management should be responsible for providing QA for design. Where an outside consultant is responsible for design management, all QA responsibilities should be contractually specified early in the relationship between the project sponsor and the design management consultant. Likewise, the QA role of the design management consultant should be specified in the contract of the organization responsible for doing the design. The project sponsor needs to maintain a quality oversight role to acquire confidence that the QMS for design is achieving the project quality objectives when an outside consultant is responsible for design management. [Figure 3-3](#) illustrates an organizational structure for QA in design using an outside design management consultant.

Where the project sponsor retains responsibility for design management, the project sponsor's PM should be responsible for implementing the design QA system established in the Quality Plan.

Where the design effort remains entirely in-house, a two-tier organization for Quality is warranted. Those producing the design should be responsible for QC activities. Those functioning as design management should be responsible for establishing a design QA activity for oversight of the design process. In this case, an independent QA audit might be conducted to assure design management compliance with design procedures.

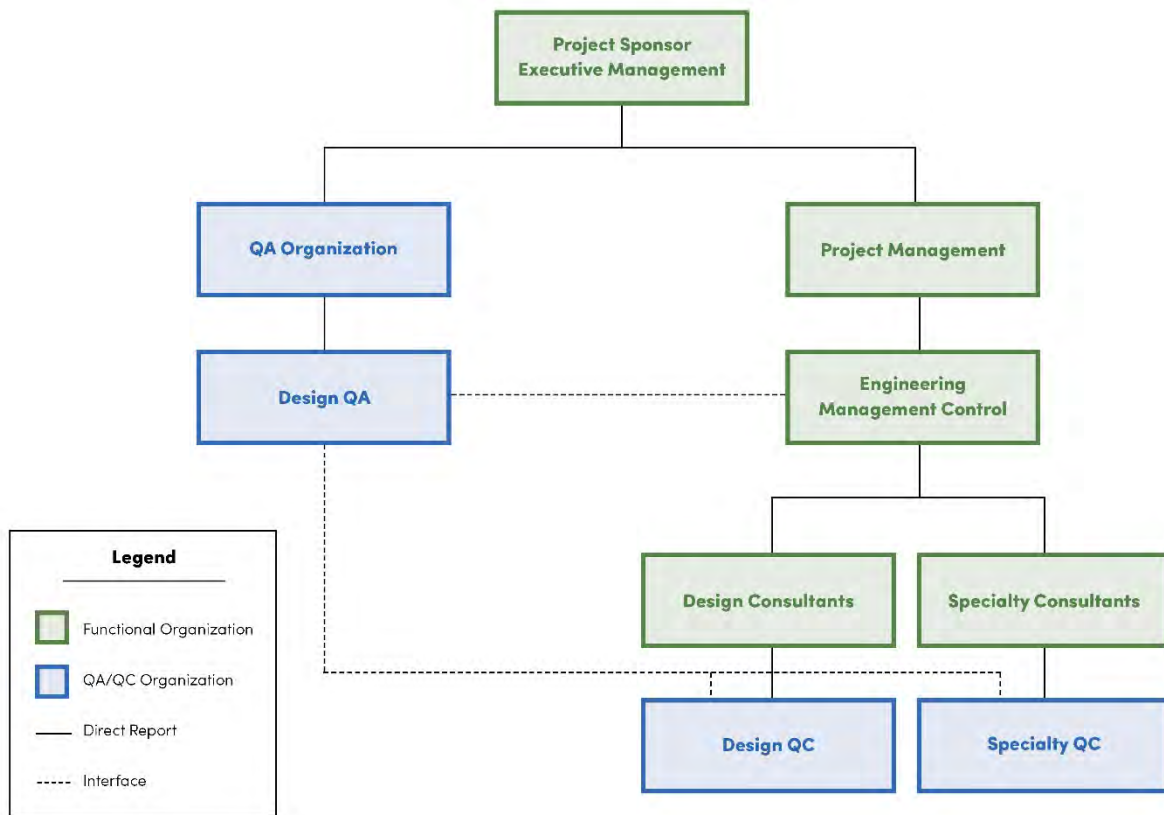


Figure 3-3: Quality Organization for Design with a Design Management Consultant

3.4.3 Quality for Small Projects

Smaller project sponsors may not be able to justify a special Quality Staff for a one-time project. Also, project sponsors may not be able to justify Quality Staff for smaller projects such as bus storage and maintenance facilities. Nevertheless, each project sponsor still has the responsibility to assure that FTA capital funds are spent wisely. The PM of a small project should develop a QMS for the project by determining which of the fifteen elements of a Quality Program are applicable to the work being performed. Where the project is simple, where design and construction methods are standard, and where the risk of failure is low, the QMS might be focused on final inspection and testing activities. Even so, many of the fifteen elements may be required to get to the final inspection and testing stage.

One approach for handling quality activities on projects of limited scope is to make the construction contractor responsible for some QA and QC activities and the project sponsor's project management responsible for QA oversight activities. For example, the construction contractor could perform inspection and testing and provide the documentation thereof, document all design changes, inspect and track all purchased products, and document all nonconformances and corrective actions. For a small project, the project management staff should undertake QA oversight activities such as witnessing testing, reviewing contractor documentation, and monitoring contractor compliance with its Quality Program and other contract requirements. An option for providing QA oversight of both the project management and the construction contractor activities is to use an outside firm for this purpose. Contract documents must clearly specify the role of each organization. Following is a Case History for a Small Project:

Case History of a Small Project

A small rehabilitation project had many interdisciplinary interfaces, and the project had to be performed while existing services were maintained. The project sponsor knew the difficulties that the project would present and started thinking about ways to control cost, schedule, and quality during the planning phase of the project. Resources, including funding and manpower, were limited. The following actions were taken:

1. The sponsor required the contractor to provide a Quality Plan to cover the scope of the work.
2. The sponsor required that the contractor provide personnel to perform quality activities.
3. The sponsor required that all the project work be identified on checklists that could:
 - Be signed off by the contractor
 - Provide hold and witness points
 - Be signed off by quality personnel
4. The sponsor identified what records would be required to be turned over as a result of implementing the Project Quality Plan.

Of the fifteen quality elements, parts of each (except for Quality Audits) were contained in the contractor's Quality Program. The benefits that were realized as a result of these actions were:

- The contractor supplied the needed human resources
- Every interface that the sponsor needed was retained
- Every document that the sponsor needed was retained
- A system to identify and rectify potential problems was established prior to the first problem becoming an issue.

3.4.4 Quality in Equipment Procurement

The purchase of services or major capital equipment by a transit agency is another process where the application of the fifteen quality elements is appropriate. The project sponsor's QMS should include procedures for purchasing. The PM or project engineer in charge of the purchasing effort would be responsible for determining which quality elements and procedures should be applied to the equipment procurement on their project. If the project sponsor has a quality function, a member of the quality staff should help determine which quality elements and procedures should be applied.

Alternatives for purchasing vary from requirements for the supplier to have a complete fifteen-element Quality Program to requirements for a program limited to final inspection and testing. In either case, the project sponsor will have to provide QA oversight to assure that the supplier programs are consistent with the project quality objectives and are effective in meeting project sponsor expectations.

An adequate supplier Quality Program and the responsibility for QA oversight are both critical. The role of QA oversight on complex procurement projects requires highly knowledgeable staff. Where such staff is not available, a project sponsor should consider hiring a consultant to assist with the QA oversight activities.

3.4.5 Quality in Design-Build Projects

Unlike a conventional project delivery method (i.e., Design-Bid-Build), the Design-Build (DB) project development approach combines both responsibilities of design and construction under the auspices of a

single entity: the DB Contractor. With such an arrangement comes modification to the roles and responsibilities of the parties involved, which will undoubtedly affect many aspects of the project. The DB concept utilizes the combined expertise of both the design and construction industry to promote innovative designs, speed project delivery, and reduce cost. The project sponsor may relinquish detailed oversight to obtain complete benefit of this project delivery system. Naturally, this transfer of responsibility generates significant concern over whether the DB team will adequately address quality. This section focuses on how quality is addressed under the DB approach.

DB project delivery has many unique characteristics. Several of these are listed below:

- Includes variation to virtually all project development tasks
- Combines many task contracts into more limited number of contracts
- Combines design, construction and installation functions
- Increases emphasis on procurement documents
- Redefines relationships among all contracting parties
- Reallocates risk among project development organizations

There are several variations of DB project delivery, two of which are outlined below:

- Super Turnkey: Combines all the elements of DB and includes financing mechanisms. This variation can also allow for ownership of the completed project.
- DBOM (Design-Build-Operate-Maintain): Under this type, the DB contractor is also responsible for operating and maintaining the system after its completion. The period of operation and maintenance is stipulated in the contract agreement, after which this responsibility is transferred to the project sponsor.

In order to assure the success of Quality Programs in DB project delivery, agencies need to consider several key practices:

- Clearly define roles and responsibilities of parties involved early in the bid documents.
- Clearly define requirements of the Quality Program in the contract documents.
- Clearly define contractor and agency's roles and responsibilities in various levels of design and construction decision making and acceptance process.
- Clearly understand the impact resulting from risks shifted to the agency by the DB contractor.
- Commit to a higher level of agency oversight activities in order to assure effectiveness of the Quality Program. Where agency in-house expertise is limited, the use of independent specialized consultants can prove beneficial to the effectiveness of the program.
- Require additional levels of reporting and/or detail by the DB contractor team.
- Maintain a proactive and systematic Quality Program that encompasses all of the project lifecycle stages.

Quality Program effectiveness hinges on clear allocation of roles and responsibilities to the involved parties. Ideally, the best results are achieved when quality roles and responsibilities are clearly defined in the contract documents and, more importantly, are agreed upon by the parties at the outset. Under DB project delivery, the project sponsor may elect to shift some of the quality roles and responsibilities to the DB contractor. In such cases, it is recommended that the project sponsor conduct audits, require quality hold points, and testing at every stage of the quality process, and retain ownership of the resident database. In less ideal cases, agencies have elected to retain the QA role only, with the DB contractor performing the QC activities. Crucial to the success of this arrangement is the DB contractor's level of experience and the project sponsor's in-house oversight capabilities. Typically, DB projects provide DB contractors with added responsibility for program implementation. There are some perceived

disadvantages to the shift in responsibilities from the agency's perspective. As was previously stated, a major concern in the DB environment has been the potential for conflict of interest when the DB contractor performs its own quality oversight of the project. Although this is a legitimate concern, it can be adequately addressed through careful stipulations and requirements delineated in the contract documents. As indicated earlier, the project sponsor could place more quality responsibility on the DB contractor while retaining a more stringent oversight role.

One example of a project sponsor maintaining a stringent quality oversight or QA role over a DB contractor can be seen in Case Study #3 contained in Appendix C of these *Guidelines*. This example deals with the Maryland Mass Transit Administration (MDMTA), now the Maryland Transit Administration (MTA), and their role in the Baltimore Central Light Rail Line (CLRL) Phase II Extensions project, which was a DB project. The organizational structure utilized on this project is illustrated in [Figure 3-4](#). The figure shows that although the DB contractor utilized its own Quality Manager, the project sponsor's quality organization maintained direct QA oversight of their work.

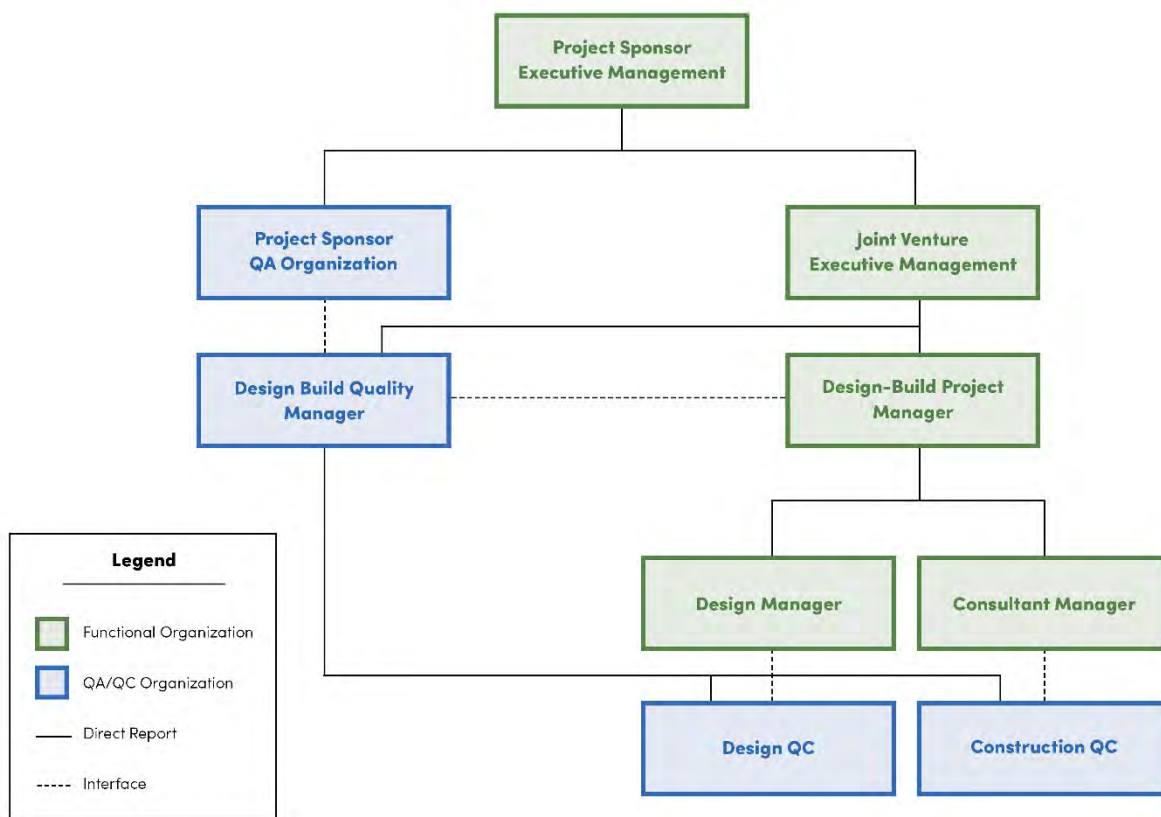


Figure 3-4: Quality Organization for a Design-Build Project

Responsibility for quality under the DB method requires a clear definition of roles for both the project sponsor and DB contractor. The sponsor and DB contractor must carefully define the Quality Program, including roles and responsibilities within the bid documents so that the participants' requirements are clear. As with other areas of project management control, it is necessary for project sponsors to monitor the Quality Program. The project sponsor may have to provide more monitoring than would be anticipated in the DB contract to ensure that the contractor has a full understanding of requirements for quality management and corrective actions.

3.5 Independent Assurance Program

3.5.1 Description

Another alternative to the project QMS is to have an independent contractor responsible for the Quality Program. This alternative was proposed previously in Section 3.4.3, *Quality for Small Projects*. It is also useful when the transit agency undertakes multiple projects simultaneously, such that the agency's quality staff is unable to adequately cover all of the project quality oversight requirements. It is also useful, when the construction management consultant does not possess a sufficiently experienced quality team.

In the case where there is a project/construction management consultant or there is a DBOM contractor, the responsibility for hiring the independent quality firm may rest with them.

When there is in-house construction management, the responsibility for hiring the independent outside firm should rest with the agency's existing quality function, or with the PM when no quality function exists. When the quality function performs the hiring, the outside firm should report directly to the agency's quality function, with dotted line or matrix responsibility to the PM. When the PM performs the hiring, the outside firm should report to the PM, but provide written reports to transit agency senior management.

It is important to note, that in either case, responsibility for project quality still rests with agency senior management, quality management, or project management. The agency cannot abdicate responsibility for satisfying all the project quality requirements.

3.5.2 Advantages and Disadvantages of an Independent Assurance Program

Advantages of an Independent Assurance Program include:

- Additional independent assurance resources will allow the existing project sponsor's quality function to cover all of their projects without spreading their resources so thin as to become ineffective.
- With additional resources, the existing project sponsor's quality function can effectively play a leadership role on all projects, while still accomplishing its day-to-day quality activities.
- An independent outside firm can immediately provide experienced, professional personnel with having to undergo a minimal learning curve. The project sponsor can review and accept or refuse these personnel on an individual-by-individual basis.
- The outside firm personnel can provide resources that can be dedicated to one or more specific projects.
- The outside firm can provide an independent approach to quality.

Disadvantages and associated mitigation of an Independent Assurance Program include:

- There will be some learning at the start of the project by the outside firm; so it is advisable to bring it into the project in the planning stage or as early as possible.
- Depending on the program management structure, allegiance on the part of the outside firm may become an issue, depending on who directly pays the salaries of the outside firm's personnel. Roles, responsibilities, reporting, and allegiance must be clearly defined prior to hiring the outside firm and included in the firm's contract.
- Depending on whether the hired firm is local or distant, on-site availability may become an issue; but at a minimum, dedicated on-site support should be negotiated with the outside firm.

3.5.3 Methods of Control

As was stated earlier, the project sponsor cannot abdicate responsibility for satisfying the project quality requirements. Therefore, it is necessary to implement methods of control to assure that the requirements are being met. Recommended methods include:

- Development and approval of mutually agreeable, well defined contract requirements that include clearly defined roles, responsibilities, and reporting.
- Frequent status reports and review meetings with the outside firm.
- Contract language clearly indicating that the outside firm must act in an independent professional manner and additional contract language that provides for an immediate termination option by the project sponsor in the event of an irresolvable conflict.
- Oversight by the project sponsor, tailored to the scope of the project and responsibilities of the outside firm.

3.6 Test Lab Accreditation and Quality Personnel Qualifications

3.6.1 Test Lab Accreditation

Depending on the type of project, test labs may be used for several types of testing, such as:

- Soil testing
- Aggregate testing
- Concrete testing
- Structural bolting testing
- Electrical testing
- Mechanical and welding testing
- Nondestructive examination operations
- Calibration of measuring and test equipment

When test labs are required, projects should only use accredited laboratories. These accredited labs may be local, national or international. In any case, the accreditation of the labs that perform various types of tests is the formal recognition that a laboratory is competent to carry out specific tests or types of tests or calibrations.

Accreditation is different from certification. Accreditation is the procedure by which an authorizing body gives formal recognition that a given entity has written procedures in place in accordance with standards and technical regulations and is competent to carry out specific tasks such as testing, calibration, certification, and inspection. Certification is the action of an independent third party/authorizing body who verifies that an end product, process, or service fulfills all the specified requirements of relevant standards or technical regulations.

The difference between accreditation and certification lies in the fact that accreditation is the formal recognition of competence and is based on proven technical knowledge and therefore requires the consultation of a technical expert for the entity to be accredited. Certification primarily involves ensuring/verifying conformity with a given norm, e.g., a management system or a product.

3.6.2 Accreditation Agencies

The International Laboratory Accreditation Cooperation (ILAC) is an international cooperation of laboratory and inspection accreditation bodies formed in 1977 to help remove technical barriers to trade. ILAC is the organization for accreditation bodies operating in accordance with ISO/IEC 17011:2017 and

involved in the accreditation of conformity assessment bodies including calibration laboratories (using ISO/IEC 17025:2017), testing laboratories (using ISO/IEC 17025:2017), and inspection bodies (using ISO/IEC 17020:2012). Accreditation is the independent evaluation of conformity assessment bodies against recognized standards to carry out specific activities to ensure their impartiality and competence. Through the application of national and international standards, government, procurers, and consumers can have confidence in the calibration and test results, inspection reports and certifications provided by an Accredited Agency. Accreditation bodies are established in many countries with the primary purpose of ensuring that conformity assessment bodies are subject to oversight by an authoritative body. Two of the original signatories from the United States to the ILAC Mutual Recognition Arrangement for both testing and calibration are:

1. The American Association for Laboratory Accreditation (A2LA)
2. The National Voluntary Laboratory Accreditation Program (NVLAP)

The ILAC and its associated members enter into mutual recognition arrangements with national and international accreditation associations so as to eliminate unnecessary duplication in the development and promulgation of accreditation efforts. As a result, once a facility is accredited by one agency, its accreditation is recognized by all national and international agencies with which agreements have been made. Project sponsors can consequently be assured that labs, which have been accredited by agencies recognized by ILAC, have all met the same rigid standards and are competent to carry out the tests in the areas for which they have received accreditation.

3.5.2.1 American Association for Laboratory Accreditation (A2LA)

The American Association for Laboratory Accreditation (A2LA) is a nonprofit, non-governmental, public service, membership society. A2LA is the only independent, non-profit, internationally-recognized accreditation body in the United States that offers a full range of comprehensive laboratory and laboratory-related accreditation services and training. Established in 1978 as a non-profit, public service membership society, A2LA is dedicated to the formal recognition of competent testing and calibration laboratories, inspection bodies, proficiency testing providers, and reference material producers.

A2LA provides comprehensive services in laboratory accreditation and laboratory-related training. Services are available to any type of organization, be it private or government. Laboratory accreditation is based on internationally accepted criteria for competence (ISO/IEC 17025:2017). A2LA also offers programs for accreditation of inspection bodies, proficiency testing providers, reference material producers, and product certification bodies.

3.5.2.2 National Voluntary Laboratory Accreditation Program (NVLAP)

The National Institute of Standards and Technology (NIST) is an organization within the US Department of Commerce and is headquartered in Gaithersburg, Maryland. Formerly the National Bureau of Standards (NBS), NIST administers the National Voluntary Laboratory Accreditation Program (NVLAP). NVLAP's objectives for quality are to:

- Facilitate cross-border trade through the establishment and maintenance of international MRAs; to promote confidence in the technical competence of NVLAP-accredited laboratories and the reliability of their results;
- Communicate frequently with customers and stakeholders to determine their accreditation needs and requirements;
- Develop accreditation programs, using balanced input from technical experts, industry, and interested parties;
- Meet the highest professional standards for integrity, impartiality, and ethical conduct;

- Manage resources in a manner that maximizes delivered value to customers;
- Afford employees the opportunity to develop their full potential in a working environment that recognizes individual and group quality achievements and encourages excellence.

NVLAP provides accreditation services through various Laboratory Accreditation Programs (LAPs), which are established on the basis of requests and demonstrated need. Each LAP includes specific tests or calibration standards and related methods and protocols assembled to satisfy the unique needs for accreditation in a field of testing or calibration. NVLAP accredits public and private laboratories based on evaluation of their technical qualifications and competence to carry out specific calibrations or tests. NVLAP provides third-party accreditation to testing and calibration laboratories. NVLAP's accreditation programs are established in response to Congressional mandates, administrative actions by the Federal Government, and requests from private-sector organizations and government agencies.

3.6.3 Quality Personnel Qualifications

Sections 3.4 and 3.5 of these *Guidelines* provide various organizational suggestions that can be utilized on project sponsor's projects. These alternative organizational structures identify the quality organization, quality management, and lines of communication. Personnel filling these positions should have the requisite education and experience required to accomplish a successful project Quality Program. It would be unrealistic to identify one set of requirements that would satisfy all of the needs of every organization or project. However, the following suggestions are recommended:

- **Management/Supervisors** should possess understanding of the general concepts and objectives established in these *Guidelines* to assure that they are considered in major capital projects.
- **Quality Management/Supervisors** should possess experience managing professional personnel in similar circumstances or on similar projects. They should have experience with matrix organizations and managing multiple projects. They should have excellent communication skills and a working knowledge of quality and quality management. They should possess certification as quality professionals from ASQ – preferably a Certified Manager of Quality/Organizational Excellence (CMQ/OE) or other appropriate certifying bodies or have successfully completed training courses in the quality discipline.
- **Quality Engineers** should have a Bachelors or Masters degree in the necessary fields of study (Civil, Electrical, Mechanical Engineering, etc., as appropriate) for the project; experience commensurate with the type of project and size of the quality department; and, depending on the project, one or more engineers should be a licensed Professional Engineer in the state where the project is taking place. Certification as a quality professional, e.g., an ASQ Certified Quality Engineer (CQE), ASQ Certified Quality Auditor (CQA), or other certification from ASQ, is desirable.
- **Software Quality Engineers** should have software experience. Certification as an ASQ Certified Software Quality Engineer (CSQE) is desirable.
- **Quality Auditors** should have taken one of the many courses available for quality auditors. Certification as an ASQ Certified Quality Auditor (CQA) is desirable.
- **Inspectors** should have the appropriate education or experience commensurate with the job responsibilities. They should possess the necessary certifications required for assignments (e.g., American Welding Society (AWS), American Society for Testing and Materials (ASTM), American Concrete Institute (ACI), etc.). Certification from ASQ as a Certified Quality Inspector (CQI) may also be beneficial to inspectors, but it is more critical for inspectors to focus on certifications which directly affect their work.

3.6.4 Software Quality Assurance (SQA)

Software plays an increasingly important role in every product and organization. Of the number of mission critical applications, those with a high cost of failure (e.g., Automatic Train Supervision and Automatic Train Protection software), or high cost to fix (e.g., communication equipment and other consumer products), have increased exponentially in recent years. Software for embedded systems more often than not fits a mission-critical profile, and with the forecast for embedded systems continuing to accelerate, the need for proactive quality assurance is higher than ever before.

The software developer or vendor should understand the value of having a formal software QMS and should be committed to utilizing the best available standards, methods, practices, and dedicated resources to ensure all software meets a well-defined quality objective. SQA encompasses the entire software development process, which includes processes such as requirements definition, software design, coding, source code control, code reviews, change management, configuration management, testing, release management, and product integration. SQA is organized into goals, commitments, abilities, activities, measurements, and verifications.

There are two key elements that make up a sound software QMS: the Vendor's Quality System (VQS) and the Vendor's Software Development Process (VSDP).

The VQS consists of procedures assuring that quality is addressed and implemented in all aspects of project management and product development. These procedures should be developed in accordance with ISO 9001:2015 or the requirements of another applicable Quality Standard. In addition, the VQS defines the QMS requirements, the policy stating the vendor's belief in the requirement, the resources responsible for implementing the policy, and the standard operating procedures that describe how the vendor conforms to the software QMS requirements.

The VSDP describes the detailed and comprehensive development process that translates the software QMS requirements defined in the VQS. The VSDP includes project planning; project execution; product creation, verification, and validation; and installation and support functions. The VSDP identifies and defines the roles and responsibilities of project team members; project deliverables; and a monitoring mechanism based on measurements, analysis, and continuous improvement. Key audits and reviews are performed in order to track status and progress and to ensure that the project meets its requirements and milestones. The VSDP should be developed in accordance with Element 2 of these *Guidelines: Documented Quality Management System*.

The QA department within the vendor's organization performs configuration management, verification and validation, and quality assurance activities to ensure that the VQS is adhered to throughout the project development lifecycle. The VSDP ensures that the project sponsor's/client's needs are fully understood and captured, and that project planning, development, and testing activities are documented prior to product creation. The VSDP should be flexible to allow tailoring to meet any solution that project sponsors/clients require.

A Software QMS process needs to set expectations for the project sponsor/client, project team members, and the vendor's organization and should support these expectations through the VQS and VSDP. The most important characteristic of the software QMS is predictability; the vendor should be able to predict the budget, the schedule, and the quality of deliverables. This translates to project sponsor/client satisfaction since the project will be delivered on time, within budget, and with the best quality.



4.1 Goals and Objectives

The goal of a Quality Plan is to explicitly plan for and describe the quality related activities needed to ensure that the project meets the requirements of the project sponsor and complies with regulatory requirements. The Quality Plan should be developed hand-in-hand with the PMP for the project. It is a living document in that it will probably have to be revised as the project progresses from the Project Planning Phase through Preliminary Engineering (PE), Final Design (FD), Construction/Procurement, and Testing and Start-up.

4.2 Responsibilities

The Project Manager (PM) is ultimately responsible for implementation of the Quality Plan. The person in charge of Quality should approve the plan.

4.3 Approach

Where a project sponsor has detailed procedures for carrying out the elements of the Quality Policy, the development of a Quality Plan for a project is straightforward. The Quality Plan should provide an overview of the entire Quality Program for the project and should provide enough detail, either through incorporation of or reference to written procedures to demonstrate objectives based on the project sponsor's Quality Policy and the expectations of the FTA and/or other project stakeholders are met during the different project phases of Project Planning; Preliminary Engineering and Final Design; Construction and Equipment Procurement; and Testing and Start-Up. [Table 4-1](#), below, shows details of the Project Quality Plan at various project phases.

Where written procedures have not been adopted by the project sponsor, they will have to be developed specifically for the Quality Plan. Thus, if a project sponsor expects to be involved in multiple capital projects using FTA funding, the project sponsor should consider the formal development of written procedures.

The Quality Plan should be written to provide project management with easy access to the quality requirements. When the Quality Plan references procedures or standards, those items should be readily available.

4.4 Technical Requirements During Each Project Phase

While it is possible that one Quality Plan, applicable throughout the project, could be written at the end of the Planning Phase, the more likely situation is one where the Quality Plan evolves as the project progresses. This is because the organizations may change and the level of quality assistance required by contractors can vary. Also, the procedures, forms, reports, etc., initially proposed for a Quality Program, may be changed during the course of the project or not used at all. Changes should be reflected in the Quality Plan if they improve the final documentation and quality of the work.

There are exceptions to the traditional phased approach to a project. In design-build situations, one contractor could be responsible for several project phases. Therefore, the Quality Program requirements should be completely specified at the time of the project bid and design-build contractor selection. The project sponsor may choose to require that a Project Quality Plan or an outline be submitted with each proposal/bid, to aid in the selection process.

The following sections describe the type of detail that is desirable in a Quality Plan during the relevant project phases. The description is for the desired detail for a complex project where all of the quality system elements should be included at some time during the project. Less detail may be appropriate for simpler projects.

4.4.1 Project Planning

Project Planning can include the bus maintenance facility planning process, rail modernization planning, and the Alternatives Analysis (AA) process for major capital investments for which FTA has established detailed procedures. Responsibility for bus maintenance facility planning and rail modernization planning typically rests with the operating agency. For AA planning, the responsibility may be spread among several agencies. The lead agency need only have the charter, authority, and capability to perform the planning and receive the grants required to accomplish the AA.

For major capital projects, a PMP should be initiated during the Project Planning Phase and completed and approved before entering into Final Design. The project sponsor should develop the PMP, which may be different from the organization implementing the Project Plan. Generally, the PMP must be submitted during the project grant review process and as part of FTA's grant application review. A Quality Plan is required as part of the PMP and is usually prepared as a stand-alone document.

At this early phase, much is still unknown about the project. All of the participants may not be known, so that the Quality Plan cannot name organizations and persons. Schedules, budgets, construction techniques, and so forth have yet to be decided. Initially, therefore, the Quality Plan should consist of a general description of the fifteen basic quality elements as applicable to the project sponsor, and how they relate to the project. The Quality Policy and appropriate existing procedures should be included in the Quality Plan.

Development of the Quality Plan is important at this phase to set an overall expectation, objectives, and direction for quality for the project, and to clearly spell out quality requirements for procurement of the design consultants. [Table 4-1](#) indicates the quality system elements for which design-related detail might be appropriate at this initial phase. The Table then displays requirements for each element as the project progresses through Testing/Start-Up.

There may not be a quality requirement for submittal of a Quality Plan for projects which are not major, and which do not have a PMP requirement. However, the development of a Quality Plan can be beneficial

for project management and project control purposes on any project. Again, at this phase, the major planning effort should be focused on the quality requirements for the design activity.

4.4.2 Preliminary Engineering and Final Design

The Preliminary Engineering Phase is initiated at the conclusion of Project Planning. In PE, the design is developed enough to provide a more accurate estimate of project costs and impacts. The resultant technical and financial information forms the basis for subsequent funding and implementation decisions. During PE, the merits of all sound configurations and designs are investigated.

The Final Design Phase is the last project development phase prior to construction. During this phase, the design consultant and/or in-house design staff prepares the plans, specifications, and bid documents required for awarding the individual facility construction and equipment fabrication/installation contracts.

Management of PE and Final Design is the responsibility of the project sponsor, who must ensure that knowledgeable personnel are available to perform the required services.

Two basic alternatives exist for organizing the PE effort. The chosen alternative may be continued into Final Design or a different alternative can be established at that point. The two alternatives are: 1) the project sponsor staff performs all design, or 2) consultants have the primary responsibility for design. There are also organizational alternatives to these extremes that mix the use of project sponsor staff and consultant staff. For larger projects, either the project sponsor or a general design/engineering consultant can supervise and manage the work of firms retained to design sections of the project.

As design consultants are chosen and the design management organization is put into place, the PMP should be updated to reflect these actions. The Quality Plan should be updated to reflect each new organization of quality activity, and it should be updated to reflect more closely the planned quality activities during the Final Design Phase. The Plan should begin to answer more specifically the questions of who is responsible and when in time actions should occur.

More importantly, the Quality Plan should be updated to reflect the quality requirements for the next phase in the process. Since an important product of the design phase is construction contract documents for construction contractors, decisions about quality requirements for construction and manufacturing need to be planned and included in the contract documents. [Table 4-1](#) indicates the detailed descriptions of quality requirements that might be appropriate at this phase in the Project Quality Plan.

4.4.3 Construction and Equipment Procurement

During the Construction and Equipment Procurement Phase, suppliers, contractors, and/or agency force account employees construct the fixed facilities, fabricate/install equipment, and integrate them into a functioning system. During this phase, the Quality Plan should be updated in sufficient detail to guide the project sponsor in appropriate QA, QC, and quality oversight procedures.

During this phase, the first task is to procure the required contractors. These include the Project or Construction Management Consultant (PMC or CMC), the construction contractors, and/or the equipment manufacturers. Where procurement regulations allow, contractors should be prequalified. Evidence of an acceptable Quality Program should be part of the prequalification process.

Where the specifications for the various contracted project tasks require the contractor to assume responsibilities for specific quality activities, the contractor should prepare written documentation of its Quality Program. This program should be reviewed and approved for adequacy by the project sponsor's PM and the QM, or equivalent position.

Key quality elements that need to be specified in detail in the Quality Plan and, where appropriate, in contract documents, are procedures for nonconformance and corrective action during manufacturing and/or construction. In particular, the process for stopping work should be spelled out. Persons authorized to issue stop-work orders, procedures for doing so, approvals required, and restrictions need to be clearly understood by the contractors as well as the project sponsor. The project sponsor's role in providing quality oversight for the project should be described, and any audit activities should be planned. [Table 4-1](#) indicates the detailed descriptions of quality requirements that might be appropriate at this phase in the Project Quality Plan.

4.4.4 Testing and Start-Up

The Testing and Start-up Phase is the bridge between the Construction and Equipment Procurement Phase and the beginning of revenue service. The purpose of this phase is to accept the newly constructed or modernized facility, and/or the newly procured equipment. This phase also includes integration testing of the operating system prior to beginning or resuming revenue service. This phase overlaps with the Construction and Equipment Procurement Phase, since some testing is performed in accordance with contract requirements during the earlier phase.

The Quality Plan should be modified prior to the beginning of the Testing and Start-up Phase to include detailed procedures for those tests required for the transfer of facilities and equipment from the constructing organization to the operating organization. Although contractually required testing will have been done as part of Construction and Equipment Procurement, other testing may be required by the project sponsor to accept the facilities and equipment. Acceptance criteria, however, must be specified at the end of the Final Design Phase and included in the construction contract documents.

Assurance of the testing program at this point is the responsibility of the project sponsor. A test management team, as part of the project staff, should manage testing. A test engineer should manage the program with assistance from consultants and project sponsor staff, as appropriate.

An exception to this situation would be when the contractor constructing the new system will also be responsible for operating the system for a period of time. In this case, all system integration testing would be performed as part of the contract with the constructing/operating organization. The tests must therefore be detailed in the Final Design Phase.

Preparation for revenue service start-up also includes the training of personnel to operate and maintain the facilities. Prior to service start-up the project sponsor should simulate service to test whether all system elements are functional and perform as designed. Start-up operations should verify the competence of the personnel and ensure a smooth and safe transition into operations.

The Quality Plan for the project should also reflect the need for ongoing maintenance contracts, as well as project sponsor/operator actions required to keep the contractual warranties in force. [Table 4-1](#) shows the detailed descriptions of quality requirements that might be appropriate at the beginning of the Testing and Start-up Phase.

Given the existence of a detailed Project Quality Plan and given that the Plan is carefully executed, each of the project phases from Project Planning through Testing and Start-up should meet the quality requirements of the project sponsor and provide excellent service. This, ultimately, is the objective of the Quality Program.

Table 4-1: Details of the Project Quality Plan at Various Project Phases

Quality Program Element	Project Phase			
	Project Planning	Preliminary Engineering and Final Design	Construction and Equipment Procurement	Testing and Start-Up
1. Management Responsibility	Describe the quality responsibilities of the project team and the organization responsible for quality for the project sponsor. Identify policy and objectives. Identify specific positions where possible.	Describe the quality responsibilities of the project team and the organization responsible for quality for the project sponsor and for the design consultant. Identify policy and objectives. Identify specific positions where possible.	Describe the quality responsibilities of the project sponsor project team and the organization responsible for quality for the project sponsor and for construction management consultants, construction contractors, and equipment manufacturing contractors. Identify policy and objectives. Identify specific positions where possible. Identify project sponsor functions responsible for quality oversight activities.	Describe the quality responsibilities of the project team and the organization responsible for quality for the project sponsor and for construction management consultants, construction contractors, and equipment manufacturing contractors. Identify policy and objectives. Identify specific positions responsible for acceptance, demonstration, and integration testing. Identify project sponsor functions responsible for the testing program.
2. Documented Quality Management System	Incorporate by reference any written quality procedures applicable to the project. Applicable existing procedures can be referenced for any of the Quality Program elements.	Incorporate by reference any written procedures for quality applicable to the project. Construction and/or equipment manufacturing related procedures are particularly relevant.	Incorporate by reference any written procedures for the Quality Plan applicable to the project. Construction and/or equipment manufacturing related procedures are particularly relevant.	Incorporate by reference any written procedures for the Quality Plan applicable to the project. Testing related procedures are particularly relevant.

3. Design Control	Specify quality requirements for review & sign-off for design from departments, such as Construction and Operations, and other relevant agencies. Specify required design reviews during the PE and Final Design Phase. Specify any contract quality requirements for PE or Final Design consultants. Describe the procedures to be followed for design changes, including sign-off and documentation .	Describe the quality procedures to be followed for design or specification changes or waivers of requirements during construction. Sign-off of the responsible design consultant is desirable as well as sign-off by those originally responsible for the design approvals. Requirements for "as-built" documents should be stated.	Describe the quality procedures to be followed for design or specification changes or waivers of requirements during construction. Sign-off/concurrence of the responsible design consultant is desirable as well as sign-off by those originally responsible for the design approvals. Requirements for "as-built" documents should be stated. Construction Phase Services procedures should be defined,	Describe the quality procedures to be followed for fixing problems that are uncovered during final testing. Configuration management practices should be identified and followed.
4. Document Control	Describe procedures for the control of project documents. These procedures may be modified as contractors and consultants	Describe procedures for the control of project documents incorporating the design consultants for the project. These procedures may be modified as	Describe procedures for the control of project documents as relates to the various construction contractors and consultants for the project. Contractor obligations should be specified and should be included in the contract documents.	Describe procedures for the control of documentation from the testing program.

	join the project.	construction contractors and construction management consultants join the project.		
5. Purchasing	Describe procedures to obtain a list of qualified contractors/consultants for the design service. Provide a statement of general requirements, including quality requirements, and any past demonstrated capability and performance requirements. Describe the process to ensure that purchasing documents are reviewed and approved by a designated authority prior to release.	Describe procedures to obtain a list of qualified contractors for the desired service. Provide a statement of general requirements, including quality requirements, and any past demonstrated capability and performance requirements. Describe the process to ensure that purchasing documents are reviewed and approved by a designated authority prior to release.	Describe requirements for purchasing control to be placed upon construction contractors or equipment manufacturing contractors for the project. Describe purchasing and receiving control procedures to be followed by the project sponsor.	In addition to the requirements for testing of materials defined in the purchasing contract documents, specify in the Quality Plan random testing by the project sponsor of products for which fabricators submit material certificates or certificates of compliance. Testing should also be conducted when the validity of the materials/products or documentation are questionable.
6. Product Identification and Traceability	N/A	Describe requirements for product identification and traceability to be placed in contract documents,	Describe requirements for product identification and traceability that should be included, where appropriate, in contract documents.	Describe the requirements for product identification and traceability for products and materials turned over to the project sponsor at the project conclusion.

		where appropriate, for equipment manufacturers or others supplying products for the project. Describe where these requirements are appropriate.		
7. Process Control	N/A	Describe requirements for process control and procedures for special processes to be placed in contract documents, where appropriate, for contractors. Describe where these requirements are appropriate.	Describe requirements for process control and procedures for special processes, which should be included, where appropriate, in contract documents. These procedures should specify any sequencing of work requirements.	Describe plans for maintenance of the facility and equipment, especially as required for warranty purposes.
8. Inspection & Testing	N/A	Describe requirements for inspection and testing to be placed in contract documents, where appropriate, for contractors. Inspection and testing can include source inspection,	Describe requirements for inspection and testing for each contract, as appropriate. Inspection and testing can include source inspection, receiving inspection, in-process inspection and testing, and final inspection and testing. State the	Describe plans for acceptance testing, demonstration testing, and integration testing of the system and equipment. Acceptance tests verify that performance of all delivered equipment is in conformance with specifications. Demonstration tests illustrate the reliability of the system equipment. System integration

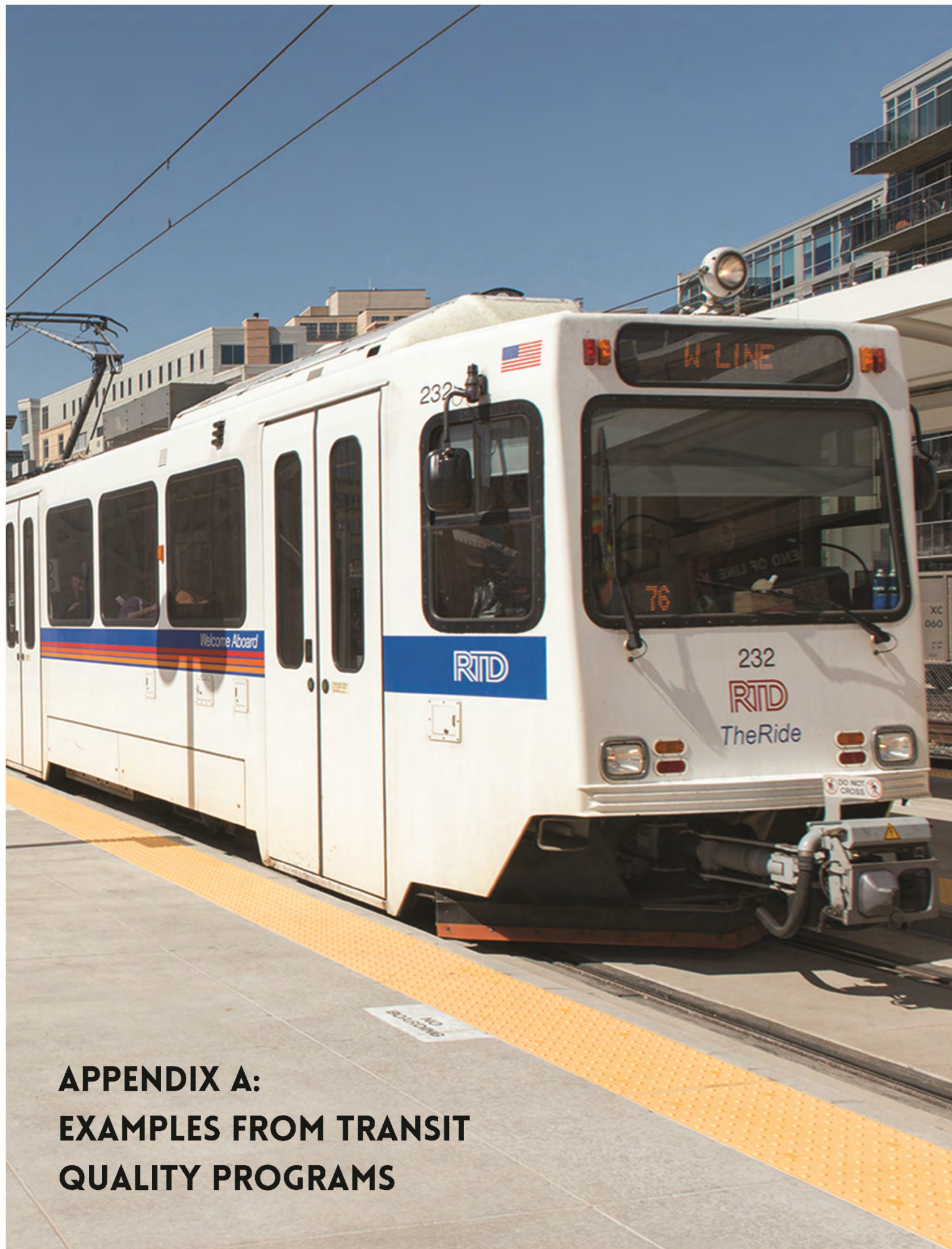
		receiving inspection, in-process inspection and testing, and final inspection and testing. Specifications should indicate the types of tests required and the standards to be met. Describe where these requirements are appropriate.	types of tests required and the standards/ specifications to be met.	testing demonstrates the ability of various subsystems and facilities to work together as a system and for the new or modernized system to function with an existing system. Tests that affect system safety should be reviewed independently in a safety review to ensure that potential hazards are identified and fixed.
9. Inspection, Measuring & Test Equipment	N/A	Describe requirements for calibration and maintenance of inspection, measuring, and test equipment to be placed in contract documents, where appropriate, for contractors. Describe where these requirements are appropriate.	Describe requirements, as appropriate, for calibration and maintenance of inspection, measuring, and test equipment for each contract.	Describe requirements, as appropriate, for calibration and maintenance of inspection, measuring, and test equipment as required for final testing.
10. Inspection & Test Status	N/A	Describe requirements to be placed in contract documents, where	Describe requirements, as appropriate, for contractors to identify the inspection and test	Describe requirements, as appropriate, to identify the inspection and test status of work during final testing.

		appropriate, for contractors to identify the inspection and test status of work during production and installation. Describe where these requirements are appropriate.	status of work during production and installation.	
11. Non-conformance	Describe procedures for managing nonconforming work. Potential design consultants/contractors should be made aware of these procedures.	Describe project sponsor procedures for managing nonconforming work. These procedures should be included in contract documents to clarify future expectations.	Specify project sponsor procedures for managing nonconforming work in detail. All contractors should be made aware of the procedures. Procedures include defining responsibilities, stating conditions that would cause work to stop, and providing documentation. Specify the requirements for the contractor to have their own procedures.	Describe procedures for managing nonconforming work. These procedures should be maintained during final testing.
12. Corrective Action	Describe procedures for managing corrective action. Potential design consultants/contractors should be made aware of	Describe project sponsor procedures for corrective action and include these procedures in contract documents to clarify future expectations.	Describe procedures for taking corrective action in detail. Each contractor should be made aware of the procedures. Specify any requirements for the contractor to have their own procedures.	Describe procedures for taking corrective action. These procedures should be maintained during final testing.

	these procedures.			
13. Quality Records	Specify procedures for establishing and maintaining quality records. Requirements for consultants and contractors should be specified and made part of bid contracts and specifications.	Specify procedures for establishing and maintaining quality records. Requirements for contractors should be specified, and made part of contract documents.	Specify procedures for establishing and maintaining quality records. Requirements for contractors should be specified, and made part of the contract documents.	Specify procedures for maintaining quality records for a specified period of time after project completion.
14. Quality Audits	Describe an audit program with the initial focus on the design process at this phase in the project.	Plan and implement a quality audit system for the design activities during PE/Final Design. Requirements for consultants and contractors to cooperate with quality audits should be stated, and included where appropriate, in contract documents.	Plan and implement an audit program for the construction and equipment manufacturing activities.	A final audit should be planned to ensure that project quality records are complete and in satisfactory condition.
15. Training	Identify specific training required for personnel.	Identify specific training, competency, and qualification requirements	Identify specific training, competency and qualification requirements required for project sponsor and	Identify specific training required for personnel performing final test. Identify specific training, competency and qualification(s) required for project sponsor

		required for project sponsors and consultant and contractor personnel.	contractor personnel.	operating and maintenance personnel to ensure a smooth transition to operations.
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APPENDIX A: EXAMPLES FROM TRANSIT QUALITY PROGRAMS

The 15 Elements as Covered by Various Agencies

The following examples are procedures and excerpts from quality plans which illustrate how a number of project sponsors have implemented different aspects of the 15 elements provided in the Guidelines. Each example follows a description of why it has been included and which aspects of the revised Guidelines it may or may not cover.

The 15 Elements as Covered by Various Agencies	1
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Element 1: Management Responsibility

The following is Section 1 of Revision 13 (April 2016) of the Charlotte Area Transit System (CATS) Project Quality Plan, which has been generously provided by CATS – Charlotte NC.

This example has been provided because it specifies that an effective Quality Management System (QMS) defines the responsibilities of various levels of management, including the Chief Executive Officer (CEO).



1 Management Responsibility

1.1 Purpose

Authority, accountability, and responsibility are identified defining the organization, the function of each element of the organization, and the reporting chain of command.

1.2 Scope

The Project Quality Organizational Chart is shown in Figure 1-1. A detailed Project Organization Chart is described in each *Project Management Plan* (PMP).

The project organization is structured in such a manner that:

- Persons or organizations charged to verify quality are not directly responsible for performing the work.
- The organization responsible for quality has the authority, access to work areas, and organizational freedom to identify quality problems; verify implementation of solutions; and assure that further processing, delivery, or installation is controlled until proper disposition of a deficiency, nonconformance, or unsatisfactory condition has occurred.
- Quality is achieved and maintained by those who have been assigned responsibility for performing the work.
- Quality verification functions will report to a level of management which provides sufficient authority and organizational freedom to assure appropriate action is taken to resolve conditions adverse to quality.
- The Quality Assurance Manager and the management of the organizations implementing the project quality plans will regularly assess the adequacy and effectiveness of the plans.



1.3 Responsibility

CATS' Chief Executive Officer (CEO) is the public official responsible and accountable for implementation of CATS projects in accordance with federal and state requirements using sound management practices. The CATS CEO reports administratively to the City Manager and receives policy direction from the Metropolitan Transit Commission (MTC).

CATS' Deputy Director is responsible for overseeing the development and implementation of the Corridor Programs and other development projects. CATS' Deputy Director is responsible for ensuring the coordination of the corridor projects and other development projects in working with other City departments to monitor the development system planning effort. CATS' Deputy Director reports to the CATS CEO.

CATS Project Manager is responsible for the day-to-day activities of the projects through all phases (engineering, design, construction, and start-up). The Project Manager reports to CATS' Deputy Director.

The A/E Consultants' Project Manager reports to CATS Project Manager. The selected A/E Consultants have quality assurance responsibilities for preliminary design, final design, construction, and startup as described in the referenced procedures. Consultant organizational charts are detailed in their project management plans.

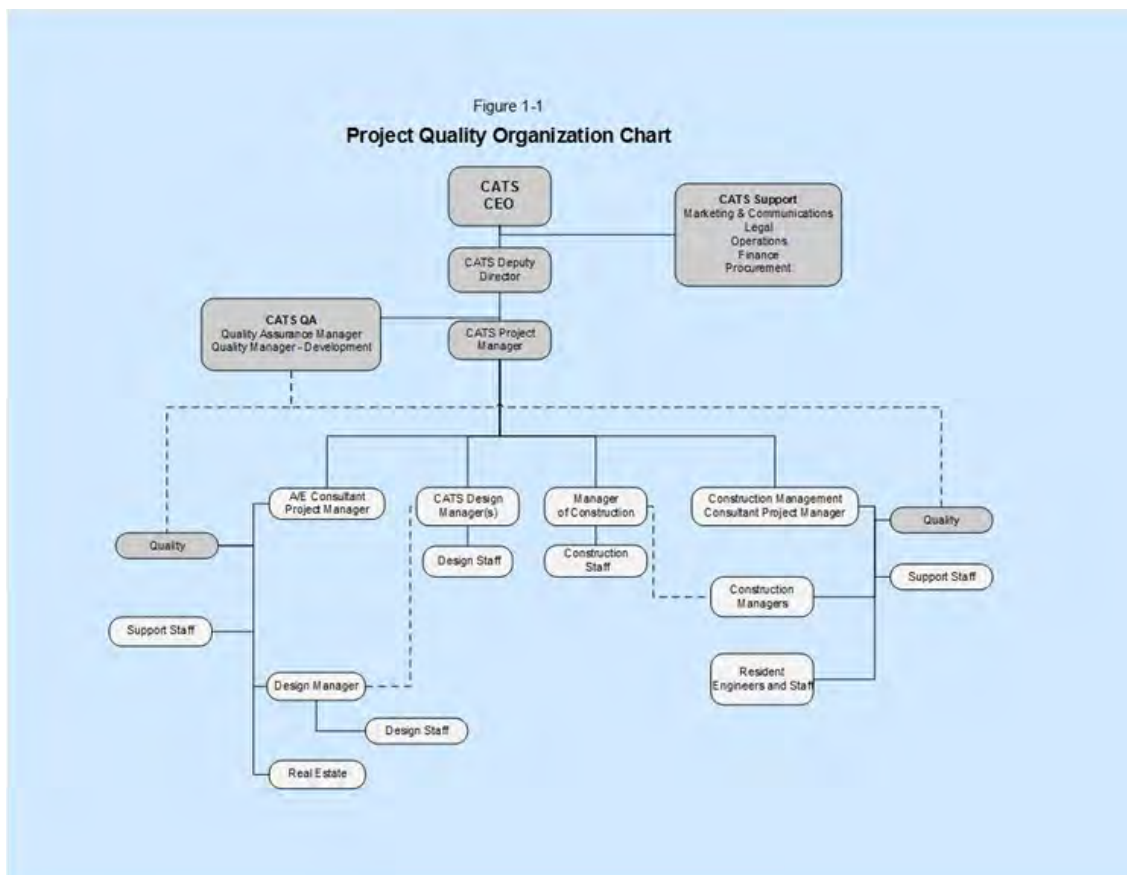
The Quality Assurance Manager, reporting to CATS' Deputy Director, is responsible for assuring the development, establishment, implementation, evaluation, and administration of the Quality Program.

These activities include but are not limited to:

- Assuring that appropriate CATS and project level quality assurance plans are established, implemented, and maintained.
- Consulting with contractors, design consultants and suppliers regarding CATS quality requirements.
- Monitoring and evaluating plan implementation adequacy and effectiveness;
- Staffing CATS Quality Assurance Organization.

- Coordination and correlation of the CATS *Project Quality Plan* with the quality assurance plans of consultants and their subcontractors, ensuring that the CATS Quality Policy is not compromised.
- Resolving conflicts regarding the intent of CATS *Project Quality Plan*.
- Auditing consultants, contractors, suppliers and CATS internal processes to assure the PQP is being followed.
- Reviewing contract documents.

Decisions made by the Quality Assurance Manager regarding the applicability and/or interpretation of the *Project Quality Plan* to the project contractors, consultants, and suppliers or others who may work on the project is not subject to interpretation by the project staff.



Element 2: Documented Quality Management System

The following is Section 02 (August 2019) of the Maryland Transit Administration (MTA) Quality Assurance Program Plan, which has been generously provided by the MTA – Baltimore, MD.

This example has been provided because it stipulates that quality plans should be updated as required. The guidelines state that QMS documents need to be regularly reviewed and updated. The frequency of these reviews should be determined by the specific needs of the project sponsor or capital project involved, and are not required to be referenced in the project sponsor's quality manual, though they may be. This example also requires that each consultant and contractor, as required by contract, shall be responsible for documenting and publishing a Quality Control Plan

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Office of Engineering and
Construction
Quality Management System Plan**



2. DOCUMENTED QUALITY MANAGEMENT SYSTEM

2.1 Purpose

To describe the QMS requirements for MTA engineering projects and to assign responsibility for developing, approving and implementing quality procedures for the program.

2.2 Scope

These Quality Management System requirements apply to all Office of Engineering and Construction staff, consultants, and contractors who perform activities that affect quality on MTA engineering projects and all other projects undertaken by the Office of Engineering and Construction.

2.3 Policy

2.3.1 This Office of Engineering and Construction QMSP establishes elements pursuant to a documented QMS that ensures MTA engineering project quality objectives are satisfied. The requirements of the MTA's QMS shall be extended to consultants and contractors as appropriate.

2.3.2 This QMSP should be reviewed for continued applicability and updated as appropriate. Change/Impact review should flow through all other manuals, plans, procedures, instructions, and forms whenever it is deemed necessary, including upon an update to the FTA's Quality Management System Guidelines. At a minimum, the QMSP will be reviewed every two years. If no changes are required as a result of the review, the reviewer will document the review's occurrence through email or internal memorandum.

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2.3.3 This Office of Engineering and Construction QMSP defines the requirements contributing to the attainment of a safe, convenient, reliable, and economical transportation system. The MTA QA/QCM shall be responsible for the administration of this program.

2.3.4 The Office of Engineering and Construction also maintains manuals for various departments that operate within it. These manuals contain quality procedures, forms, and checklists for use involved with the performing of duties related to the related departments. They include, but are not limited to:

- *Requirements of Quality Management Plan for A&E Design Consultants*
- *Drawing and CADD Standards*
- *Document Control Center Policies and Procedures Manual (DCC-PPM)*
- *Resident Engineer's Manual*
- *Facilities Engineering Design Procedures Manual*
- *Systems Engineer's Manual*
- *Commissioning Guide*

2.3.5 Each MTA engineering project contract shall be reviewed to determine the elements of this Office of Engineering and Construction QMSP that shall be implemented. Consultants and contractors shall be required to develop, implement, and maintain a QMS that is consistent with the quality requirements stated in the contract documents applicable to its Scope of Work.

2.3.6 Each consultant and contractor, as required by contract, shall be responsible for documenting and publishing a CQCP/QMP in response to the MTA's pursuit of consultant and contractor services. In the event that a consultant or contractor subcontracts any portion of the contracted work, the accountability for the quality program shall remain with the primary consultant or contractor. The subcontractor may be required to prepare a quality plan.

2.3.7 All personnel who manage or perform activities affecting quality shall be qualified on the basis of appropriate education, training, and/or experience, and are subject to approval by the MTA. See Section 15, *Training*, of this QMSP.

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2.4 Requirements

2.4.1 This QMSP identifies requirements for the development, implementation, maintenance, auditing, compliance review, and reporting of quality activities.

2.4.2 Department manuals identify procedures and requirements pursuant to the activities of each department.

2.4.3 All Invitations for Bids (IFBs), Request for Proposals (RFPs), Purchase Orders (POs), and ancillary assignments under existing contracts shall include a requirement/specification for quality considerations.

2.4.4 All bids and proposals shall include the quality effort as defined in the program.

2.4.5 All consultants, as required by contract, shall prepare, publish, maintain, and utilize a QMP addressing the work they are performing. The Plan shall be submitted to MTA and approved prior to the Notice to Proceed (NTP).

2.4.6 All contractors, as required by Special Provision Section 01450, shall publish, maintain, and utilize a CQCP specific to the projects bid. The Plans shall be submitted to the MTA within time periods specified in Section 01450.

2.4.7 This QMSP and consultants' and contractors' QMPs/CQCPs shall be reviewed and updated as necessary to remain current.

2.4.8 All consultants and contractors shall be required to maintain quality records, and quality records must be available for Quality Surveillance and compliance reviews. Quality Records shall be transmitted to the MTA's Project Manager in accordance with contractual requirements.

2.5 Responsibilities

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- 2.5.1 The MTA Project Manager shall be responsible for ensuring that appropriate quality requirements are included in specifications, drawings, statements of work and bid packages.
- 2.5.2 The Procurement organization shall be responsible for assuring that quality requirements are included in every procurement package.
- 2.5.3 The QA/QCM has responsibility and commensurate authority for:
- Implementation and administration of this QMSP
 - Verifying the effectiveness of this QMSP
- 2.5.4 The assigned Office of Engineering and Construction Staff Member shall be given responsibility and commensurate authority for:
- Review of all applicable IFBs, RFPs, POs and contracts prior to issuance for bid to determine and designate the specific quality provisions to be implemented.
 - Review of all proposals for concurrence with the proposed quality provisions.
 - Approval of QMPs/CQCPs.
 - Approval of consultant and contractor quality personnel.
- 2.5.5 Consultant and contractor Quality Managers shall be responsible for:
- Preparation, implementation, and maintenance of their organization's quality plans.
 - Quality assurance of their subcontractors, suppliers, and vendors, as applicable.
 - Verifying the effectiveness of its organization's quality plan.
 - Maintaining verification of records and providing access to these records upon request.

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2.6 Procedure

- 2.6.1 Contract documents to consultants and contractors shall include a stipulation that they develop and implement effective quality programs for their assigned task orders that meets MTA's quality requirements.
- 2.6.2 Quality requirements shall be outlined at pre-proposal and pre-bid conferences, and project kick-off meetings. Consultants and contractors shall be formally notified of the quality requirements and shall be required to acknowledge their understanding of, and ability to adhere to these requirements.
- 2.6.3 Each consultant and contractor performing work on MTA engineering projects shall prepare a QMP/CQCP, as applicable, for its assigned task order. Consultant plans shall be submitted to the MTA's QA/QCM for review and approval. Contractor plans shall be submitted to the Resident Engineer for review and approval.
- 2.6.4 The QA/QCM or assigned Project Manager/Resident Engineer shall conduct a compliance review of each consultant's and contractor's quality plan to assure its adequacy, assess its effectiveness, and confirm that it is consistent with MTA's specifications and contractual requirements. Each plan shall be updated as necessary to remain current.

Element 3: Design Control

The following is Section 4.0 of Revision 3 (April 2012) of the Regional Transit District of Denver (RTD) FasTracks Quality Assurance Program Plan, which has been generously provided by RTD – Denver, CO.

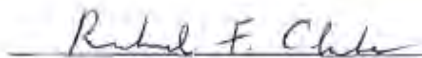
This example has been provided to illustrate that an independent person of equal or higher authority (the Lead Assessor) should review the work of the person performing the Design Review (the Assessor). In the case of RTD, there are two elements of Design Review: Reviews against the contractually defined requirements and General design comments.



QMO Section 4.0
Design Review
Revision 3, April 2012

THIS IS A CONTROLLED DOCUMENT; PLEASE DO NOT DUPLICATE. IF ADDITIONAL COPIES ARE REQUIRED, PLEASE REQUEST THEM FROM FASTRACKS DOCUMENT CONTROL. THIS WILL ASSURE THAT ALL RECIPIENTS OF THE DOCUMENT RECEIVE REVISIONS AND ADDITIONS.

Approved By:

Richard F. Clarke, Assistant General Manager, Date
Capital Programs



QMO-P4, DESIGN REVIEW

1.3 PURPOSE

The purpose of this procedure is to describe the method for performing Design Reviews on design documents prepared by Designers for projects comprising Fastracks. This procedure is applicable during all phases of design.

1.4 SCOPE

1.4.1 Overview of Design Review

- 1.4.1.1 Design Review is performed to gain confidence that the Designer is performing the design work in accordance with the design requirements for the project.**
- 1.4.1.2 This procedure is applicable to Design Reviews performed on design documents prepared by Designers during Basic Engineering, Preliminary Engineering and Final Design phases for projects comprising Fastracks.**
- 1.4.1.3 The person performing a design review is known as the "Assessor". The person responsible for coordinating RTD's design review and approving of each review report is known as the "Lead Assessor".**
- 1.4.1.4 Design Reviews are conducted during interim (or "over the shoulder") reviews, and at formally planned reviews for design documents submitted at designated design completion milestones. Design Reviews performed at milestones are formally planned in order to prioritize design review efforts based on sound engineering judgment, perceived risk, and past performance of design efforts.**
- 1.4.1.5 Two elements of Design Review include:**
 - o Reviews against the contractually defined requirements**
 - o General design comments**
- 1.4.1.6 Reviews against the contractually defined requirements enable an objective measurement of design conformance and performance measurement. They should be conducted when the design document is deemed substantially complete, typically at 90% degree of completion.**



- 1.4.1.7 General design comments allow Assessors to communicate additional relevant information to the Designer regarding the design documents. These comments may focus on level of completion, errors and omissions, value engineering, design interfaces, and constructability. Comments are typically made on interim design documents during design development.
- 1.4.1.8 The QMO database application documents, tracks, and reports the results of Design Reviews. It stores contract requirements and collects the results of the reviews performed by Assessors. Additionally, the application allows the Designer to record responses to detected nonconformances and comments. Reports listing the status of open non-conformances and comments can also be produced and used by interested parties. The database allows for the tracking of comments and any detected nonconformances (NC), and the communication of updates regarding the resolution of NC's to the Designer and Lead Assessor via email.
- 1.4.1.9 A Comment Review meeting is conducted to screen all review issues prior to formally submitting them to the Designer. Note that this meeting may be informal, depending on the needs of the project.

1.4.2 Available Design Review Types (Scheduled & Unscheduled)

- 1.4.2.1 There are two types of reviews that can be performed. These review types are defined below:

Available Design Review Types

Scheduled
Review
(milestone
submissions)

A Review is classified as 'Scheduled' if it is a review of the submitted design documents performed at specific pre-determined design completion milestones.

Unscheduled
Review
(interim
"over-the-shoulder")

A Review is classified as 'Unscheduled' if:

It is an interim "over-the-shoulder" design review that is investigating a specific requirement(s) that appears to be a nonconformance.

It is a review responding to unexpected events or is a proactive measure to help mitigate re-design (if review was delayed until the next milestone submission), and typically only nonconforming observations are recorded. It is conducted as an early action item, outside of the schedule milestones.



1.5 METHOD

1.5.1 Planning the Design Review

1.5.1.1 Lead Assessor:

- o Review the project schedule to determine and confirm the date of a milestone submission. Ensure that Assessors are available and ready to perform the design review.
- o Ensure that the Designer has designated an individual (Designer Representative) to specifically receive the results of the review and respond to each detected nonconformance or comment.
- o If an unscheduled review is required, ensure that an Assessor is made aware of the issue to be assessed and is prepared to carry it out.
- o Ensure that the requirements list includes all of the applicable requirements relating to the design work to be assessed. If necessary and appropriate, add additional requirements to the data set.
- o Document aspects of the priority plan for the design review. Consider using the design review planning template shown in the appendix to identify the focus of the review.

4.3.1.2 QMC Design Review Coordinator or Project Design Manager:

- o Coordinate with and assist the Lead Assessor, as necessary, to carry out the steps of planning a Design Review; use the QMO database application; and develop a priority plan.
- o Log-on to the QMO database application and set-up the review based on design review planning information provided by the Lead Assessor (i.e. milestone %, names of reviewers, design review timeframes, and other planning aspects).

1.5.2 Performing Reviews during Design Development

1.5.2.1 **QMC Design Review Coordinator or Project Design Manager: Assist the Assessor, as necessary, to ensure that the Assessor is able to perform a review, and provide assistance on the use of the QMO database application.**

1.5.2.2 **Assessor: where applicable, make general comments associated with design development in order to assist the Designer to better understand what the design needs to accomplish so that the Designer can progress the design to completion. These comments can pertain to other design related issues such as the following:**



- o Designer QC Issue
- o Missing or Incorrect Information
- o Value Engineering Issue
- o Constructability Issue
- o Multi-discipline Integration Issue

1.5.3 Performing Reviews when Design is Substantially Complete

1.5.3.1 Assessor:

- o Perform the Review by verifying that the design documents conform to the requirements. Support the conformance or nonconformance decision by documenting objective evidence.

Note: In order to confirm that the applicable design requirements have been incorporated into the design documents, use methods such as:

- Performing supporting calculations
- Examining Designer's design notes/calculations
- Reviewing the design submission documents such as drawings or specifications, to determine that the requirements are being correctly followed
- Using engineering judgment
- Comparing the design with proven designs of a similar type

Discuss with the Lead Assessor the initial results of the review. Review all observations and reach consensus on which observations are to be considered nonconformances. Complete the categorization of observations into conforming observations (C) and nonconformances (NC). See the following definitions:

- Conforming Observations (C): Observations made by the Assessors that indicate the requirements have been fully incorporated.
- Nonconforming Observations (NC): Observations made by the Assessors that indicate the work performed does not fulfill the contractual requirements. These observations are sub-classified as Level 1, 2 or 3, depending on the importance of the requirement or the severity of the non-conformance.



- ❖ Level 1 nonconformance indicates an issue that potentially affects a program goal or may have a significant impact on the performance and safety of operations or an end user.
- ❖ Level 2 nonconformances indicate that the requirement has not been met and significant re-design must occur to rectify the issue.
- ❖ Level 3 nonconformances indicate that the work is technically nonconforming, but it can be judged to be relatively minor.

1.5.4 Submit Design Review to Lead Assessor for Approval

1.5.4.1 Lead Assessor: Review the submitted data file and ensure that the design review results accurately reflect the results of the review. A design comment review meeting should be held with the review staff by the Lead Assessor prior to approval to ensure accuracy and consistency. When satisfied that the design review results are accurate and appropriate, approve the design review. Note the approval action will initiate the submitting of the results to the design consultant.

1.5.4.2 Assessor: Upon completion of design review, electronically submit via the QMO database application the results to the Lead Assessor.

1.5.5 Propose Response to NC and Comments

1.5.5.1 Designer Representative:

- o Propose a response to each NC/Comment, and discuss with the Lead Assessor, if necessary.
- o Review results and respond to each NC/Comment within the database application by selecting one of the following responses:
 - Will Comply
 - Clarification Required
 - Not Applicable
- o Document the response to each NC/Comment within the QMO database and return it (electronically via database interface application) to the Lead Assessor.

1.5.6 Conduct a Comment Resolution Meeting

1.5.6.1 Project Manager or Designee: If deemed necessary, conduct a meeting called and chaired by the Project Manager between the Designer's discipline staff, and RTD's design Assessors and Lead Assessor(s) to discuss responses to NC/Comments.



- 1.5.6.2 **Lead Assessor:** Discuss with Designer counterparts the responses to identified NCs/ Comments. Ensure that at the end of the comment resolution meeting, all comments with a response of Clarification Required becomes either a Will Comply or Not Applicable.
- 1.5.6.3 **QMC Design Review Coordinator:** Make available to the Assessors and Lead Assessors a 'hardcopy' summary log of the Designer's responses to Design Review so that they can be reviewed prior to the comment resolution meeting. Ensure that the Lead Assessors update the database application to record the results of the discussions.

1.5.7 Close-Out NCs/Comments

- 1.5.7.1 **Assessor:** For each subsequent design review submission, verify that the Designer has implemented the planned response to NCs/comments in the updated design documents. Once verified, close the NC/comment within the QMO database application. For unacceptable responses to NCs/comments record the reasons and send back to the Designer Representative communicating that they need further clarification/action to resolve the NC.
- 1.5.7.2 **At the end of a contract, all NCs/comments should have a resolution and be closed for final plan acceptance. If there are NCs/comments open that need to be carried over to a new contract with a potentially different Designer Representative, the Lead Assessor shall notify the QMC Design Review Coordinator. The QMC Design Review Coordinator with the help of the project design staff will create a new Assessment with a generic contact and Designer Representative, (to be revised at a future date) and will roll all remaining open NCs/comments into it. The QMC Design Review Coordinator will then close the original NCs/comments with a closed reason referencing the new Assessment.**

1.6 APPENDICES

- o Appendix 1 – Design Review Planning Template

1.7 REVISION RECORD

Revision Level	Revision Date	Summary	Approval Date
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RTD **FasTracks**

0	March 15, 2006	1st issue of procedure	March 15, 2006
1	January 31, 2009	Revised format at signature level to be consistent with FasTracks Document Control procedures, incorporated minor program updates, and incorporated changes associated the priority planning process.	February 08, 2009
2	June 2010	Minor outline structure modification and revised Design Review Planning Template.	June 14, 2010
3	April 26, 2012	Format change to add new FasTracks logo. Various minor updates throughout.	April 30, 2012

Appendix 1

Design Review Planning Template

--Package --% Plan Review

RTD FastTracks

Lead Assessor – --		
RTD Civil		
Discipline	Assessor	Open Assessments
General Civil		
Drainage		
Utilities		
Trackwork		
Structures / Geotechnical		
CADD		
Park n Ride / Platforms		
Landscape / Urban Design		
RTD Other		
Discipline	Assessor	Open Assessments
Safety / Security		
Systems Integration		
ROW		
FERG		
Service Planning		
Operations		
Maintenance		
Construction		
DCS		
Outside Agencies		
Agency	Assessor	Open Assessments
Lead Assessor – --		
RTD Systems		
Discipline	Assessor	Open Assessments
Communications		
Signals		
Fare Collection		
TP/ Corrosion Control / SCADA		

SCHEDULE

RTD **FasTracks**

Design Submission Date:

Database / Review Plan meeting:

Location:

Design Review Start Date:

Design Review Close Date:

Design Review Resolution Meeting:

Response from designer by:

Review Performance Meeting:

Element 4: Document Control

The following is Section 4 of Revision 4.1 (March 2019) of the Tri-County Metropolitan Transportation District of Oregon (TriMet) Quality Assurance Program Manual, which has been generously provided by TriMet – Portland, OR.

This example has been provided because it includes stipulations for the systematic control of documents developed during design and construction. Responsibilities of consultants and contractors are also included. The procedure provides for the archiving of documents at the completion of the project

Section 4 - Document Control

4.1 Purpose

This section describes the processes utilized for the systematic control of documents developed during design and construction.

4.2 Scope

These requirements apply to agency staff or consultant/contractor prepared design and construction documents that are issued as TriMet project documents and all documents received by the project. These requirements do not apply to documents such as the *DCMM*, *IM*, specific *Project Management Plans (PMPs)* or the *QAPM*, which are addressed in the division *Business Practices Manual (BPM)*.

4.3 Policy

Project documents will be controlled in accordance with established document control procedures. Quality measures will be used to verify conformance.

4.4 Procedures

4.4.1 Document Control: An electronic database will be used for cataloging both incoming and outgoing documents. Documents will be assigned a control number for identification and filing. Document control files will be centralized.

Field offices will also use the document control system. At the completion of the field activity, the field files will be merged with the central files. All project files will be archived at the completion of the project in conformance with statutory requirements according to TriMet's Engineering & Construction Division's *BPM* and *Records Management Plan (RMP)*.

Consultants and Contractors for the project may be required to develop a filing system for their documents. All project documents sent to TriMet, or developed for TriMet's issuance, will be incorporated into TriMet's document control system and central files. Contract drawings and specifications will be handled separately and are discussed below.

4.4.2 Drawing and Specification Control: TriMet has established a computerized, internet-based database system for storage, distribution and management of all project engineering drawings and specifications. Consultants are provided access rights to read and/or write to the files depending on assigned "ownership" of the individual drawing. Documents are checked out during design activity and are checked back in by the end of the current week, to expedite a design effort. Final document production and distribution is the responsibility of TriMet. Exceptions shall be documented and submitted to TriMet for review and comment.

Documents checked back into the database will be checked by TriMet for adherence to required standards as follows:

- Reference files will be reviewed on the system before being returned to the database.
- Sheet files will be plotted and reviewed to confirm acceptability.
- Random checkplot reviews will be conducted on an ongoing basis.

NOTE: In instances when TriMet's electronic document database is not viable the consultant shall utilize their own document management system after coordination with and approval by the TriMet CAD manager.

4.4.3 Quality Assurance: The project document control system and the contractor's document and drawing control systems will be subject to surveillance or audit by the TriMet ECD QA manager at any time.

4.5 Responsibility

Consultant and contractor project managers are responsible for organization and control of their internal files and for providing required project documents to TriMet for inclusion in the document control system.

The TriMet CAD manager is responsible for the electronic document management system (EDMS).

The TriMet project directors, PMs, DMs and CMs are responsible for ensuring ongoing management of the document control system.

The TriMet ECD QAM is responsible for QA audits/surveillances of the document control systems.

4.6 Attachments

Not applicable

Element 5: Purchasing

The following is Section 5 of Revision 13 (April 2016) of the Charlotte Area Transit System

(CATS) Project Quality Plan, which has been generously provided by CATS – Charlotte NC.

This example has been provided because it extends purchasing requirements to all contractors and suppliers, including consultants (in paragraph 5.4.1 of the Project Quality Plan). It is important to note, somewhere in a project sponsor's quality and/or contract documentation, that these requirements are extended to third parties, as many will be procuring services, materials, etc. as a part of their contract performance.



5 PURCHASING

5.1 Purpose

To outline the requirements of the Quality Program to be incorporated into procurement documents.

5.2 Scope

The requirements of this procedure apply to all procurements for FTA funded projects.

5.3 Responsibility

As identified in CATS Project Management Plan, CATS Chief Procurement Officer has primary responsibility for procurement and contract administration.

CATS' Chief Executive Officer, Deputy Director, Project Manager, and other key personnel have contributor/support responsibilities as identified in the PMP and as appropriate based on the scope of the contract.

CATS Quality Section, working with CATS' Procurement and Contract Management (P&CM) Section and City Legal staff, shall identify the quality assurance requirements to be included in the contract documents.

CATS QA Section is responsible for the review and acceptance of the QA plans of their consultants, contractors, and suppliers.

5.4 Procedures

CATS' Procurement and Contract Management Section has developed the Procurement Manual, which details the requirements for all important activities, such as preparation of purchase orders, contracts for services, bid lists and supplier (vendor) quality requirements.

The Procurement Manual identifies the legal requirements for purchasing for local governments and the level of authority guidelines for contracting actions including change orders and amendments.

Contracts for procurement involving federal financial assistance are made in accordance with and include the appropriate contract clauses from FTA Circular 4220.1F, the FTA Master Agreement and all other provisions required as a condition of federal financial assistance.

Pre-Award Surveys may be necessary to determine the contractor's technical performance capability under the terms of the proposed contract. Pre-Award Surveys



may include a qualification hearing, verification of a bidder's financial capability, labor resources, skills and/or an on-site inspection of plant and facilities.

Documents which are used to procure materials are to be reviewed by CATS staff to verify that data necessary to assure quality is included or referenced in such documents. Revisions to these documents are subject to the same review as the original.

5.4.1 Contractors and Suppliers

Contractors are responsible for review and acceptance of their sub-contractors' Quality Programs.

Contractors shall either ensure that their sub-contractors have implemented an acceptable Quality plan or require the sub-contractors to follow the Contractor's Quality plan. When a subcontractor follows a contractor's QA/QC Plan, the contractor's plan should be written to include quality requirements for the subcontractor's specific scope of work.

Contractors and suppliers are responsible for the quality of work under their contract, including the work of their subcontractors, and for providing QA/QC in accordance with contract documents and their approved quality control plan.

5.4.2 Audits

Contractors and suppliers are responsible for performing audits as required by their contract and according to their approved quality plans.

As specified in the contract document, CATS has the right of access to the contractor and/or subcontractor facility to inspect, audit or otherwise verify the specified purchasing requirements are being fulfilled.

Element 6: Product Identification and Traceability

The following is Section 6 of Revision 4.1 (March 2019) of the Tri-County Metropolitan Transportation District of Oregon (TriMet) Quality Assurance Program Manual, which has been generously provided by TriMet – Portland, OR.

This example illustrates the importance of establishing requirements for traceability for the project sponsor or project. These requirements, ideally, should specify that materials be traceable both to their source (or production batch) and to where/how they were incorporated into the work. In the case of TriMet, suppliers and contractors are responsible for including adequate material control procedures in their quality plans and are fully responsible for providing materials that conform to the contract documents.

Section 6 - Control of Materials, Product Identification and Traceability

6.1 Purpose

This section describes the procedure for control of materials, parts, and components used to construct the project.

6.2 Scope

These requirements apply to all materials incorporated into the project.

6.3 Policy

Procedures will be established to control materials and provide traceability to ensure that project materials and components are correct and free from defects.

6.4 Procedures

Contractors and suppliers for the project contracts will be required to include procedures for control of materials in their quality plan. These procedures must be sufficient to provide confirmation and documentation that the incorporated materials meet the quality requirements of the contract and that the provided materials are, in fact, the same ones that have been submitted, tested, or otherwise approved for use. The approved quality plan requirements shall also apply to lower-tier subcontractors and suppliers, if those entities do not have appropriate and acceptable quality procedures in-place. This evaluation shall be performed by the prime contractor/supplier.

Physical identification and control, through such means as identification markings, serial numbers, model numbers, lot numbers/tags, etc. will be used whenever possible. These identifications shall be referenced on quality control test and inspection documents to provide an auditable trail from fabrication or testing to installation on the project. Where physical identification is impractical, other means, such as physical separation and handling, will be used. TriMet CMs and their inspection staff will verify and document in Daily Inspection Reports that the items delivered and installed are as identified in applicable certifications and reports (i.e. qualification and functional test reports, data reports, nondestructive examination reports, first article inspections, etc.). Quality assurance will primarily be provided via the audit of these records. A surveillance of the process may also be utilized to ascertain the adequacy of this effort.

6.5 Responsibility

TriMet's design team (staff and consultants) is responsible for determination of the required quality requirements and standards for the materials included in the contract.

The supplier or contractor is responsible for including adequate material control procedures in its quality plan and is fully responsible for providing materials that conform to the contract documents.



The TriMet CM and inspection staff are responsible for verification of materials upon delivery.

The TriMet ECD QAM is responsible for quality assurance audits and surveillances during the term of the contract.

6.6 Attachments

Not applicable

Element 7: Process Control

The following is Section 1 of Revision 13 (April 2016) of the Charlotte Area Transit System

(CATS) Project Quality Plan, which has been generously provided by CATS – Charlotte NC.

This example establishes the requirements for the control of special processes. It requires contractors/suppliers/fabricators to be responsible for performing special processes in accordance with their contract documents and quality control plan.



7 Process Control

7.1 Purpose

To establish the requirements for the control of special processes, as identified herein.

7.2 Scope

These requirements apply to all special processes, including, but not limited to, welding, heat treatment, cleaning, concrete and asphalt placement, plating, water proofing, non-destructive examination, and testing.

7.3 Responsibility

Contractors/suppliers/fabricators shall identify and plan the production, installation, and servicing process that directly affect quality. The Construction Resident Engineers (RE) or Project Manager shall ensure that these processes are carried out under controlled conditions.

The contractor's quality control plan will address the following:

- Identification of special processes.
- Special process production procedures and instructions in accordance with applicable codes, standards, specifications, and drawings.
- A work plan for special process productions or installation that provides for an appropriate work sequence, suitable working environment, and appropriate equipment.
- Appropriate certifications for special process production procedures.
- Appropriate qualifications for personnel performing or inspecting special processes.
- Equipment warranty requirements.

Contractors/suppliers/fabricators are responsible for performing special processes in accordance with their contract documents and quality control plan.

In addition, the contract documents will identify required hold points or special inspection requirements.



7.4 Procedure

Special processes will be controlled and accomplished by qualified personnel using approved procedures and/or instructions in accordance with applicable codes, standards, or specifications and as specified by contract. Records of procedure qualification as well as personnel qualification and certification are to be maintained in QC files. Operations and maintenance procedures for equipment will be required as a deliverable in each system's procurement contract.

Element 8: Inspection and Testing

The following is Section 8.00 of Revision 0 (October 2017) of the San Francisco Bay Area Rapid Transit District's (BART's) Transbay Corridor Core Capacity Program (TCCCP) Quality Management Plan which has been generously provided by BART – San Francisco, CA.

This example describes the recommended requirements for preparation of an Inspection and Test Plan (ITP) for a specific project. Special Task-related procedures to be prepared and included in the ITP shall include: Receiving inspections; In-process inspections; Final inspections; and Unique or non-standard tests requiring special attention in order to produce a quality product.



Quality Management Procedures
BART Transbay Corridor Core Capacity Program (TCCCP)

QP 8.00,
Inspection & Test Plan

REVISIONS						ORIGINAL
REV	DATE	BY	APRV		DESCRIPTION	Sponsor: TCCCP Program
0	12/2017	AML			Issued for Approval	
						Approved By:
						Date:

1.0 PURPOSE AND SCOPE

This guideline describes the recommended requirements for preparation of the Inspection and Test Plan (ITP). Referenced documents provide supporting information and details related to this procedure. This procedure is developed and maintained in accordance with the TCCCP Quality Management System.

2.0 RESPONSIBILITIES

Position Title	Description of Responsibilities
TCCCP RE/Construction Oversight Manager	The TCCCP RE/Construction Oversight Manager (RE/COM) is responsible for the preparation and issuance of the ITP in coordination with the contractor and Vehicle Builder.

3.0 DEFINITIONS

None

4.0 PROCEDURE



4.1 Inspection and Test Plan

The ITP is prepared by the RE/Construction Oversight Manager who will determine the content of the plan necessary for successful completion of the project based on its nature, size and complexity. The CQM shall refer to the TCCCP COM and contract documents to ensure that the ITP is compatible with their guidelines and requirements. The ITP is distributed to key Project and TCCCP staff. If subsequent contract modifications significantly alter the content of the ITP, the TCCCP COM revises and reissues the plan. The following elements shall be included in the ITP:

A discussion of the scope of testing and inspection services: acceptance or oversight. If acceptance, the plan shall capture the required inspections and tests required for acceptance and compliances purposes. If oversight, the plan discusses the approach or procedures used to develop the scope of oversight inspection and testing services. Typical procedures for oversight services include:

- Performing one oversight test for every ten tests the Contractor performs
- Inspecting or testing any suspect work / materials; and

Providing special oversight inspection / tests for work that has historically created repair, maintenance or rework problems for the District on previous build-out projects. Identification of the individuals or groups responsible for performing the inspection or test, including material testing laboratories to include the following:

- Contact names, phone numbers (office, site, cell, etc.); and
- Contact Protocol such as:
- Dispatch information and advance notice requirements; and
- Approval / authorization requirements for use, overtime, etc.
- Preliminary schedule in bar chart form showing inspecting and testing staff level of effort;
- Quality procedures and work instructions:

Procedures pertinent to the project are referenced in the ITP. Any BART-mandated procedures are also to be referenced. Special Task-related procedures to be prepared by the TCCCP Project Manager and included in the ITP shall include:

- Receiving inspections;
- In-process inspections;
- Final inspections; and
- Unique or non-standard tests requiring special attention from the TCCCP COM in order to produce a quality product.

The TCCCP RE/COM determines which project elements require special attention and prepares procedures to address them. Potential issues include: technically difficult



aspects, the application of an unproven technology or products, or ill-defined existing conditions.

List of inspections and tests as follows:

- Item to be inspected;
- Location of the inspection or test;
- Identification of characteristics and activities to be inspected or tested;
- A description of the method of inspection or test;
- Where a sample is used to verify acceptability of a group of items, the sampling procedure shall be based on recognized sampling practice.

Acceptance criteria;

- Where mandatory inspection or test hold points are required, beyond which work shall not proceed without the specific consent of the TCCCP COM, the specific hold point(s) shall be indicated in appropriate documents procedures and status plan.
- Identification of required procedures, drawings and specifications; and
- Frequency of the required inspections or tests.
- Recordkeeping
- Document Control Procedures
- Laboratory Test Database Program

5.0 PROJECT-SPECIFIC PROCEDURE

RS&S – IPP Section 5.3.1.7 (Quality Assurance Plan)

5.3.1.7 Inspection Program Plan (071-IPP-00xx)

The Inspection Program Plan (IPP) is specific to the BART project and based on the contractual requirements. The BART Project IPP describes the planning of all inspection and testing activities from receiving inspection through the final testing and acceptance of the product. They also define which documents will be used to perform the activities, and which documents will be generated to document the activities.

The IPP allows Quality Assurance to ensure that all required inspections have been done during manufacturing of the car and all reports have been issued. The following IPP will be issued for the BART:

- a) The Car IPP (071-IPP-000X) will cover all of the carshell manufacturing, harnesses, subassembly and assembly activities to the Car final acceptance.
- b) The Truck Assembly IPP (071-IPP-0002) will cover all of the Truck Assembly manufacturing process from receiving inspection of parts to Truck Assembly final acceptance.
- c) The Field Service IPP (071-IPP-0020) will cover all Quality activities performed by



BT at the District site. This document is typically issued four (4) months prior to delivery of the first production car.

6.0 REFERENCES

TCCCP Quality Management Plan

- Section 8.0 – Inspection and Testing
- Section 14.0 – Quality Audits

RS&S Quality Assurance Plan

- Section 5.3.1.7 Inspection Program Plan

Element 9: Inspection, Measuring, and Test Equipment

The following is Section 9.00 of Revision 0 (December 2017) of the San Francisco Bay Area Rapid Transit District's (BART's) Transbay Corridor Core Capacity Program (TCCCP) Quality Management Plan which has been generously provided by BART – San Francisco, CA.

This example stipulates that contractors must prepare a log of all certified measuring and test equipment under their control. Measuring and Test Equipment shall be calibrated against standards that have a known, valid relationship to national standards prior to use, and periodically thereafter. The Contractor shall select an independent calibration laboratory that meets the ISO/IEC 17025 General Requirements for the competence of Testing and Calibration Laboratories.



Quality Management Procedures
BART Transbay Corridor Core Capacity Program (TCCCP)

QP 9.00,
Calibration Procedure

REVISIONS						ORIGINAL
REV	DATE	BY	APRV		DESCRIPTION	Sponsor: TCCCP Program
0	12/2017	AML			Issued for Approval	
						Approved By:
						Date:



1.0 PURPOSE AND SCOPE

This procedure establishes the methods and requirements for controlling inspection, testing and measuring and test equipment to assure tools, gages, instruments, and other devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within required limits.

2.0 RESPONSIBILITIES

Position Title	Description of Responsibilities
Project Manager/Construction/Vehicle Oversight Managers	The PM and/or Construction/Vehicle Oversight Managers are responsible for ensuring that the provisions of this procedure are provided to TCCCP's contractors / consultant's and construction inspection / materials testing agencies through the technical provisions of contracts
Contractor	An organization identified as a Construction Contractor, Vehicle Builder, Consultant, or Subconsultant working under contract either to BART directly or to a BART TCCCP Owner's Representative that performs inspection, testing and measuring services with equipment that requires calibration or documented control (the selection of Measuring and Test Equipment shall be based on the application as specified by the Contract technical specification requirements) shall assign a person (Quality Control Representative) responsible for implementing the provisions of this procedure
Contractor Quality Manager (CQM)	A member of the Contractor's senior project management staff; assigns qualified team members to perform Quality Control reviews of project; performs Quality Control inspection activities and oversight of sub-consultant activities as they relate to technical specifications and contract requirements.



3.0 DEFINITIONS

None

4.0 PROCEDURE

4.1 Certified Measuring and Test Equipment Log

The Contractor Quality representative(s) will prepare a list of all certified measuring and test equipment under their control in a log (Attachment A). The log shall include calibration frequency and accuracy requirements. Determination of calibration frequency shall be established by the Contractor's Quality Manager and shall be at intervals of not more than 12 months. A record of each item of Measuring and Test Equipment shall be recorded and filed with the following information

- Serial number;
- Description;
- Other identification information, and
- Calibration information.

These logs will be provided to TCCCP PMs for review and concurrence.

4.2 Checkout of Measuring and Test Equipment

The Contractor Quality Manager or designee shall be responsible for recording the name and location of individuals and/or organizations that check out Measuring and Test Equipment.

4.3 Calibration Recall

The Contractor Quality Manager or Designee will review the Log and will distribute a routine and periodic (monthly is recommended) listing of all items requiring calibration. The Contractor Quality Manager or designee will:

- Assure that all tools subject to recall are delivered to a designated location for calibration; and
- Collect any recalled Measuring and Testing Equipment, which is not delivered to the designated area.

4.4 Coordination with Calibration Laboratory

The Contractor Quality Manager or designee shall select an independent calibration laboratory that meets the ISO/IEC 17025 General Requirements for the competence of Testing and Calibration Laboratories.

4.5 Calibration Process



Measuring and Test Equipment shall be calibrated against standards that have a known, valid relationship to national standards prior to use, and periodically thereafter, to provide for the accurate reporting of quality testing and inspection results. In the case that no national standard exists, the basis for calibration will be identified and documented. Written procedures or manuals will identify points to be checked, tolerance, and standards to be used.

New or reworked measuring instruments must be calibrated prior to use. Measuring equipment which will not be used for an extended period may be tagged as requiring calibration prior to use; it may be removed from the use area or otherwise rendered unusable until such calibration is performed. If rented equipment is used, dated calibration certificates will be provided each time equipment is rented.

The tolerances used in calibration should be in accordance with the manufacturer's recommendation or as otherwise specified or documented. Environmental conditions for calibration shall be consistent with the location where inspection and testing is performed.

Calibration shall be performed in accordance with approved calibration procedures. These procedures shall specify the following:

- Details of equipment type
- Identification number
- Location (as required)
- Calibration method
- Acceptance criteria
- Action to be taken if results are unsatisfactory

The independent calibration laboratory shall submit a calibration report to the Contractor Quality Manager that shall include the following as a minimum:

- Identification
- Accuracy required
- Individual performing calibration
- Current status (accept/reject)
- Method of calibration
- The date calibration was performed
- Reference to traceable calibration standard

Measuring and Test Equipment, which has been demonstrated to be in current calibration, shall be identified with an adhesive label signifying calibration status. The label shall include the following information:

- Last date calibrated
- Next calibration date
- Serial number or assigned equipment number



After completion of calibration, the outside calibration laboratory shall arrange for shipping of all calibrated equipment along with required calibration reports and certificates to the Contractor Quality Manager with copy to the TCCCP Quality Manager.

4.6 Updating Calibration Data

Upon receipt of calibrated equipment from the outside calibration laboratory the Contractor Quality Manager shall update the Certified Measuring and Test Equipment Log to reflect the current calibration status.

4.7 Use and Control of Measuring and Test Equipment

Prior to use in the field Measuring and Test Equipment will be verified for calibration by checking the calibration tag or sticker on the equipment or by checking the serial number against the calibration log. Any Measuring or Test Equipment that has exceeded its calibration period will be re-calibrated before use.

Calibration inspections that identify equipment, which does not conform to requirements, are brought to the attention of the Contractor Quality Manager and the TCCCP PM or designee for determination of the impact on production quality and material disposition, if required. Corrective action consists of equipment recalibration (after any required repairs) or removal from service.

Measuring or Test Equipment that does not appear to be functioning properly will be re-calibrated before continued use.

5.0 RECORDS

A master copy of all Measuring and Test Equipment documentation shall be maintained at the contractors / consultant's office as part of the Quality Records file. A copy of the current master log shall be sent to the TCCCP PM and Quality Manager monthly, or as is warranted.

6.0 REFERENCES

TCCCP Quality Management Plan

- Section 9, "Inspection, Measuring and Test Equipment"
- Section 14.6, "Quality Records" RS&S QAP TS 21.1

7.0 ATTACHMENTS

- None

Element 10: Inspection and Test Status

The following is Section 10 of Revision 4.1 (March 2019) of the Tri-County Metropolitan Transportation District of Oregon (TriMet) Quality Assurance Program Manual, which has been generously provided by TriMet – Portland, OR.

This example shows that it is important to establish requirements for inspection and test status that meet the needs of the project sponsor or project. It specifies that contractors and suppliers include test and inspection procedures in their Quality Plan. The test and inspection procedures must include means and methods of communicating the current status of tests and inspections to TriMet. The test and inspection status will be identified by means of markings, tags, labels, routing cards, records of results, physical location, or other suitable means.

Section 10 - Inspection and Test Status

10.1 Purpose

This section describes the requirements for communicating the status of tests and inspections throughout the course of the work.

10.2 Scope

These requirements apply to all supply and construction contracts requiring tests and inspections for quality control.

10.3 Policy

Identification of the status of tests and inspections during production and installation is required to ensure that only work that has passed inspections and tests is incorporated into the project.

10.4 Procedures

Requirements for testing and inspection are included in the contract drawings and specifications. Contractors and suppliers must include test and inspection procedures in their Quality Plan for the contract in accordance with Section 8 of this manual. The test and inspection procedures must include means and methods of communicating the current status of tests and inspections to TriMet to ensure that only acceptable components and materials have been provided.

Test and inspection status will be identified by means of markings, tags, labels, routing cards, records of results, physical location, or other suitable means. The status will indicate pass/fail history of previous tests and inspections.

TriMet CMs and inspection personnel will verify that the appropriate test /inspection status is provided with delivered or installed materials in accordance with the approved Quality Plan.

10.5 Responsibility

The supplier or contractor is responsible for inclusion of test/inspection status procedures in its quality plan and implementation of these procedures accordingly.

The TriMet CM and inspection staff are responsible for verification of test/inspection status.

The TriMet ECD QAM is responsible for quality assurance audits and surveillances during the term of the contract.

Element 11: Nonconformance

The following is Section 11.00 of Revision 0 (October 2017) of the San Francisco Bay Area Rapid Transit District's (BART's) Transbay Corridor Core Capacity Program (TCCCP) Quality Management Plan which has been generously provided by BART – San Francisco, CA.

This example contains an attached Nonconformance Report (NCR) form. NCR forms are commonly used in transit projects. NCR form templates differ from project sponsor to project sponsor or project to project, but the information logged on the NCR forms often includes aspects of Element 12, "Corrective Action". Some project sponsors combine these two elements in their Quality Plans. This example also contains an NCR log.



Quality Management Procedures
BART Transbay Corridor Core Capacity Program (TCCCP)

QP 11.00,
Control of Nonconforming Product / Nonconforming
Reports Procedure

REVISIONS						ORIGINAL
REV	DATE	BY	APRV		DESCRIPTION	Sponsor: TCCCP Program
0	12/2017	AML			Issued for Approval	
						Approved By:
						Date:



1.0 PURPOSE AND SCOPE

The purpose of this procedure is to describe the Non-Conformance Report (NCR) system, instruct its users on the proper method of form utilization, and to provide TCCCP Management and Contract participants with a benchmark by which to measure project quality. The system also, in turn, provides easy traceability of deficiencies and accountability for the disposition of discrepancies.

This procedure is applicable to all Contracts and shall apply to all Contractors, Subcontractors, and Suppliers implementing a TCCCP approved non-conformance reporting-system

2.0 RESPONSIBILITIES

Position Title	Description of Responsibilities
Contractor	An organization identified as a Design/Build Contractor, Consultant, or Subconsultant working under contract either to BART directly or to a TCCCP Owner's Representative; are responsible for determining the content of the report, identifying, and assigning the appropriate personnel (Authors) to prepare the report. The Design Quality Control Manager is responsible for assigning a Checker who reviews the report.
TCCCP Quality Manager	Implementation and administration of the TCCCP Quality Assurance Program; and identification and evaluation of quality problems; initiating, recommending, or providing solutions for and controlling further processing, delivery, or installation of non- conforming or deficient items or services through the NCR system until proper disposition is obtained. A Corrective Action Request (CAR) system will also be implemented, as necessary, to document, address, and resolve quality issues.

3.0 DEFINITIONS

Accept-As-Is: A disposition which may be imposed for a non-conformance when it can be established by proper competent authority that the discrepancy will result in no adverse condition and that the item under consideration will continue to meet all engineering functional requirements including performance, maintainability, fit, and safety. This disposition must be accepted by TCCCP.



Corrective Action: Changes to processes, work instructions, workmanship practices, training, inspection, tests, procedures, specifications, drawings, tools, equipment, resources, or material that result in preventing, minimizing, or eliminating non-conformances.

Non-Conformance: A deficiency in characteristic documentation or procedure that renders the quality of an item unacceptable with respect to quality program criteria (fit, form and function).

Reject: The action taken to eliminate a non-conforming item from its specified use.

Repair: A procedure that reduces but does not completely eliminate a non-conformance. Repair is distinguished from rework in that the characteristic after repair still does not conform to the applicable original acceptance criteria.

Rework: A procedure applied to a non-conformance that will completely eliminate it and result in a characteristic that conforms completely to the applicable acceptance criteria.

4.0 PROCEDURE

4.1 Evaluating the Contract Participant's NCR Program

The TCCCP Quality Assurance team shall review the Contractor Quality Plan submittals, and establish that the Contractor has delineated a satisfactory system for the identification and control of nonconforming items.

4.2 Who Can Write an NCR

Non-Conformance Reports, (see Attachment A) can be initiated by any of the following: Members of the Contractor's / Subcontractor's / Supplier's Quality Organization, Field Quality Control Organization, or Construction Management Oversight – BART/TCCCP Authorized Representative (Field Engineer/Inspector); members of the QA Organization; or anyone affiliated with TCCCP having the requisite technical competence to identify the NCR.

4.3 When to Write an NCR

Receiving Inspection - Nonconformances identified during the receipt of material or product that has been delivered to the jobsite or to a storage location near the jobsite, which is identified by the contract as being within the criteria for payment for materials-at-hand, shall be reported controlled, and documented by use of an NCR.

* *During in-process work activities* - Non-conformances discovered during in-process work activities, which are not immediately correctable by further prescribed processing and within the authority of the Statement of Work, shall be reported, controlled, and



documented by use of an NCR.

**Note: Prior to final inspection completion - Discrepancies discovered prior to final inspection completion, and which are correctable by further prescribed processing may be controlled by the use of open inspection report or deficiency lists.*

After completion of the work - All non-conformances discovered after the completion of work activities and related inspections/tests, shall be reported, controlled, and documented by use of an NCR.

4.4 NCR Initiation Procedure

Immediately upon identification of a non-conformance, the individual detecting the discrepancy shall initiate an NCR by completing part 1 of the Non-Conformance Report. In the "Description of Non-Conformance" entry, it is important to describe in detail, the non- conforming condition and include sketches and photos at any opportunity where it may help expedite the NCR disposition. It is also important to identify the requirement (e.g. drawing, specification, etc.) that the Non-conformance is being written against.

After initiation, the NCR shall be forwarded to the Contractors and to QA. The Contractor's Quality organization will assign a unique serial number (by the order of initiation) and provide that number to the QA to be entered in the Master NCR Log and Database, (see Attachment B), which serves to identify and track the closure of open NCRs.

Upon the NCR being logged, an NCR tag shall be attached to the non-conforming item. The control of multiple items shall be by the use of multiple tags. Where a large physical area is identified as non-conforming, the area may be identified for control purposes, by the use of flagging ribbon or stakes, if necessary.

Parts and/or Materials that are easily transported should be taken to the Contractor NCR Storage Area and Work suspended until the NCR is dispositioned. Notification of the non- conformance, to the Supervisor in charge, should be made as soon as practical. Further work incorporation or utilizing non-conforming items shall not continue until implementation of the approved disposition and acceptance by the responsible Quality Organization.

4.5 Dispositioning

Each NCR shall include description of its disposition. The description shall identify actual performance of the action selected to correct the noted deficiency. NCRs shall be dispositioned by one of the four procedures or actions defined (e.g., Repair; Rework; Reject; Accept-As-Is).



Non-conformances are to be dispositioned in a timely manner. Dispositions not obtained in 30 days(calendar), shall be expedited by the Contractor's Quality Organization, and will be reported to the TCCCP Authorized Representative as part of its contractual obligation to provide monthly progress reports.

Dispositions of repair or use-as-is, shall be by the Engineer of Record (EOR); such dispositions require concurrence by BART/TCCCP.

Prior to implementing the action required for resolution, each dispositioned NCR shall be reviewed by the Contractor's Quality Organization, who will assure that the disposition is fully responsive to the condition(s) described in the NCR and proper authorization has been given to implement the required action(s).

4.6 Re-Inspection and Acceptance

Upon completion of the required rework or repair dispositions, the Contractor's Quality Control Organization shall re-inspect the item(s), to establish conformance to the applicable requirements, including the NCR disposition. If the item is found acceptable; the Contactor's Quality Control Organization shall document the acceptance by signature and date on the original NCR.

If the disposition is "Reject", the Contractor's Quality Control Organization shall sign and date the accepted disposition, only after assuring that adequate measures have been taken to prevent inadvertent installation or use of the item or by removing the already-placed material in a timely fashion.

4.7 NCR Tracking, Reporting, and Analysis

NCRs shall be copied and promptly routed to the TCCCP Authorized Representative and the TCCCP Quality Manager. Copies are required at the following junctures: at NCR initiation/logging; at assignment of NCR disposition; at implementation of disposition, and at acceptance by the Contractor's Quality Control Organization.

4.8 Corrective Action to Prevent Recurrence

The responsible Quality Organization shall route a copy of each NCR to the organization responsible for control of the activity where the non-conformance was identified.

The implementation of specified the corrective action(s) to prevent recurrence, shall be verified by the responsible Quality Organization and documented on the NCR Form.

4.9 NCR Coding and Trend Analysis



The "CODE" blocks in the NCR forms are for entering a corresponding three-digit number by the TCCCP Quality Manager that allows for easy and quick quantitative and qualitative analysis of nonconformance's, their cause, and corrective action (see Attachment C).

A Trend Analysis shall be performed on non-conformances cause and of the corrective action measures taken to prevent recurrences no less than bi-annually. The Trend Analysis shall include a narrative analysis of the results, both of which shall be distributed to TCCCP Program Management.

5.0 PROJECT-SPECIFIC PROCEDURE

None Required

6.0 REFERENCES

TCCCP Quality Management Plan, Section 11.0 – Non-Conformance

7.0 ATTACHMENTS

Attachment A - Non-Conformance Report

Attachment B - Non-Conformance Report Log

Attachment A – Non-Conformance Report



**REPORT FOR DOCUMENTING INVESTIGATIONS,
NONCONFORMANCE AND PROPOSED
CORRECTIVE ACTIONS**

The TCCCP Quality Mgr. will assign the:
Nonconformity Report No.: **QA**
Corrective Action Request No.: **0**
Investigation Request No.: **000**

REASON FOR ISSUING
A CORRECTIVE
ACTION (Check Box):

AUDIT NON-CONFORMITY: ☐

PRODUCT NON-CONFORMITY: ☐

CUSTOMER COMPLAINT: ☐

INVESTIGATION: ☐

BART Transbay Corridor Core Capacity Program(TCCCP)

DATE:

THIS REPORT DOCUMENTS A (check box):

Nonconformity ☐

Investigation ☐

Corrective Action ☐

ORIGINATOR / DATE

QMS MANAGER / DATE:

NOTE: These THREE lines are only to be used to record a Customer Complaint.

Cost Ctr NO.:

CUSTOMER'S NAME:

DATE OF COMPLAINT:

Location.:

Asset NO:

TELEPHONE NO.:

Employee Reporting ID:

DESCRIPTION OF INVESTIGATION REQUIRED, COMPLAINT, OR POTENTIAL NONCONFORMANCE

EXPLAIN THE PROPOSED CORRECTIVE ACTION – OR – THE PROPOSED PREVENTIVE ACTION

ORIGINATOR / DATE:

GROUP MANAGER / DATE:

APPROVED BY / DATE:

TITLE:

CLOSE OUT

WAS THE PROP. ACTION IMPLEMENTED?

YES ☐

NO ☐

IF NO, WHY WASN'T THE PROPOSED ACTION IMPLEMENTED?

CUSTOMER COMPLAINT FOLLOW-UP
COMPLETED ON:

DATE:

BY:

Element 12: Corrective Action

The following is Section 17.0 of Revision 3 (December 2017) of the Regional Transit District of Denver (RTD) FasTracks Quality Assurance Program Plan, which has been generously provided by RTD – Denver, CO.

This example contains an attached Corrective Action Request (CAR) form. CAR forms are often used in transit projects. CAR form templates differ from project sponsor to project sponsor or project to project, but the information logged on the CAR forms is common to all project sponsors or projects. Some project sponsors combine Elements 11 and 12 in their Quality Plans.

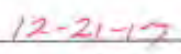


QMO Section 17.0
Corrective Action Procedure
Revision 3, December 15, 2017

This is a controlled document; please do not duplicate. If additional copies are required, please request them from Fastracks Document Control. This will assure that all recipients of the document receive revisions and additions.

Approved By:


Henry J. Stopplecamp, P.E., Assistant General Manager,
Capital Programs


Date



SECTION 17.0

QMO P17, CORRECTIVE ACTION

17.1 PURPOSE

The purpose of this procedure is to describe the process to investigate nonconformances detected in work performed by contractors producing work for FaTracks, identify the root cause(s), and prevent their recurrence.

This procedure describes the method of planning, executing, and recording the actions taken for corrective and preventive actions.

17.2 SCOPE

17.2.1 Corrective and Preventive Actions are implemented to take Corrective and/or Preventive action on current and potential problems associated with the implementation of the contractor's quality program.

17.2.2 Consultants/contractors will maintain their own quality management programs. When the FaTracks team detects systemic issues associated with implementation of the Contractors' programs, the FaTracks team may initiate a corrective action request (CAR).

17.2.3 The Administrator for Corrective Actions is the QMC Program Manager who is responsible for assigning the Corrective Action and ensuring that the problem statement is documented.

17.2.4 Corrective Action is taken on problems, such as:

Nonconformances detected during RTD FaTracks management systems audits.

Major product or process nonconformances detected during RTD FaTracks oversight of the work.

Systemic trends in performance in implementing quality plans (or other management plans) detected during RTD FaTracks oversight efforts.

17.3 METHOD

17.3.1 Detect Nonconformance:

17.3.1.1 Lead Assessor: Ensure that the description of the nonconformance or the need for corrective action is clearly communicated to the QMC Program Manager.

17.3.1.2 QMC Program Manager:

Review problem statement with Lead Assessor to complete the Corrective Action Form using the following format:

The numbering convention is CAR-Proj.-20XX-NN where:

Proj. – the name of the project (E.g. NM- North Metro, SERE – South East Rail Project)

20XX is the year



NN is a sequential number

Ensure that the lead Assessor agrees and concurs with the way the problem description has been documented.

17.3.2 Determine Corrective Action Team

17.3.2.1 Quality Oversight Manager:

Assign a Contractor Representative (typically the contractor's QA Manager) to represent the contractor in dealing with the corrective action.

17.3.3 Determine Root Cause of Nonconformance or a specific Corrective Action

17.3.3.1 Contractor Representative:

Ensure the nonconformance is assessed and the cause(s) of the nonconformance or the aspects, which can lead to improvement, are effectively identified.

Recommend a proposed action that addresses the cause(s) of the nonconformance.

Document proposed action on the CAR form, or an equivalent format from the Contractor's approved quality management plan.

17.3.4 Implement Proposed Action

17.3.4.1 Contractor Representative: Ensure the proposed action is implemented.

17.3.5 Verify Corrective Action

17.3.5.1 Lead Assessor: Verify the action that was taken has corrected the problem and will prevent recurrence.

17.3.5.2 Quality Oversight Manager: Ensure the Corrective Action Form includes a description of the basis of accept/reject, and approve and date the closure section of the Improvement Action Form.

17.3.6 Close Corrective Action

17.3.6.1 QMC Program Manager:

Ensure the Corrective Action Log is updated to reflect the status of the Corrective Action.

17.4 APPENDICES

Appendix No.1, Sample Corrective Action Form (for use with consultants and contractors)



17.5 Revision Record

Revision Level	Revision Date	Summary	Approval Date
0	March 31, 2008	1st issue of procedure	March 27, 2008
1	January 31, 2009	Incorporated minor program updates.	February 08, 2009
2	April 26, 2012	Format change to add new Fastracks logo.	April 30, 2012
3	December 1, 2017	Revised CAR numbering to match current practice	December 15, 2017

RTD **FasTracks**

Appendix 1

	
FasTracks Quality Management Oversight Program Corrective Action Request (CAR)	
CAR NO. _____ CONTRACTOR _____ FASTRACKS REPRESENTATIVE _____	Issue Date _____ Response Due Date _____
Description of Non-Conformance	
Cause of Non-Conformance	
Corrective Action to Prevent Recurrence of Non-Conformance	

RTD **FasTracks**

Contractors Representative _____		Date _____	
FasTracks Representative _____	☐ accept ☐ reject	Date _____	
Comments _____ _____			
Verification of Corrective Action			
FasTracks Representative _____	☐ accept ☐ reject	Date _____	
Comments _____ _____			
		CAR Status	☐ open ☐ closed

Element 13: Quality Records

The following is Section 13 of Revision 2 (August 2019) of the Maryland Transit Administration (MTA) Quality Assurance Program Plan, which has been generously provided by MTA - Baltimore, MD.

This example lists the different categories of quality records and examples of each. Other important items covered in this example include the specification that records be prepared, filed, and maintained in a way that ensures they are readily retrievable and the statement that retention requirements for the various types of records be specified in contract documents. This procedure also applies to consultants and suppliers that generate quality records. This procedure includes a requirement that storage facilities for Quality Records shall include fire-resistant steel file cabinets that preclude damage from fire, condensation, and extreme temperature variation. In lieu of fire-resistant files, a second (backup) copy of each Quality Record can be maintained at an off-site location. It is important that provisions be made to safeguard quality records.

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ADMINISTRATION
Office of Engineering and
Construction
Quality Management System Plan**



13. QUALITY RECORDS

13.1 Purpose

To define the requirements for the accumulation and maintenance of records for MTA engineering projects which provide the objective evidence that the quality requisites of the contract documents have been met.

13.2 Scope

These Quality Records requirements apply to all Office of Engineering and Construction staff, consultants, and contractors who perform activities that affect quality on MTA engineering projects and all other projects undertaken by the Office of Engineering and Construction.

13.3 Policy

It is the policy of the Office of Engineering and Construction that records for engineering projects be maintained to show achievement of quality objectives and appropriate functioning of the quality management system. Records providing objective evidence of conformance to requirements or relating to achievement of quality objectives shall be identified, collected and stored in a readily retrievable manner and preserved to preclude damage, loss or deterioration. Electronic records should be backed up regularly, with backups stored offsite. These records shall be provided in the required format, and with retention periods defined, at the completion of the project, in accordance with the FTA's requirements. The ability to retrieve records should be tested regularly.

13.4 Requirements

13.4.1 Quality Records are defined as documents that provide objective evidence of compliance of materials, products and services to specified acceptance criteria, including compliance with approved procedures and quality objectives.

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13.4.2 Quality Records shall be legible and identified by title, contract number, revision, and activity description, with dated signatures of responsible personnel as appropriate.

13.4.3 Quality Records shall be made available to authorized persons as required.

13.4.4 The following list is a guide to documents considered to be Quality Records that are required to be collected, stored, and preserved in a manner that precludes damage, loss, or deterioration, and should not be construed as a complete listing:

- **Design Records**

- Consultant's response to MTA's *Requirements of Quality Management Plan for A&E Design Consultants*.
- Design procedures and manuals
- Applicable criteria used in design
- Design calculations and checks
- Drawings (reference, directive, contract, working)
- Standards
- Design review reports
- Design deviations and changes
- Contract specifications
- Quality compliance review records
- Nonconformance Reports and tracking logs
- Corrective Action Requests
- Request for Information (RFI) Responses

- **Procurement Records**

- Procurement procedures and manuals
- Surveillance inspection reports
- Pre-award surveys
- Contract specifications and modifications
- Change Orders
- Certificates of compliance
- Quality compliance review records
- Manufacturers'/suppliers' test results
- Applicable contract data items

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- **Construction, Manufacturing, and Installation Records**
 - Shop drawings
 - As-built drawings and supporting information
 - Contractor data submittals
 - Quality plans
 - CQCPs and QMPs
 - Process and personnel certifications
 - Daily inspection reports
 - Material certifications
 - Warranties
 - Test procedures
 - Test results
 - NCRs and tracking logs
 - Quality compliance review records
 - Surveillance reports
 - Release for shipment notices
 - Inspection and test plans
 - Calibration records
 - Quality compliance reviews/audits
 - Specific documentation required for the Safety Certification program
 - Test witness reports
 - Semi-final and final inspection reports
 - Punch lists and resolution of status reports
 - Acceptance reports
 - Corrective Action Requests
 - Lessons Learned
 - Contract closeout documentation
 - Equipment manuals, manufacturer's data/documentation, and Operations & Maintenance manuals/documents

13.4.5 The Document Control section of the Office of Engineering and Construction is responsible for the collection, indexing, filing, and retention of engineering and quality records.

13.4.6 The QA/QCM is responsible for the filing and retention of Lessons Learned.

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Construction
Quality Management System Plan**



13.4.7 Contractors and Consultants are responsible for retaining quality records and other project documents as required by contract, applicable regulatory agency, or for a period of greater than seven years after the acceptance of the constructed product.

13.5 Procedure

13.5.1 Quality Records shall be considered valid only if stamped, initialed or signed, and dated by authorized personnel. These records may be either the original or a reproducible copy.

13.5.2 Corrections/revisions to Quality Records, as a minimum, shall receive the same review and approval as the original document.

13.5.3 Quality Records shall be subject to Quality compliance reviews.

13.5.4 Transmission and Retention of Quality Records

- Quality Records shall be prepared, filed and maintained in such a manner that will make them readily retrievable when requested by authorized personnel. They should be identified in a manner which ensures traceability.
- Consultants and contractors, including their subcontractors, vendors, and suppliers generating Quality Records, shall be responsible for their retention during the period of construction, inspection, assembly and/or installation, testing, and during period of storage as per Federal and State regulations.
- Storage facilities for Quality Records shall include fire-resistant steel file cabinets that preclude damage from fire, condensation, and extreme temperature variation. In lieu of fire-resistant files, a second (backup) copy of each Quality Record can be maintained at an off-site location.
- Specific retention requirements for Quality Records shall be enumerated in contract documents.
- Unless otherwise stated in the contract, Quality Records shall be turned over to the MTA's Project Manager/Resident Engineer at the completion of the contract.

Element 14: Quality Audits

The following is Section 11.0 of Revision 4 (May 2014) of the Regional Transit District of Denver (RTD) FasTracks Quality Assurance Program Plan, which has been generously provided by RTD – Denver, CO.

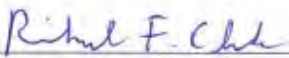
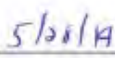
This example extends the requirements of Element 14 of the Guidelines to surveillances (external audits). This update of the Guidelines specifies that requirements apply to external audits as well as internal audits. It also stipulates that pre- and post-audit conferences (or meetings) be held as a part of the audit process, which reflects another statement that was added in this update to the Guidelines. In addition, this example lists their associated forms which may provide further insight into the audit process.



QMO Section 11.0
Internal Quality Auditing Procedure
Revision 4, May 30, 2014

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Approved By:

	
Richard F. Clarke, Assistant General Manager Capital Programs	Date



SECTION 11.0

QMO-P11, INTERNAL QUALITY AUDITING

11.1 Purpose

The purpose of Internal Quality Auditing is to investigate and determine the effectiveness of the overall Fastracks Internal Project Management Plans, procedures, and processes that have been implemented throughout the Fastracks Program. Each Internal Quality Audit also contains recommendations on potential improvements which could be made to the Fastracks Program.

This Auditing procedure describes the method used for planning, execution, recording of actions taken, and verification activities in order to conduct an Internal Quality Audit.

11.2 Scope

Internal Quality Audits are conducted to assess the implementation of the RTD Fastracks Program/Project Management Plans and supporting procedures such as the Project Controls Procedures Manual, the Quality Oversight Program Manual, the Environmental Methodology Manual, the Public Information Strategic Plan, and other documents that describe the key business processes for the Fastracks team. This procedure does not address auditing of suppliers, which is covered in QMO-P7, Management Systems Audits; nor does this procedure include those audits conducted by the RTD Internal Audit division.

Each Internal Quality Audit is conducted in accordance with ISO 19011:2002, Guidelines for Quality and Environmental Management Systems Auditing and this Internal Quality Auditing procedure.

11.3 Method

11.3.1 Prepare the Internal Quality Audit

Director of Quality Assurance:

- In consultation with the QMC Program Manager and Project Quality Oversight Managers, develop a preliminary list of activities to be audited during the calendar year. Consider risk to the project or program, schedule, and the amount of time that has passed since last audit when developing the list.
- Review the list with Fastracks Senior Management in the final Quarterly Quality Management Review of the preceding year, and
- Include in the QMC annual Scope of Work.



Internal Quality Auditor:

- Develop an Audit Schedule for a period of one year based on input for the Director of Quality Assurance.
- Prepare a draft of the Notice of Audit.
- Hold an Audit Scoping meeting with the QMC Program Manager to determine the scope of the Internal Quality Audit and the deliverable dates.
- Document the information from the Audit Scoping meeting into the Notice of Audit.
 - The Internal Quality Auditor should begin a dialogue with Auditee management in order to ensure there are no conflicts with the Audit timeframe, but all other dialogue with the auditees should be withheld until after the Opening Meeting.
 - Arrange and schedule the Opening and Closing Meetings, and interviews with the identified participants.
 - Finalize and transmit the written Notice of Internal Quality Audit to the Auditee(s).

11.3.2 Conduct the Opening Meeting

Internal Quality Auditor:

Discuss the overall Internal Quality Audit process with the participants in the area being audited, including the Method, Scope, and Results of the Internal Quality Audit. Notify participants that the Internal Quality Audit process includes communication of what is performing well, observations that were made which could be positive or negative, identify new Improvement Actions, and provide information on Opportunities for Improvement that should be investigated even though they do not warrant the formality of an Improvement Action.

11.3.3 Perform the Internal Audit

Internal Quality Auditor:

Conduct the Internal Quality Audit by verifying that the actual activities being performed comply with the management endorsed documentation being used in that area, as defined in the Scope for the Internal Quality Audit. The Internal Quality Auditor will assemble copies of any objective evidence to verify Compliance(s), Improvement Actions (IA), Opportunities for Improvement, and Observations (O).

Note: Evidence to support Observations should be collected through examination of documents and records, and observation of activities and conditions in the areas of concern. Evidence collected during personal interviews should be considered tentative unless the information can be corroborated by multiple sources or physical evidence.



If significant, and where appropriate, Opportunities for Improvement will be noted. Areas that are outside the Scope of the Internal Quality Audit will be documented in the Audit Report for follow-up during future Internal Quality Audits or Management System/Process Audits.

11.3.4 Categorize the Internal Audit Observations

Internal Quality Auditor:

Review and categorize all observations in the Preliminary Findings document either Compliance (C), Improvement Actions (IA), Opportunities for Improvement (OFI), or Observations (O).

Compliances (C) – Observations made by the Internal Quality Auditor which show that the Auditee is effectively implementing the approved processes. These observations will be communicated as areas that are performing well.

Improvement Actions (IA) – Observations made by the Internal Quality Auditor whereby the actual performance of a procedure or process does not comply with the documented procedure/process that has been endorsed by management. NOTE: Management endorsement is typically indicated by the signature of the RTD Assistant General Manager of Capital Programs and/or Planning, except where this authority has been delegated. Improvement Actions are observations which are deemed systematic by the Internal Quality Auditor based on evidence collected during the Internal Audit and will result in the issuance of an Improvement Action in accordance with the procedure QMO-P12, Improvement Action. This is not a punitive action, but rather a means of promoting continuous improvement.

Opportunities for Improvement (OFI) – Observations made by the Internal Quality Auditor, which are potential Opportunities for Improvement, and if the recommended improvements are implemented, could result in a more efficient procedure/process and possible cost savings.

Observations (O) – Observations made by the Internal Quality Auditor which did not indicate a significant trend, but were noteworthy.

Note: In determining whether or not to issue a formal Improvement Action, the Internal Quality Auditor should consider if the observation is a systemic problem which critically affects the work process(es), or could lead to excessive risk to the Fastracks Program.

11.3.5 Conduct Findings Review meeting

Internal Quality Auditor:

- Conduct a Findings Review meeting with the Director of Quality Assurance, Project Quality Oversight Manager, and the QMC Program Manager. The purpose of this meeting is to review and finalize the Audit Findings prior to the Closing meeting, and to verify that the audit is complete.



11.3.6 Conduct the Closing Meeting

Internal Quality Auditor:

Upon full completion of all evidence collection activities, conduct and verbally report the results of the Internal Audit at the Closing Meeting. This verbal report will briefly cover the highlights in terms of Areas that are Performing Well, Observations that were made, any potential Opportunities for Improvement that were identified, and any Improvement Actions that will be issued.

11.3.7 Write the Audit Report

Internal Quality Auditor:

- Prepare an Internal Quality Audit Report, which will document the results of the Internal Audit and will include the following information:
 - Title, Date, and Scope of the Internal Audit;
 - Identification of the participants;
 - Results of Audit, specifically;
 - o Details on Areas Performing Well;
 - o Details on Observations.
 - o Details on Opportunities for Improvement;
 - o Details on Improvement Actions;
- Document any assigned Improvement Action(s) in the QMO Improvement Action module for follow up and tracking. A notification email will be sent to the appropriate management staff to request Corrective and/or Preventive Action(s) to be taken on the systemic problems noted.

11.3.8 Issue Audit Report

Internal Quality Auditor:

- Email a draft of the report to the Director of Quality Assurance, QMC Program Manager, and Quality Oversight Manager for editorial review.
- Upon resolution of editorial review, provide a final draft of the audit report via Aconex to the Audit participants and Project Manager for a courtesy review. This review will include the report and improvement actions only, audit working papers will not be included. Any actions that are taken by the Auditee to resolve the findings that were identified during the Internal Audit will be included in the Final Internal Quality Audit Report. Any changes to the final draft of the Audit



Report should be reviewed again by the Director of Quality Assurance, QMC Program Manager, and Quality Oversight Manager to ensure they are in agreement with any changes.

- Upon resolution of the courtesy review, the Improvement Actions will be input into the QMO Improvement Action module and the Internal Quality Audit Report is issued through Aconex to the Auditee Manager, QMC Program Manager, Quality Oversight Manager, Director of Quality Assurance, Fastracks Senior Management Team, and FTA Project Management Oversight Consultant (if applicable). These documents will also be provided to the Project's Document Control to be filed as a record of the Internal Quality Audit, and saved on the X drive.

11.3.9 Implement and Perform Surveillance Verification on Past Improvement Action(s)

Auditee:

Per QMO P12, access the Improvement Action via the QMO Improvement Action module, identify the Root Cause(s) of problem(s) for any Improvement Actions that have been issued, take Corrective Action, then record the Action(s) taken, and the effectiveness of those Actions in the QMO Improvement Action module. The Auditee will then contact the Quality Oversight Manager to schedule the Internal Auditor to perform the Surveillance Verification Activities detailed below to determine if the Improvement Action is ready to be closed out.

Internal Quality Auditor:

- Surveillance Verification Activities: Once the Proposed Action has been implemented and an appropriate amount of time has passed so records have been produced to show if the Action(s) taken were effective, the Lead Auditor will:
 - o Review the actions that were taken by Auditee management and determine the verification activities that are needed.
 - o Meet with the appropriate individual(s) to verify that the Proposed Action(s) taken were effective; thus, addressing and fixing the Root Cause.
 - o If the Proposed Action(s) have been fully implemented, the Improvement Action will be updated, and marked as closed in the QMO Improvement Action module. Refer to QMO P12, *Improvement Actions*.
 - o All Improvement Actions will be reported during the next regularly scheduled Quarterly Quality Management Review and the updated status of "closed" is noted.



- o Working papers supporting the Improvement Action Surveillance findings will be maintained by the internal auditor.

Note: In the case of the RTD FasTracks Program, the Auditee and the Client are a single entity. The nature of any Improvement Actions will ultimately be the decision of the FasTracks Director of Quality Assurance, in the interest of continuous improvement within the FasTracks Quality Management Oversight Program.

11.3.10 Internal Audit Feedback

QMC Program Manager: Provide the Internal Quality Auditor with written feedback on the conduct of the audit, so that continuous improvement can occur.

11.4 Related Forms

- Notice of Internal Quality Audit
- Internal Quality Audit Schedule
- Internal Quality Audit Checklist
- Internal Quality Audit Report
- QMO Improvement Action



11.5 REVISION RECORD

Revision Level	Revision Date	Summary	Approval Date
0	March 15, 2006	1st issue of procedure	March 15, 2006
1	March 31, 2008	Revised format at signature level to be consistent with FaTracks Document Control procedures, and incorporated minor program updates	March 27 2008
2	June 14, 2010	Revised description/format of related forms used to perform auditing.	June 14, 2010
3	April 26, 2012	Format change to add new FaTracks logo. Updated process to prepare the audit, review draft audit, and conduct surveillance. Added internal audit feedback step.	April 30, 2012
4	May 26, 2014	Updated based on changes made to the Internal Quality Audit Program per IA-PW-5	May 30, 2014

Element 15: Training

The following is Section 15.00 of Revision 0 (December 2017) of the San Francisco Bay Area Rapid Transit District's (BART's) Transbay Corridor Core Capacity Program (TCCCP) Quality Management Plan which has been generously provided by BART – San Francisco, CA.

This example states that the following topics will be covered in training: the Quality Management Plan, Procedures and Work Instructions, and the use of specified forms and quality documentation. A sample Training Record form is included in this procedure. This organization does not require that craft journeymen with special skills be trained, however their competency shall be verified and a record maintained (e.g., welders reject rates etc.)



Quality Management Procedures
BART Transbay Corridor Core Capacity Program (TCCCP)

QP 15.00,
Training Procedure

REVISIONS						ORIGINAL
REV	DATE	BY	APRV		DESCRIPTION	Sponsor: TCCCP Program
0	12/2017	AML			Issued for Approval	
						Approved By:
						Date:



1.0 PURPOSE AND SCOPE

The purpose of this procedure is to describe the quality awareness training for the TCCCP Quality Program. This procedure documents the process that the TCCCP Quality Manager uses to assure that personnel assigned to TCCCP have the skill and knowledge to perform their assigned tasks in a competent manner.

2.0 RESPONSIBILITIES

Position Title	Description of Responsibilities
TCCCP Quality Manager	Formulates the instruction required to ensure that their personnel attain proficiency levels suitable for performing assigned quality tasks and activities; trains personnel by general discussions of specific procedures, individual reading and review assignments, or individual training; maintains programming and training records.

3.0 DEFINITIONS

None

4.0 PROCEDURE

4.1 Quality Program Programming and Awareness Training

The TCCCP Quality Manager will schedule and provide Quality Program Indoctrination and Awareness training to the TCCCP functional organizations. This training will focus on the TCCCP's documented quality system, and will cover the following topics:

- TCCCP Quality Management Plan
- Procedures and Work Instructions
- Use of Specified Forms and Quality Documentation

Training will focus on improving competency and skill for those personnel performing activities that materially impact quality.

- a) Position descriptions defining the requirements of the various positions required in conducting activities affecting quality
- b) Personnel records documenting each person's experience and current education/training accomplished relative to current/projected position assignments
- c) documented evaluations of said experience and training, including



determination of what training is required to become fully qualified for the activities to which the person is intended to be assigned

- d) documented plan to accomplish any training deficiency
- e) records documenting accomplishment of the training and
- f) education, experience and licensure used as a basis for qualification of individuals should be verified.

All personnel shall be trained in the project procedures applicable to their work, craft journeymen with special skills need not be trained, however their competency shall be verified and a record maintained (i.e., welders reject rates etc.)

Training attendance will be documented and kept on record in the QA Manager's training files (TCCCP and Contractors) If required, follow-up sessions will be held throughout the life of the program, and/if when significant revisions are made to the documented quality system.

5.0 REFERENCES

TCCCP Quality Management Plan

- Section 8.0 - Inspection and Testing
- Section 14.0 - Quality Audits



6.0 ATTACHMENTS

Attachment A - Training Record (Sample)

Attachment A – Training Record

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APPENDIX B: QUALITY IN TRANSIT OPERATIONS AND MAINTENANCE

B-1 Background

These guidelines were written to address quality as it applies to capital projects, but the fifteen quality elements also apply to Operations and Maintenance (O&M) activities in transit agencies. The purpose of this appendix is to define and demonstrate how these elements can be applied to a total O&M operation.

Delivery of quality services results in safe, accessible, easy-to-use, reasonably priced, reliable, and dependable transportation. Acknowledging and working to the quality elements can lead to increased ridership; opportunities for increased funding and growth; improved image; lower life-cycle costs; an involved, interested, and satisfied work force; and more public support for transit.

To better understand the differences between quality applications in capital projects and O&M activities, it is helpful to consider the construction of a light rail system from initiation. The capital project quality program applies to the project phase of building the system, including right of way acquisition and construction, vehicle procurement, contract administration, etc. After an estimated five years of operation, all components of the system have worn to varying degrees, but the need to maintain quality has remained the same. The objective of this appendix will be to show how the 15 quality elements can be applied to the O&M of the system.

Briefly stated, the quality process during the construction phase focuses on the delivery of the administrative devices that bring the project into being, e.g., designs through the various phases of the project, project specifications, procurement of all the contracts and materials that comprise the project, inspection and testing of project elements, product traceability, and the records that are kept, such as as-built drawings, to document how the project was constructed. In other words, is the project being delivered in the manner intended and are all the records in place?

The purpose of Quality Assurance (QA) in the O&M phase of a light rail system operation is more centered on whether or not the system components are being properly maintained to both internal and external parameters. An example of an internal parameter that needs to be met would be compliance with the organization's maintenance standards for the particular component, e.g., does the track comply with the organization's maintenance standards or are the signals being inspected on the prescribed organizational schedule? Also, consider the processes by which these parameters themselves are established, reviewed, updated, and disseminated throughout the O&M organization. External parameters that may need to be met include regular inspection and documentation of vehicles, tracks, signals, etc. for compliance with Federal Transit Administration (FTA) or Federal Railroad Administration (FRA) standards.

B-2 Application of the 15 Quality Elements

B-2.1 Element 1: Management Responsibility

Much of what appears in the Chapter 2, Section 2.2.1, discussion of *Management Responsibility*, also applies to O&M. The management of every organization is always responsible to develop, implement, update, and maintain that organization's quality program, regardless of whether it is a project organization or an O&M organization. In this regard, there is no difference between the project and O&M organizations. What does differ, however, may be the organization of a quality staff, the types of activities monitored, and the manner in which

the quality elements are applied. Subsequent sections of this appendix will present examples of how the quality elements can be applied within an O&M organization.

QA Personnel should retain independence from O&M staff and report directly to agency managers. Due to the nature of O&M organizations where there is limited, if any, funding for quality, most grantees will not have an individual to devote to quality functions, even on a part-time basis. Nonetheless, that does not relieve that organization from the need to dedicate attention to its Quality Management System (QMS). The goal of any transit agency is to deliver a quality product to its customers as efficiently and consistently as possible and an effective QMS helps to ensure that this occurs.

This cannot be done unless proper attention is paid to quality. In many cases within an O&M organization, it is the senior line manager's responsibility to not only manage the day-to-day operations/maintenance of the system, but to administer the quality program as well. This designation, including the associated authority and required interrelationships, should be defined in the O&M Quality Plan.

B-2.2 Element 2: Documented Quality Management System

Much of what appears in the Chapter 2, Section 2.2.2, discussion of *Documented Quality Management System*, applies to O&M. The agency's documented Quality Management System (QMS) should contain written procedures and instructions for the processes used to manage and control the O&M activities of the transit agency.

The agency's O&M processes must evolve over time to match the changing nature of the ongoing activities that it controls. Just as in Chapter 2's discussion of Element 2, these O&M processes should be regularly evaluated and updated. The regularity of these updates should be determined by the agency based on the need.

B-2.3 Element 3: Design Control

After a system has been constructed and operating for a length of time, the original designs of the various components that comprise the system are of concern to the O&M management when they must remediate something that doesn't work. The O&M manager's primary concern will be to maintain all of the system components to their respective standards as set forth in the organizations' maintenance manuals. An example is: "What is the allowable size of flat spots on rail wheels before wheel truing becomes necessary?"

The development of these maintenance standards and their subsequent inclusion in an organization's documented maintenance manual then becomes, in essence, a form of design control for O&M. Procedures that explain how these documents are to be established and maintained should exist within the O&M organization and be complied with by O&M management and support staff.

It is also the responsibility of senior management to provide manuals and procedures either by engaging an external subject matter expert or by using internal organizational experience to develop them. The line manager then becomes responsible to implement and manage the various inspections and to assure compliance with the organization's manual(s)/procedure(s). In the case of a small organization, this responsibility may belong to only one individual, in which case the check-and-balance nature of the quality program is particularly critical.

For additional guidance, see Chapter 2, Section 2.2.3, *Design Control*, some of which applies to O&M.

B-2.4 Element 4: Document Control

Documents such as updated procedures, work instructions, manufacturer's maintenance and operations manuals, completed checklists, and many more have to be controlled to ensure that the organization's staff is using the most current approved documents and that they are following the most recently approved procedures and standards. To control such documents, an organization must establish a prescribed procedure for the proper dissemination of each document. This includes, at a minimum, who should receive it, when it was received, and how that person should acknowledge receipt. The document control procedure also includes a summary of these actions.

As mentioned previously, all system components need to be inspected on a regular basis to assure their respective fitness for continued service. Written documentation of these inspections by qualified inspectors is required to comply with FTA or FRA regulations. If the records of these inspections are not kept in the manner prescribed by the organization, or if the written records are deficient in any way, the organization and/or the individual inspector is subject to fine and/or imprisonment. Records of remedial action taken to correct particular identified conditions are also part of the document control process.

Some examples of operations and maintenance documents that need to be controlled follow:

- Operations documents to be controlled include policies, inspection/test procedures, drawings, specifications, work instructions, operating manuals, and templates for reports, checklists, and other forms.
- Maintenance documents to be controlled include manufacturer-provided maintenance manuals and service bulletins, maintenance procedures, and templates for inspection reports, checklists, and other forms.

For additional guidance, see Chapter 2, Section 2.2.4, *Document Control*, some of which applies to O&M.

B-2.5 Element 5: Purchasing

Much of what appears in the Chapter 2, Section 2.2.5, discussion of *Purchasing*, applies to O&M. Purchasing's role in an O&M organization can tend to be overlooked, but it can become very critical depending upon the given situation. Assuming that contracts were only let during the construction phase of a light rail system, the major function of purchasing in an O&M organization is to purchase materials for worn system components. The operating system itself is comprised of the infrastructure and the vehicles, both of which have hundreds of specific items that make each work. The replacement of one component, even a set of trucks on a vehicle, cannot be left to chance. It is the responsibility of Purchasing (with strong support from the O&M department) to ensure that the material procured for replacement will perform properly for the given situation.

B-2.6 Element 6: Product Identification and Traceability

Product identification and traceability is as important in an O&M organization as it is during the project phase. Chances are greater that system components will fail during operation after full loads have been applied rather than during the construction phase of a project. As a result, it is just as important for an O&M organization to establish an effective product identification and traceability process as it is during the construction phase of a project.

Vehicles, as well as track and signal components, have identification numbers on them that allow traceability back to the beginning of the manufacturing process. For example, rail that has been installed in track has a series of identification symbols on it that can be traced back to the ingot the molten steel was poured from. Similarly, each part on every vehicle has an identification on it that will allow traceability back to the bench on the manufacturer's floor where the part was made.

Traceability is particularly important because, if a factory defect results in an in-service failure, the organization needs to know if it has components from the same batch still in service and, if so, where they are. In this manner, the organization can install a pre-emptive replacement to prevent additional failures. In a large system, particularly a railroad which has thousands of miles of right of way, other locations on the system where similar components have been installed can be identified and replaced if necessary.

As a result, it is incumbent on each O&M organization to establish a written procedure to keep track of where its in-service system components are, maintain a history of service failures and their causes, and develop a list of potential solutions to the given failures. From these, a "lessons learned" file could be generated, which can help the organization revise its existing standards, procedures, etc., at the proper time.

For additional guidance, see Chapter 2, Section 2.2.6, *Product Identification and Traceability*, which offers additional relevant guidance on the application of this element to transit maintenance activities.

B-2.7 Element 7: Process Control

Much of what appears in the Chapter 2, Section 2.2.7, discussion of *Process Control*, also applies to O&M. Process control within an O&M organization will provide the details and parameters around which the system is intended to operate. Functions such as dispatching of buses, trains, or vans, emergency communications, employee qualifications, etc., will be contained in that organization's Operating Book of Rules, Safety Manuals, Maintenance Standards, respective discipline procedures, Procedures Manuals (for administration), etc

B-2.8 Element 8: Inspection and Testing

The primary activities of most operations and maintenance organizations are focused on the inspection and testing of their system components. The main purpose of an operating system is to perpetuate its own existence. As a result, O&M organizations, whether bus, light rail, railroad, or other, dedicate a majority of their efforts to the two separate functions of inspection and testing.

Every system component needs to be inspected periodically to ensure its fitness to remain in service and to ensure the safety of the travelling public. Busses, light rail vehicles, rail cars, and other vehicles that are used to transport the public are all subject to inspections that are based upon federal guidelines. Similarly, infrastructure components such as track, trolley wire, third

rails, and rail and highway signal systems are also subject to inspections based on other federal guidelines. All of these systems must work in concert with one another for the entire system to operate properly. Those elements that are inspected and found to be deficient must be removed from service and replaced.

There are also two levels of testing which must occur on an operating system. The first is testing of the individual working components such as traffic signals or the brakes of a vehicle to ensure that they are working properly. The second level of testing is for the component operators to ensure that they maintain their fitness for duty. Conditions on a right of way will change over time and an organization must assure itself that its operators keep current with the changes.

For additional guidance, see Chapter 2, Section 2.2.8, *Inspection and Testing*, some of which applies to O&M.

B-2.9 Element 9: Inspection, Measuring, and Test Equipment

Much of what appears in the Chapter 2, Section 2.2.9, discussion of *Inspection, Measuring, and Test Equipment*, also applies to O&M. Because component wear and suitability is so critical to an operating system, it is extremely important to use tools that are properly calibrated. There are many meters, gages, and other measuring devices that are used in operations and maintenance to perform inspection and testing of system components. Examples include wheel gages, track gages, signal meters, and meggars. All such devices can become worn and/or go out-of-calibration at any time. Each device should be inspected before every use by the inspector to determine suitability for use at the moment. Additionally, all measuring and test equipment should be periodically tested by an independent agency to determine if re-calibration or replacement is necessary. A list of all calibrated equipment should be maintained. This list should contain the equipment name, model, serial number, date the equipment was calibrated, and the due date of the next calibration. The proper procedure for employee inspection and independent inspection should be detailed in the organizations' inspection manual.

B-2.10 Element 10: Inspection and Test Status

Much of what appears in the Chapter 2, Section 2.2.10, discussion of *Inspection and Test Status*, also applies to O&M. It is important for management staff in the O&M organization to be aware of, and maintain documentation related to, the status of inspections. Use of an inspection schedule may be an effective way to achieve this. Test status for a particular device should be kept on file as part of the organization's test program until an ultimate disposition for that device is determined.

B-2.11 Element 11: Nonconformance

Much of what appears in the Chapter 2, Section 2.2.11, discussion of *Nonconformance*, also applies to O&M. In addition to equipment and hardware, O&M management should also consider driver/operator performance as either conforming or nonconforming. If a dispatcher is not performing in accordance with established requirements, or if a bus or train operator is not performing in accordance with established procedures and training, then their work should be considered nonconforming. For safety's sake, all equipment, hardware, and personnel that do not conform within allowable O&M parameters should be documented and removed from service.

B-2.12 Element 12: Corrective Action

Much of what appears in the Chapter 2, Section 2.2.11, discussion of *Corrective Action*, also applies to O&M.

B-2.13 Element 13: Quality Records

It is important that an O&M organization maintain all its written records as quality documents. It must be remembered that many system components may be in service for as long as 30, 40, or maybe even 50 years. The history of what maintenance has been done to particular system components can be extremely helpful when estimating how long the life of the component can be prolonged, if at all.

It is crucially important that any federally mandated inspection records be kept as quality records. This is because the federal agencies that monitor these records review not only the content of the reports, but also the frequency of inspection and the locations inspected. As a result, it is imperative that the O&M organization develop a record monitoring procedure that senior management can review to quickly determine if its record keeping system is being properly administered.

Some examples of operations and maintenance records that need to be controlled follow:

- Operations records requiring control include dispatch records, stand check records, daily track inspection reports, operator qualification and training records, customer survey data, digital data including audio and video records generated in the operations center and on transit vehicles, accident data, test reports, inspection reports, non-conformance reports, corrective action reports, and audit reports.
- Maintenance records include receiving inspection reports, checklists, parts inventories, inspection reports, non-conformances, corrective actions, and audit reports.

For additional guidance, see Chapter 2, Section 2.2.13, Quality Records, some of which applies to O&M.

B-2.14 Element 14: Quality Audits

Much of what appears in the Chapter 2, Section 2.2.14, discussion of *Quality Audits*, also applies to O&M. Because O&M organizations may not have dedicated quality personnel, it may be necessary for these organizations to perform self-administered audits. An important factor in these audits is for the auditor to remain as objective as possible.

Although self-audits are not the accepted method of quality auditing, nonetheless, they can be effective because the entire organization is responsible for the safety of the travelling public. To provide a safe operation, it is essential that everyone with responsibility within a given discipline be aware of the existing operating conditions. Oftentimes, the only practical way to accomplish this is to have a strong audit program. The entire audit program should be detailed in the organization's O&M manual.

B-2.15 Element 15: Training

Much of what appears in the Chapter 2, Section 2.2.15, discussion of *Training*, also applies to O&M. O&M management should take special care in ensuring that the training for certain transit personnel, such as drivers/operators and dispatchers, establishes the requirements for performance set by the Grantee organization.

The training of employees is an integral part of every program, regardless of whether it's for a construction project or an operations and maintenance organization. It is particularly important in an O&M organization because O&M is an ongoing, long term function as opposed to a construction project that has a fixed life. The more qualified personnel a system has, the easier it is for everyone within the organization to do their respective jobs. A robust training program also assures that there will be sufficient trained personnel available when attrition or other job vacancies occur.

B-3 Final Thoughts

Ensuring that O&M activities have procedures for the work they perform is the responsibility of O&M management and is a quality function. If the transit agency has a quality function, then O&M management should coordinate with that function to make sure that O&M are part of the transit agency's overall QMS. Working under this QMS umbrella will afford O&M management the greatest opportunity to consistently deliver the highest quality service to its customers

O&M activities operating in a transit agency that does not have a formal agency-wide quality function are encouraged to establish a QMS for their activities. Using these Guidelines and consulting with other transit agencies, O&M management can develop a quality program that will result in the safe, reliable, and efficient delivery of transit services to the traveling public.

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APPENDIX C: DOCUMENTED CASE STUDIES

A Collection of 10 Quality Case Studies

The following case studies document past quality practices and their successes and/or failures. Each study identifies one or more lessons, though the reader can draw other lessons from these selections as well. Case studies 9 and 10 are new to this revision.

- **Quality Case Study #1: Benefits of Implementing “Cost of Quality” and “Proactive Walk Down/Turnover and Project Closeout”** details the benefits yielded by activities with upfront quality costs on two different projects
- **Quality Case Study #2: Southeastern Pennsylvania Transportation Authority Market-Frankford Rehabilitation Program** compares preventative quality cost activities to the cost of nonconformance, and deals with dismissive attitudes toward quality
- **Quality Case Study #3: Design-Build: Baltimore Central Light Rail Line Phase II Extensions Project** discusses the grantee’s role in quality assurance
- **Quality Case Study #4: Regional Transportation District of Denver FasTracks Plan** discusses the contractor’s role in both quality assurance and quality control, as well as the elements of a successful quality management system (including continual improvement)
- **Quality Case Study #5: Dallas Area Rapid Transit Light Rail Project** details the correction of a nonconformance, including the root cause analysis
- **Quality Case Study #6: Southeastern Pennsylvania Transportation Authority Market-Frankford Rehabilitation Procurement** details the difficulties encountered during a procurement process involving an ISO-certified supplier
- **Quality Case Study #7: New York City Transit 63rd Street Connection Project** provides an overview of the quality program utilized for the project, focusing on preparatory phase effort, performance measurement, and just-in-time training
- **Quality Case Study #8: Washington Metropolitan Area Transit Authority Metrorail Project** recounts the institution of a quality awareness program that was later deemed to be unsuccessful
- **Quality Case Study #9: Charlotte Area Transit System Blue Line Extension (BLE) Project** details two Lessons Learned: Planning and Organization for Systems Integration Testing (SIT) and the Risk Assessment Process
- **Quality Case Study #10: Regional Transportation District of Denver FasTracks Plan** consists of five separate Lessons Learned

Quality Case Study #1 Benefits of Implementing “Cost of Quality” and “Proactive Walk Down/Turnover and Project Closeout”	
Delivery Methods:	1. Design-Build for Tri-Rail 2. Contract Manager/General Contractor (CMGC) for RTD West Corridor LRT
Program Description :	1. <u>Tri-Rail</u> The \$340 million Tri-Rail project is a commuter rail line linking Miami, Fort Lauderdale, and West Palm Beach, Florida, United States. It is run by the South Florida Regional Transportation Authority (SFRTA). The 70.9-mile- long (114.1 km) system has 18 stations along the South Florida coast. The system connects directly to Amtrak at numerous stations, and the Metrorail in Hialeah (Miami) at the Tri-Rail and Metrorail Transfer Station. Tri-County Commuter Rail's (TCRC's) Quality Plan was structured in conformance with ISO-9001:1994 (ANSI/ASQC Q91:1994) and related standards. The Quality Management Plan incorporated the provisions of the 2002 update of the <i>FTA Quality Assurance and Control Guidelines</i> and SFRTA's Quality Assurance Program. 2. <u>West Corridor Light Rail Transit</u> The \$430 million West Corridor LRT Project consists of 12.1 miles of Light Rail Transit (LRT) extending from the existing light rail line at Auraria West Station, west across the South Platte River, then west traversing the existing Associated Railroad right-of-way between Decatur Street in Denver and Quail Street in Lakewood as well as through the Lakewood Industrial Park, and crossing West 6th Avenue into the Denver Federal Center. West of the Denver Federal Center, the alignment, which was to run on the north side of West 6th Avenue along US 6 is being shifted to the south side of US 6 up to Indiana street where it will cross back over to the north side and parallel the highway at-grade within the CDOT right-of-way to the Jefferson Country Government Center. The LRT Alternative includes the development of twelve stations: Auraria West, Federal/Decatur, Knox, Perry, Sheridan, Lamar, Wadsworth, Garrison, Oak, Denver Federal Center, Red Rocks and Jefferson County Government Center. Parking will be provided at six of the 12 stations, providing approximately 5,614 parking spaces. This project is a component of the FasTracks program being managed through a team approach consisting of Regional Transportation District of Denver (RTD) staff, supported by a

	Program Management Consultant with expertise in program management, budget and schedule controls; a Quality Management Consultant for documentation and quality oversight; a Public Involvement /Information Consultant; and other expertise required to form an integrated team to manage, oversee design and deliver the FasTracks program on schedule and within budget. Individual corridor consultants have been retained for environmental, preliminary engineering, final civil design and systems design. Denver Transit Construction Group (DTCG) is the established joint venture company consisting of Herzog Contracting Corporation of St. Joseph, Missouri as LEAD PARTNER and Stacy and Witbeck, Inc. of Alameda, California.
Total Program Costs:	1. Tri-Rail - \$340 million 2. RTD West Corridor LRT - \$430 million
Lessons Learned:	
Lesson 1 - Cost of Quality A. Tri-Rail Project Experience Assessments of project procedures implementations at various project sites were performed to identify not only non-conformities, but also areas of excellence and good practices, opportunities for improvement, corrective and preventive actions. After careful review and analysis of “root causes” of findings from the mini-audits, it was determined that a serious need to establish a “quality cost database” to record all costs resulting from conformance to quality (preventive and appraisal costs) and nonconformance to quality (internal failures impacting Herzog or the joint venture partners and external failures or losses involving the customer). The four cost of quality categories (prevention, appraisal, internal failure and external failure) were collected and stored in a database with necessary details and breakdown of costs into elements and cost drivers for analysis. At Tri-Rail, the total number of non-conformance reports was 50. The estimated rework cost was 0.45% of the total project cost. Please see Table C-1 and Figure C-1.	

Table C-1: Estimated Cost of Rework

COST ITEMS	% of Cost Revenue
Costs of Internal Failure (Rework)	0.45
Cost of Appraisal	0.55
Cost of Prevention	0.35
Total Costs of Quality	1.35

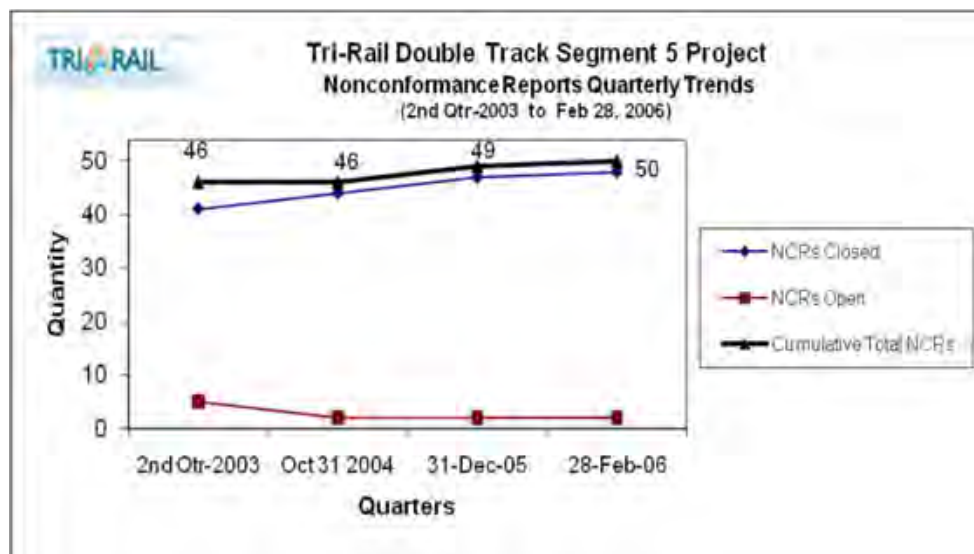


Figure C-1: Nonconformance Reports Quarterly Trends

B. RTD West Corridor LRT Project Experience

Quality failures or losses can be associated with particular strategic objectives, and improvement projects selected that will have a direct impact on those objectives. The costs were pulled from expenses due to reworks, testing, warranties, inspections, services, damaged reputations, claims and even litigations.

After introducing the concept of “cost of quality” monitoring to the DTCG project manager, construction managers, cost engineers and field engineers, the DTCG quality team, under the direction of Herzog’s Corporate Quality Manager, commenced its collection and analysis of quality cost data from reworks/repairs due to nonconformities, bad materials, or poor design beginning the 1st quarter of 2010. Refer to the Figure C-2 below (Cost vs Activity). Herzog Procedure # 060.191 – Costs of Quality Data Collection, Analysis and Reporting (see attached) describes the process for collecting, analysis and reporting quality cost data base.

Through the cost categories, the DTCG project management team identified potential operational savings in terms of cost reduction (expenses or capital savings), cost

avoidance (cost prevention) and labor productivity (time savings).

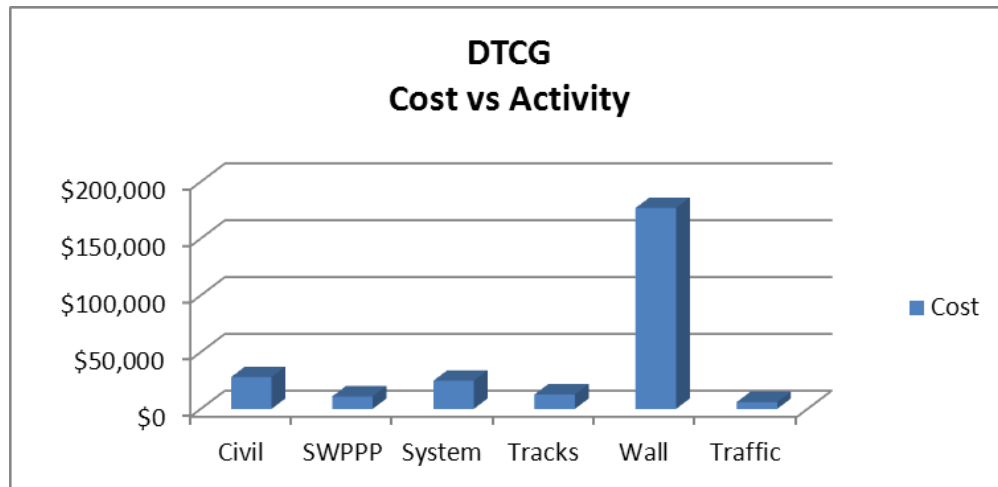


Figure C-2: Cost of Activities (as of November 30, 2011)

Lesson 2 - Proactive Area/Systems Walk Downs/Turnover and Project Closeout

C. Tri-Rail Project Experience

From commencement of the first construction package, the TCRC project management team implemented its project procedure for area/systems walk downs, punch listing and turnover of completed construction/installation works. The TCRC Project Quality Manager directed the entire process through active participation of the Construction Quality Manager, the various discipline construction managers, Quality Control (QC) inspectors, field engineers, subcontractors representatives, and discipline design managers or their representatives. A very key factor in the success of this process was the full support and participation of the SFRTA Quality Manager, and representatives from Florida DOT, CSX, and city inspectors. The status of area/systems walk downs/turnovers were monitored, updated and periodically transmitted to all concerned TCRC project management team as well as SFRTA and stakeholders. Refer to the spreadsheet showing status of walk downs/turnovers below.

There were two major types of walk downs, namely:

1. **Preliminary Walk Down** – A preliminary walk down was conducted when the work was approximately 70% complete, or whenever a part of a system or structure was to be enclosed or buried. The objective of this walk down was to evaluate the quality of the work performed to that point. The walk downs were documented in a preliminary punch list. Required repairs or reworks of identified nonconforming conditions were completed and verified that the corrections were done prior to the final joint walk down with the clients (SFRTA, CSX, Amtrak, city representatives, and/or other stakeholders).
2. **Final Walk Down** – A joint “Final Walk Down” was conducted when a work element was complete. The purpose of this walk down was to verify that the system has been installed in accordance with the approved design. This walk

down included a verification that the supporting inspection and test documentation have been compiled and provided evidence that the installed system was acceptable.

D. RTD West Corridor LRT Project Experience

The area/system walk down/turnover project procedure describes the walk down process performed by DTCG to verify that a unit of work, work area or systems, is complete and acceptable (installed per the applicable drawings, specifications and approved field changes), and that all nonconformance reports and open items have been satisfactorily corrected, accepted and closed out prior to turnover to RTD. A walk down verifies the completeness of both the physical work and the supporting documentations. DTCG will also submit an installation safety certificate for the completed area of FasTracks West Corridor LRT Project being turned over to RTD.

Walk downs are conducted using approved drawings, specifications, design changes and field change requests. During walk downs, drawings are “redlined” to identify conditions that do not conform to the approved drawings and specifications and that no changes to the as-installed condition will be made. To the extent possible, photos are taken as a part of a walk down. This is especially true of areas where work will be buried or enclosed. When photos are taken, they are to be numbered using the oversight inspection report number and the punch list item number. If more than one photo is taken, an additional sequential number should be appended to the oversight inspection report number. For a given item number, a description of what is shown by each photo taken is entered in the punch list under the “Punch List Description” heading. The walk down process includes verification that required testing has been performed and is acceptable. This verification is performed by the Construction Quality Manager or his designee.

Walk Down Planning

The Construction Quality Manager plans for a walk down by generating Walk down Records that describe the scope of the inspection, the names of the walk down participants, the applicable drawings, specifications, design changes and other related documents and punch lists identified. The Construction Quality Manager obtains input from the field engineers, construction manager, Engineer-on-Record and RTD representatives when developing the walk down record. Walk down records are organized by work area number. Given the scope of most work areas, it is expected that there will be multiple walk down records for any given work area. The walk down requires a review of the list of outstanding items, such as Nonconformance Reports (NCRs), and tracking log to identify whether or not there are any open NCRs affecting the area covered by the walk down. Any open NCR or open issue affecting the scope of the walk down shall be listed under one line item and the line item is recorded as a “Reject.”

Walk Down Closeout

The Construction Quality Manager combines the Walk Down Record cover sheet with the punch list(s). When all items listed on the PL are closed, the original of the PL is turned over to RTD. An Installation Safety Certificate shall be routed for signature,

signed by the DTCC PE, authorized representatives of RTD and other project stakeholders certifying that installations and conditions permit beneficial occupancy of the area in accordance with contract documents and permits the partial systems tests to start or revenue operation.

Quality Case Study #2

Southeastern Pennsylvania Transportation Authority Market-Frankford Rehabilitation Program

Delivery Methods:

Design-Bid-Build, Program Manager/General Contractor, and Southeastern Pennsylvania Transportation Authority (SEPTA) Force Account Labor

Program Description:

The Frankford Transportation Center (FTC) was the largest single-site construction project ever undertaken by SEPTA and the work had to be performed with minimal disruption to the 50,000 riders that passed through the terminal each day.

FTC consisted of six overlapping projects as follows:

1. Demolition of existing buildings at Pratt Street and Frankford Avenue.
2. Construction of two new bus bays on the South side of the Bus Depot and demolition of the existing front of the old building to make room for the new Terminal
3. Construction of new East and West guideways.
4. Construction of a new Multi-Modal Terminal
5. Construction of a new Parking Garage.
6. Rehabilitation of the existing Railcar Storage yard.

The program required constructing a major terminal facility for the Market- Frankford Elevated line in a confined space with little room for storage of material and equipment. At the same time, service had to be maintained for 16 separate bus and trackless trolley routes that interchange with the elevated line at the terminal, requiring close coordination with SEPTA's Bus Operations. Although the buses only required replacement storage space in the rehabilitated bus depot, the trackless trolleys (Trolley Buses) required their overhead wiring and switching to be completely rearranged to get out of the way of the Terminal building and still operate properly.

Except for a scheduled nine-day power outage, rail service was not interrupted. During these nine days, the guideways were reconstructed and shifted to the west. As Project 3, the Guideway and Systems contract, a temporary trestle was constructed to support the elevated rail line while a new portion of Bridge Street was constructed below. In order to complete the entire task within the outage time, construction was performed around-the-clock.

Total Program Costs:	\$187 Million (based on actual costs)
Lessons Learned:	
In order to construct the new Terminal Building while maintaining access for SEPTA's 50,000 daily riders, the existing Rail yard had to be reconfigured to accommodate the new system alignment and maintain the same capacity. This involved shifting one existing turnout from Track 15 to Track 14 and installing multiple new turnouts along with all of the controls. Included in this work were two Triplex turnouts, which allow shifting a train from one track to three tracks. All of the Westbound trains were stored in this yard and its availability for daily operations was critical. The contractor needed to deliver the yard back on time early any Monday after a weekend of installing a new turnout. Preplanning was critical. Lesson 1. A contractor's attitude toward quality is often indicative of the quality of their work. The Track Contractor arrived on site with a superintendent, who resisted contractual requirements, including the requirement for a Quality Plan. The Program Manager's (PM's) Quality Manager expended much effort getting him to produce a workable Quality Plan. The contractor finally hired a subcontractor to produce a corporate plan, which he adjusted for each specific project and hired a Quality Manager. Based on the contractor's initial inability to deliver the plan, the PM decided the contractor should start by moving the existing turnout to see how close to completing on time he would be. This became problematic. For several weeks prior to the actual work, the PM suggested the contractor install gauge rods to hold the old turnout together, since some of the existing ties were loose, and the PM was concerned that the turnout would rack when lifted. This was brought up at the weekly progress meetings and put in the minutes. Furthermore, the PM had insisted the contractor ensure his surveying was accurate and the turnout moved to its correct new position. On Friday evening of the weekend for the move, the contractor began by disconnecting the turnout and installing lifting straps to move it to its new position. Of course the contractor failed to install gauge rods to save money and the turnout racked when lifted. Now instead of being able to place it directly in its new spot, he had to reassemble it piece by piece. This of course took longer than planned. Lesson 2. Prevention quality costs save money over the cost of nonconformance. On Saturday morning around 4:00 AM, the PM came to check how the work was proceeding and how his inspectors were performing. The Owner of the company was personally directing the work, which the PM noted was not correct. The final location was out of position by one full gauge. The contractor insisted he had surveyed the point several times and it was correctly in place. The PM insisted the contractor physically measure the distance, the results of which revealed that the turnout was out by one	

gauge width. The contractor had attempted to save money by using an inexperienced surveyor, resulting in major cost due to crew delays.

Naturally, the work finished late and the yard was not turned back on time, which upset the Owner. He agreed to bring in a new superintendent among other corrective actions, including the institution of weekly telephone conferences to bring the contractor, supplier and PM together to check weekly progress.

Once the work shifted from moving an existing turnout to assembling and installing new turnouts, the PM noted that the crew was having trouble assembling them in a timely manner. The foreman complained he had no plan from the supplier to show how they went together and he was using his track experience to get them done. The PM suggested the contractor send his foreman out to the supplier's plant to get the information he needed to complete the turnout for installation. In order to save money, the contractor chose to not send the foreman to the supplier, but ended up paying more in labor time than needed as a result.

After further job progress, the contractor appeared to have improved performance. However, his crew encountered great difficulty assembling the first triplex, because they had never performed similar work before and had difficulty getting the parts to properly align.

Consequently, this portion of the project was delayed. The contractor was not allowed to proceed until the turnout was correct. The supplier finally sent a man to the site and he helped get the first turnout corrected. Had the contractor sent the foreman to the supplier, these delays would have been significantly mitigated.

As a result of the delay and the fact the schedule could not afford another equally long delay, the PM insisted the contractor correct his planning and recommended again that the foreman go to the supplier plant. The Supplier also suggested the foreman come to the plant to get first-hand knowledge in the assembly. This time, the contractor agreed.

At the plant, the foreman learned the tricks of proper assembly for triplexes and got a marked up plan with working lines on it to help his assembly. As a result, the contractor was able to assemble the Triplex directly in track, which saved time and the rental costs for a second crane. The contractor made several decisions based on immediate savings throughout the project, but in many cases, profits would have been greater if the contractor had invested in quality costs related to prevention, rather than paying the cost of nonconformance afterward.

Quality Case Study #3

Design-Build: Baltimore Central Light Rail Line Phase II Extensions Project

Delivery Method:	Design-Build (DB)
Program Description:	The Maryland Mass Transit Administration (MDMTA), now called the Maryland Transit Administration (MTA), was responsible for a fixed guideway system, including heavy and light rail lines, in the Baltimore region. The Central Light Rail Line (CLRL) component was phased. The Phase II project, put into operation during 1997 by the MTA, involved three major extensions of the light rail line: a 4.3-mile northward extension; a second 2.5 mile southward line to BWI Airport; and a connection between the Mt. Royal station and Pennsylvania Station. The project was awarded the 1998 “Outstanding Civil Engineering Project” award by the Maryland section of the American Society of Civil Engineers (ASCE).
Total Program Costs:	Total Project Cost of \$106 Million for all three, simultaneous extensions
Lessons Learned:	
In the project, the grantee (MTA) provided the DB contractor with responsibility for quality requirements, including audits and inspections of all materials and facilities not supplied by the grantee. The grantee originally planned to provide a minimal effort of monitoring, while retaining the option to provide inspection deemed necessary to assure implementation of the contractor's Quality Program and thereby assure the quality of the DB contractor's work. This type of quality function implementation was new to both the grantee and the contractor. This process was adapted from the US Army Corps of Engineers' approach to the quality review process in DB projects. Lesson 1. The grantee should maintain a Quality Assurance (QA) role over the DB contractor. The MTA required the bidders to certify that they would conform to MTA's Quality Plan requirements instead of developing their own during the procurement process. In addition, MTA required review and approval of the control process and staffing plan. However, the transfer of virtually all of the Quality Program responsibilities to the contractor, as was done on other federal DB projects at that time, created unplanned limitations on the ability of MTA to adequately oversee the project. This may have had an unintended result of decreasing consideration of the Quality Plan during the procurement process.	

The CLRL Extensions project demonstrated initial constraints over roles and responsibilities between the grantee and the DB contractor, especially in regard to the DB contractor's role regarding indirect reporting of the construction management functions. Additional effort was required by MTA to get the contractor to implement the defined program within the DB project team and maintain adequate oversight once the project was underway. The MTA has maintained a larger role in the quality assurance and document control since this initial DB contract.

Lesson 2. The grantee should always maintain some QA role over the contractor and their subcontractors.

This lesson does not only apply in projects that follow the DB delivery method. In large, multi-tiered Mega Projects, the grantee may be separated from the contractors and subcontractors by a Project or Construction Management Consultant (PMC or CMC) and/or a Construction Manager (CM). In these cases, it is still beneficial to the grantee to maintain some QA role even at the contractor level. They may attend and observe meetings with the contractor/sub or quarterly audits of their activities or even perform their own audits if there is cause for concern. These additional management layers may serve a more in-depth QA role on the project, but this does not absolve the grantee of all involvement.

Quality Case Study #4

Regional Transportation District of Denver FasTracks Plan

Delivery Methods:	Design-Bid-Build, Construction Manager/General Contractor, Design- Build, and Design-Build-Finance-Operate-Maintain
Program Description:	The <i>FasTracks Plan</i> consists of nine rail lines (new or extended), two Rapid Transit (BRT) lines, redevelopment of Denver Union Station, a new Commuter Rail Maintenance Facility, and an expanded light rail maintenance facility. The Plan adds approximately 64 miles of commuter rail (East Rail, Gold Line, North Metro Rail, and Northwest Rail – Phase 1 and 2); approximately 28 miles of light rail (Southeast Rail and Southwest Rail Line Extensions, Central Rail Line Extension, I-225, and West Rail Line); Park-n-Ride improvements and/or relocations at existing Park-n-Ride lots along US 36 (US 36 BRT – Phase 1), and up to 80 miles of BRT (US 36 BRT – Phase 2 and Northwest Corridor BRT). Bus
Total Program Costs:	\$7.4 Billion (based on 2012 Annual Program Evaluation)
Lessons Learned:	
After the FasTracks Plan was passed by voters along with a Sales and Use Tax initiative in November 2004, the Regional Transportation District of Denver (RTD) needed to re-define its quality management program to accommodate multiple concurrent projects in different phases of delivery, multiple project delivery methods, and multiple transit technologies. RTD was able to achieve this through several approaches: Lesson 1. Develop a written quality management philosophy. RTD published its quality philosophy in March 2005, which included the following elements: • Public Responsibility and Citizenship – a commitment to RTD’s mission of delivering safe, clean, reliable, accessible, and cost-effective transportation services that promote improved quality of life within the region. • Building Quality In – a recognition that quality must be built in, rather than inspected in. All contractors and consultants delivering products and services to RTD shall implement effective and comprehensive quality management programs. • Management by Fact – a commitment to requirements-based assessment of contractor processes and products, and utilization of information management tools to capture and globally analyze those assessments. • Process Management – an internal focus on RTD’s own key processes, and periodic	

assessment through internal quality audits, peer reviews, and other means.

This philosophy remained largely unchanged until 2012 when a fifth element was added for Teamwork, and the recognition that everyone on the FasTracks team is part of the quality oversight program.

Lesson 2. Emphasize the contractor's role in Quality Assurance/Quality Control.

RTD requires all contractors and consultants delivering work (environmental clearance documents, design products, manufactured products, and construction) to implement effective Quality Management programs, documented in written Quality Management Plans that must be approved by RTD. These plans comply with the 2002 update of the FTA Quality Assurance and Quality Control Guidelines or ISO 9001:2008. For the DBFOM Eagle Project, RTD took the requirement one step further. The Concessionaire was required to achieve ISO 9001 registration through an accredited registrar within 12 months of notice to proceed.

RTD rejects the traditional notion that contractors are only responsible for "quality control" while owners conduct "quality assurance." RTD's accepted definition of Quality Assurance is "all of the planned and systematic activities implemented within the quality system, and demonstrated as needed, to provide adequate confidence that the product will fulfill quality requirements and will satisfy given needs." Consistent with RTD's quality philosophy of "Building Quality In," RTD expects contractors to implement quality assurance approaches that go beyond quality control techniques.

Lesson 3. Implement a comprehensive Quality Oversight Program.

While RTD places much responsibility for quality assurance upon its contractors, RTD does not abdicate its role in overseeing the contractor's program to ensure that it complies with the approved Quality Management Plan. RTD deploys several quality oversight approaches including: environmental review, design review, construction verification inspection, owner's verification testing, process audits, management systems audits, and priority planning to provide RTD management with confidence that the contractor is effectively managing its quality program.

Consistent with RTD's quality philosophy of "Management by Fact," RTD's Quality Oversight Program utilizes a database to store and maintain each project's requirements, develop assessments against those requirements, produce reports of each assessment, and track any nonconformances until satisfactory resolution.

In 2011, RTD received an ISO 9001 registration certificate from Orion Registrars for the RTD Quality Oversight Program. This certificate helps assure RTD management and its stakeholders that RTD has implemented an effective oversight program compliant with the international quality standard and the FTA Quality Assurance and Quality Control Guidelines that were derived from that standard.

Lesson 4. Implement methods for continuous improvement.

Consistent with RTD's quality philosophy of "Process Management" and FTA Element 12, Corrective Action, RTD has implemented several tools to identify opportunities for improvement, and take corrective or preventive action. These tools include:

- Internal Quality Audits – A structured review of RTD's management processes conducted

by an independent and certified auditor. These audits are conducted in accordance with ISO 19011, Guidelines for Quality and Environmental Management Systems Auditing.

- Peer Reviews – Conducted periodically through APTA or setup directly by RTD to review RTD's management organization and approaches.
- Rocky Mountain Performance Excellence Assessments – Conducted at the state level through a non-profit organization that utilizes the Malcolm Baldrige Criteria for Performance Excellence. In 2011, RTD was recognized with the Rocky Mountain Performance Excellence Timberline Award for performance excellence.
- Improvement Actions – A documented approach for identifying problems or opportunities

Quality Case Study #5

Dallas Area Rapid Transit Light Rail Project

Delivery Methods:	Construction Manager/General Contractor (CM/GC)
Program Description:	The LRT Buildout Phase II consists of approximately 46.1 miles of light rail transit lines extending northward from the Dallas Central Business District to the City of Carrollton (Northwest Corridor), including a branch from Northwest Highway out to Dallas/Fort Worth Airport (Irving/Dallas/Fort Worth Corridor). Phase II also extends the light rail transit lines southeasterly from the Dallas Central Business District to Buckner Blvd. in South Dallas (Southeast Corridor) and easterly from the Downtown Garland Station to the Rowlett Park and Ride (Rowlett Extension). The construction of Phase II includes two CM/GC contracts inclusive of pre-construction services, facilities construction, trackwork, landscaping, and systems elements installation; three design-build contracts inclusive of facilities construction, trackwork, landscaping, and systems elements installation; Northwest Rail Operating Facility contracts consisting of five lots; and contracts for major equipment, material, and vehicle procurements. Construction will be done in two phases: Phase IIA, which includes the Southeast and Northwest corridors (26.8 miles), and Phase IIB, which includes the Irving/Dallas Fort Worth Corridor and Rowlett Extension (19.3 miles).
Total Program Costs:	\$1.7 billion
Lessons Learned:	
In June 2011, Dallas Area Rapid Transit (DART) track maintenance personnel noted several direct fixated track plinths that appeared to have become delaminated from the bridge deck and were visibly seen moving on the Union Pacific Railroad (UPRR) Bridge in the SE-2 Line Section. Additionally, several other track plinths, including the moving plinths, it was noted that a white powder residue was observed adjacent to the plinth in the same area. DART Operations immediately initiated a 15 mph “slow order” through the area and track maintenance personnel installed track gauge rods to ensure that track would not move laterally until further investigation could be performed to determine the full limits and the cause of the delamination. Lesson 1. Regular Quality Control (QC) inspections are necessary for the timely detection of nonconformance. <u>Investigation</u> DART engaged the original design team to review the design of the SE-2 bridges. The design of the bridge deck, plinths and the attachment between the two proved to meet design codes and DART’s design criteria. An outside consultant was also engaged to	

perform a similar design check and oversight of the review process also reported that the noted plinth failures do not appear to be the result of a design flaw. Also, a review of the thermal rail stresses with respect to bridge geometry was made and was found to have a very insignificant, if any, contribution to the plinth failures.

Concurrently, an investigation program was implemented with DART staff, consultant staff, and Contractor personnel to perform destructive and non-destructive testing of the track plinths in an effort to determine the cause of the delamination. This investigation consisted of four major areas; demolition of several plinths that were visibly moving with the intent to inspect the rebar stirrups that used to tie the plinths to the concrete deck; a sample of the white powder residue was tested for chemical make-up; a survey of top of rail elevations compared to top of plinth elevations; and side load testing of the plinths to validate the bond strength between the plinth and deck.

Lesson 2. Root Cause Analysis should involve investigation into areas where there could be previously undetected failures, as a problem may be more pervasive than is apparent.

Also concurrently, all other bridges with direct fixated track were inspected to ensure similar plinth failures. Delaminated plinths were only found on the SE-2 Line Section, specifically on the UPRR and White Rock bridges.

Investigation Conclusions

Results of investigations revealed several plausible contributors to the conditions observed. The chemical make-up of the powder residue was consistent with a latex concrete bonding agent. There is an appearance that in several locations, the bonding agent was allowed to be washed or diluted and released from the formwork where it ran adjacent to the plinth on the concrete deck. A test was performed to determine the bonding capacity of the bonding agent. It was found, assuming proper application, the bonding agent should have had an adequate capacity to resist the vertical and horizontal design loads the plinths would experience.

During the demolition of the selective plinth and core samples, it was found that a plastic sleeve that was temporarily installed to protect the rebar stirrup (between the concrete bridge deck and the subsequent concrete plinth placement) was allowed in some cases to cover at least one leg of the stirrup into the bridge deck. This reduced the overall development length of the rebar leg allowing a plinth to move vertically as the train passes. It appeared the rebar stirrup provided the same or at least very near the same shear capacity as one properly installed.

The survey that compared the top of rail to top of plinths indicated that there were several plinths that were not properly shimmed. The most prevalent noncompliant condition found was the plinth and fastener was installed slightly lower than the adjacent fastener. This condition provided a significant uplift force from the rail and clip onto the plinth. However, it was determined that if the bonding agent has been properly installed, the bond should have been adequate to resist this upward force.

It appears that some of the plinths were experiencing an upward force because of improper vertical rail alignment and improper shimming of the rail fastener. This force coupled with rebar stirrups with an inadequate bonding agent applied between the

concrete bridge deck and the subsequent concrete plinth placement and rebar stirrups with inadequate development length, was the plausible explanation for the track plinths that delaminated on the SE-2 UPRR and White Rock bridges.

From the site survey, 27 plinths were found to be visually moving and 15 additional plinths were found with the white powder residue out of approximately 938 total plinths installed on the UPRR bridge. Sixteen (16) plinths were found to be visually moving and 159 additional plinths were found with the white powder residue out of 2,204 total plinths installed on the White Rock Creek bridge.

Implementation

Several non-destructive test methods (ultrasound, ground penetrating radar, etc.) were researched to definitely determine if a plinth had delaminated from the concrete deck and none were found to be successful. The rail operations and maintenance personnel were concerned that additional plinths would delaminate over time and that there was not a quick way to determine if a plinth had delaminated until a track inspector saw a specific plinth move under a train load.

To address the known plinth failures, as well as, potential future failures, the following measures were implemented on the UPRR and the White Rock Creek bridges:

All plinths on the entire Green Line system were checked for proper vertical track alignment and shimming. Where needed, the shimming was adjusted to remove any imposed loading of the plinth that the misaligned rail may have induced.

All plinths that were found to be delaminated from the concrete bridge deck were drilled and pinned with rebar dowels that were epoxied into the plinth and underlying bridge deck. The cross-section area of the new pins replaced the rebar stirrups that had potentially loosened from the bridge deck. After the pins were installed, epoxy adhesive was injected between the plinth and the bridge deck to fill the void created by the delamination to ensure full bearing of the plinth.

Any plinth where the white powder residue was found and had not been pinned to the bridge deck as described in the previous step had the joint sealed with a rigid epoxy adhesive. The joint between the plinth and the concrete deck was routed 1/4" deep and 1/4" wide, where the epoxy sealant was installed sealing the joint. It was determined that should the plinth further delaminate in the future, either the concrete of the plinth or the concrete deck would fail prior to the original joint widening, providing the track inspectors with a positive and quicker way to identify a delaminated plinth.

Due to the lack of a proven non-destructive test to definitely determine the full limits of any potentially delaminated plinths, the remaining plinths (those that as of the completion of the initial repairs had not shown any signs of a problem) had two epoxy "inspection tabs" installed at two opposing corners. Should there be any future plinths delaminate, these tabs are a positive means to determine a failure before complete delamination.

Conclusion

It appears that workmanship issues are the primary reasons for the plinth failures. It also appears that there were breaches in the Contractor's QC program and

possibly with the Construction Manager's QA surveillance and procedures. With proper QC inspections and checks, it would be expected that these issues could have been resolved much earlier.

However, from an overall perspective, 43 plinths were found to be delaminated and another 174 were suspected as potential to delaminated as a result of the investigation parameters of the 3,142 plinths installed on the two SE-2 bridges or 6.9% potential failure rate. There were 42,438 plinths installed as part of 20.8 miles of direct fixated track on DART's Green Line, equating to 0.5% potential failure rate.

Quality Case Study #6

Southeastern Pennsylvania Transportation Authority Market-Frankford Rehabilitation Procurement

Delivery Methods:	Design-Bid-Build, Program Manager/General Contractor, and Southeastern Pennsylvania Transportation Authority (SEPTA) Force Account Labor
Program Description:	The Frankford Transportation Center (FTC) was the largest single-site construction project ever undertaken by SEPTA and the work had to be performed with minimal disruption to the 50,000 riders that passed through the terminal each day. FTC consisted of six overlapping projects as follows: 7. Demolition of existing buildings at Pratt Street and Frankford Avenue. 8. Construction of two new bus bays on the South side of the Bus Depot and demolition of the existing front of the old building to make room for the new Terminal 9. Construction of new East and West guideways. 10. Construction of a new Multi-Modal Terminal 11. Construction of a new Parking Garage. 12. Rehabilitation of the existing Railcar Storage yard. The Program Manager maintained close coordination with SEPTA's Capital and Operations Departments, the designer, contractors, the community, and SEPTA riders. Quality Assurance, Safety, and Community Relations were essential elements of the Program Management services, in addition to the usual tasks that are included in Construction Management. The PM substantiated the inspection and certification of the contractors' material before it was shipped to the terminal as well as when it arrived on site. Except for a scheduled nine-day power outage, rail service was not interrupted. During these nine days, the guideways were reconstructed and shifted to the west. As Project 3, the Guideway and Systems contract, a temporary trestle was constructed to support the elevated rail line while a new portion of Bridge Street was constructed below. In order to complete the entire task within the outage time, construction was performed around-the-clock. The new transportation center features enclosed, climate-controlled waiting areas; a four-level, 1,000-vehicle parking garage adjacent to

	Bustleton Avenue; renovation of the historic Bridge Street station building; a two-story main hall; 7,000 square feet of retail space; and escalators and elevators to comply with the federal Americans with Disabilities Act.
Total Program Costs:	\$187 Million (based on actual costs)
Lessons Learned:	
In order to construct the new Terminal Building while maintaining access for SEPTA's 50,000 daily riders, the existing Trackless Trolley overhead Hardware had to be relocated away from the Terminal footprint and installed in the future alignment. The existing frogs in the overhead switching devices had been fabricated for the old layout and did not fit the new. Therefore, new switching devices with their own specially fabricated frogs had to be procured. Since this was a long lead item that could delay the project if not delivered timely, SEPTA procured the material and listed it in the contract as agency furnished material. There are few trackless trolley systems in the United States and few manufacturers that produce this material. Lesson 1. A quality plan or certification does not guarantee conforming product. The manufacturer chosen to produce the frogs was in North Carolina and was ISO 9000 certified, which normally means that their work is inspected to specification before leaving the plant. However, when the material arrived, it was inspected by the contractor, who discovered that many of the welds on the frogs were cracked leaving the material unusable in its current state. The Program Manager (PM) and Quality Manager (QM) for the project met with SEPTA's QM and the contractor to develop a corrective action to keep the project on schedule. The manufacturer was called to determine the cause and to get the corrective action moving immediately. The problem stemmed from the manufacturer using a non-certified welder to fabricate the frogs. Since the manufacturer did not have a welder certified for that type weld, he was asked to produce replacement material and to have it welded by a certified welder. He was able to hire a welder who was certified for that weld. The replacement parts were delivered by this welder to be on site in case of further problems. Under inspection, it was determined that the brace that came was too long and had to be fixed by the manufacturer. There were several overarching lessons that can be derived from this case. 1. When an agency procures critical long lead material to give to a contractor, they need to have an inspection plan to verify the material is as specified. Either have the agency's quality personnel visit the plant or contract with a quality consultant to perform the plant inspection and subsequent material inspections. This precludes the wrong material ending on the job site. The agency needs to perform a plant inspection and material checks in the same manner as they specify for the contractor.	

2. Just because a company is certified to ISO or any other specification, a plant inspection with all of the checks for certifications and samples of finished work still adds value and should not be seen as redundant.
3. Although a plant may have personnel that meet the specification for performing the work, make sure those people are actually the ones who do the work.

Quality Case Study #7

New York City Transit 63rd Street Connection Project

Delivery Methods:	Design-Bid-Build
Program Description:	One-third mile of new tunnel construction to connect the 63rd Street tunnel in Manhattan to the Queens Boulevard Line in Long Island City, Queens and relieve congestion in the existing 53rd Street tunnel. The project also consisted of widening the Queens Boulevard subway line between Queens Plaza and 36th Street in order to accommodate new ramps from the 63rd Street tunnel to come up between the local and express rail tracks in both directions. Other project components included new ventilation plants, pump rooms, circuit breaker houses, substations, tunnel lighting, computer-based control systems, communications equipment, and property acquisition. The project was completed while regular subway operations continued. Final track and signal work was completed in September 2001. The project was divided into five phases from project planning to testing and start-up. Innovative construction techniques were applied during the early tunnel excavation and underpinning phases.
Total Program Costs:	\$645 million
Lessons Learned:	
The 63rd Street Connection Project to the Queens Boulevard Lines is a very large and complex subway project that has involved six construction contracts and various construction activities including cut and cover, drill and blast, and pit and beam underpinning tunneling methods. Construction has spanned over 7 years while the subway has been in full operation. The project required that all general contractors possess a quality program, which New York City Transit (NYCT) monitored and evaluated. The agency also initiated and successfully implemented a quality program for the project. This program was originally intended to ensure contractor conformance for quality and safety, but evolved into a more comprehensive tool to support continuous improvements of methods and products. It was also accepted by all project participants (i.e., contractors, NYCT	

program personnel, designers, FTA, MTA, and their respective oversight consultants), ensuring strong and dynamic partnerships that minimized rework, improved communications, and provided guidance. The lessons identified by the NYCT in the documented project lessons learned of October 2000 involved three key elements of the quality program:

- Preparatory phase construction inspection
- Contractor performance rating system
- Just-in-time training

These lessons are detailed below.

Lesson 1. Place emphasis on quality during the preparatory phase of construction.

An emphasis on the preparation phase of each new construction activity enabled project participants to coordinate their efforts and review the upcoming work together to ensure that the job was done right the first time and expeditiously. A preparatory phase before construction is specified by NYCT contracts; however, the first time it was fully implemented was in the 63rd Street project. Previously, preparatory activities for construction performed by contractors were limited in scope and independent of the NYCT. Consequently, the NYCT began requiring several joint procedures before all major construction so that all activities were understood and coordinated, to clearly communicate expectations about the final product, and to limit nonconformance. These goals were accomplished by a series of meetings and other activities identified by the NYCT, which included:

A. Review of Contract Requirements with the Contractor

This is a joint effort with the contractor to review the status of submittals (i.e., materials, shop drawings, procedures, and methods); clarify installation methods; define records to be maintained; develop checklists; determine hold and witness points; outline responsibilities; identify critical safety issues; and assess training needs for NYCT and contractor staff.

B. Review of Physical Field Conditions

This is another joint effort by the NYCT, contractors, installers, the contractor's quality engineer, and the designer's field engineers to ensure that the scheduled work is ready to be performed according to a risk assessment; the availability of materials, workers, and equipment on the site; the condition of the work site; and sample work already completed (where applicable).

C. Kick-off Meeting/Summary of Preparation Phase

The kick-off meeting brings together all members of the team to discuss preparatory phase findings, points out concern, and reach agreement on the process of upcoming work. Attendees from NYCT usually included the field engineer, resident engineer, representative from the user group, project QA personnel, project safety personnel, and specialized consultant. The contractor is usually represented by the installer (superintendent and foreman), quality assurance engineer, safety engineer, and project manager. Agenda items at the meeting include discussion of the work

approach, action plan, requirements, anticipated difficulties, and a contingency plan.

D. Leadership

The highest ranking NYCT project executive, usually the program manager, personally discusses with the field engineers and contractors the importance of preparations to construction, periodically attending preparatory phase meetings to reinforce the message.

The results from the enhanced preparatory phase of the quality program identified during the 63rd. Street Connection project included:

- Better relationships between contract parties;
- Contractors (who were initially reluctant to participate) became more active participants;
- Preparatory phase inspections and consequent revisions to the work plan assisted the contractors in meeting budget and schedule targets;
- The original design was improved from consultant and contractor input;
- NYCT was able to provide better support to contractors and field staff;
- A baseline agreement was established that provided guidance when discrepancies arose; and most importantly,
- The vast majority of the work was performed correctly, minimizing punchlist items, rework, and the turnover time of the project.

Lesson 2. Measure Contractor Compliance

A second key lesson learned during the 63rd Street Connection project involved the contractor performance rating system that measured contractor compliance and became a driving force for improvement.

In the very beginning of the project, the NYCT evaluated all six, project contractors on the implementation of their quality programs on a quarterly basis. The outcome of the original process was a qualitative attribute rating (i.e., satisfactory, needs improvement, and unsatisfactory) that did not satisfy the NYCT, contractors, or oversight agencies. As a result and in partnership with the contractors, the NYCT developed a more objective numeric ratings criteria and evaluation process of contractor performance. The process was consistently implemented every quarter and for each contractor until project close-out. The goals were to "create a performance evaluation system to ensure consistent ratings for satisfactory performance, recognize success and outstanding results with uniformity for all six contractors." The steps involved in the new rating system are listed below.

- Ten basic "elements" of the contractor's quality program evaluated:
 1. Quality organization
 2. Submittal management and document control

3. Receiving, handling and storage of materials and equipment
 4. Subcontractor and supplier control
 5. Inspection and test program
 6. Control of construction processes
 7. Control of measuring and testing equipment
 8. Control of nonconforming conditions
 9. Internal audits
 10. Documentation by quality records.
- Quarterly evaluations were performed on five of the ten elements as identified by NYCT and each contractor, including two key elements that were evaluated every quarter "control of nonconforming conditions" and "inspection and test program." All ten elements were evaluated at least once per year.
 - Under the new system, each quality program element was evaluated for the approach or planning, deployment or implementation, and results or effectiveness. Therefore, a successful element is evident from a combination of planning, implementation, and demonstrated results.
- In scoring an element, several "checkpoints" were verified and evaluated. These checkpoints can be documentation or construction activities, depending on the element or nature of the work observed. The checkpoints are rated up to 30 points for being complete (planned), up to 40 points for being current and correct (implemented as planned), and up to 30 points for achieving the desired results. The ratings are tabulated directly on the checkpoint forms along with comments and an average score is calculated for each element.
- An overall contractor rating for the quarter is simply the average of the five individual element scores for the quarter. The contractor's performance is considered "satisfactory" if the final rating is greater than 75 points, "needs improvement" if between 50 and 75 points, and "unsatisfactory" if less than 50 points.
 - The contractor is allowed to review and comment on the preliminary ratings during a 48- hour grace period. The construction manager approves the final ratings.

As a result of this document review and compliance process, the NYCT saw steady progress from the contractors in achieving quality program requirements. Outstanding contractors were also recognized from the ratings process. In sum, the majority of the work for the project was done right and with minimal rework. The results justify the application of this process to other projects and contracts.

Lesson 3. Utilize just-in-time training when possible.

Training was once viewed as taking time away from "real work" and a "costly overhead expense." However, the experience of NYCT in the 63rd Street Connection project has proven that proper and timely training can provide large returns by

eliminating direct charges for rework and mistakes, and providing a safer and more productive work environment.

The challenges faced by NYCT that prompted the creation of a specific project training program, known as New Routes, included:

The NYCT program staff that managed the project ranged from veterans and experts to college interns or others with no experience in the construction methods proposed.

Standard construction hazards were exacerbated on this project by continuous subway operations, stability issues of surrounding buildings, and highway settlement.

While conscious of project and contractor budget constraints, quality and an effective interface of the program team to many disciplines and contractors were critical concerns.

The objectives of the New Routes training program were to focus on near future work activities to provide "just-in-time" training, improve the field engineering skills, increase quality and safety awareness, and help with self-improvement and team building. Therefore, the scope of the training program included technical engineering disciplines, specific work element installation processes, field engineering, construction management, project management, QA/QC procedures, general and project specific safety, and team building. The instructors came from a variety of backgrounds, both inside and outside the project, as dictated by the training needs.

They included outside experts, project managers, project team members with specialized knowledge, contractors, consultants, and FTA and MTA oversight consultants. The training was organized more like workshops rather than lectures. In fact, a number of sessions were conducted in the field to demonstrate tasks such as waterproofing, rail weld grinding, jet grouting, and concrete placement. Other training sessions were held in the project offices.

The training participants included NYCT field and office personnel on the project, user/maintenance groups, QA, safety, contractors, consultants, and project management oversight consultants. The twice-a-week training sessions were scheduled in advance, and usually fell on the same time and day of the week or at night to encourage participation from the night shift of this 24-hour operation. A training database was developed using Microsoft Access to record the training completed by each participant. This tool allowed the project to maintain an inventory of skills and disciplines and further identify the needs.

Part of the success of the training program was due to its constant emphasis by the project leadership. Although the quality representative within the program group administered the training program, the project manager did follow up on training status and attendance, and was one of the most enthusiastic participants of the sessions. Training needs and results were discussed at biweekly staff meetings and monthly quality update meetings. A training summary, including future schedules and reports, was issued monthly. Each course had a written outline and other handout materials that became a part of the technical library. The sessions were also evaluated by the participants who provided feedback to the instructors.

The results of the New Routes training program are characterized by the NYCT as a

general increase in the level of professional and technical skills. About 120 sessions were held from 1995 to 1999 that included topics such as scheduling, specifications, concrete, signal design, steel installation, general orders, waterproofing, blasting, ISO 9000 quality standards, and utilities with over 1800 participants attending. The training ensured that project safety indicators exceeded industry standards, that the proper material was installed, and that proper procedures were followed. For instance, a session on the rail weld grinding process and inspection criteria was given after mistakes and defects prompted the stop of all work on this task. After the training, no additional defects were detected. Specialized outside knowledge also enhanced productivity and reduced mistakes. For example, the NYCT inspectors received training on two complicated construction procedures, jet grouting and slurry walls.

Finally, the NYCT also believes that training improved morale and strengthened relationships between the people who performed the work and those who provide oversight. In the end, the majority of the project work was completed correctly with little to no rework and the NYCT has recommended the training program on future projects.

Quality Case Study #8

Washington Metropolitan Area Transit Authority Metrorail Project

Delivery Methods:	Design-Bid-Build
Program Description:	The 103-mile Adopted Regional Metrorail System in Metropolitan Washington was completed in January 2001 after a 32-year construction effort by the Washington Metropolitan Area Transit Authority (WMATA). The engineering and construction of this heavy rail transit system is considered one of the largest single public works projects of its type in the United States. During the first phase of the system's construction (89.5 miles), construction duration of a "typical" station and a line section from the start of excavation to systems testing and start-up was 50 and 60 months, respectively. For the second phase of the construction program (13.5 miles), construction duration of a "typical" station and a line section from the start of the excavation to systems testing and start-up was 45 and 50 months, respectively. The second phase fast-track construction program included the following projects completed from June 1997 to January 2001: • Blue Line from Van Dorn Street to Franconia-Springfield: \$74.7 million • Red Line from Wheaton to Glenmont: \$52 million • Green Line from U St-Cardozo to Fort Totten: \$7.1 million • Green Line extension from Anacostia to Branch Ave: \$145.4 million Presently, two design-build contracts are being considered for a Blue Line Extension to Largo scheduled for completion within 42 months, for both track (3.1 miles) and 2 stations with parking, respectively.
Total Program Costs:	\$9.4 billion (cost of first and second phases of Metrorail, not adjusted for inflation)
Lessons Learned:	
WMATA's Construction Contract Quality Assurance Program: WMATA required a Contractor Quality Control System (CQCS) in major civil construction contracts (in excess of \$10 million), from the mid 1980's through 2001. The construction contracts included minimum requirements for the CQCS and instructed contractors to describe the CQCS in a Quality Plan that was to be submitted and approved by WMATA prior	

to the start of work. Upon approval, WMATA's Resident Engineer and QA/QC staff monitored the implementation and effectiveness of the CQCS through field observations, inspections and audits.

Lesson 1. Review results after implementing a new quality initiative or program.

The success of the CQCS program varied depending upon the attitude of the contractor's job site personnel towards the CQCS program and the willingness of the contractor personnel to work as a team. Many contractors believed that the CQCS added little value to contractor operations. QA/QC staff was viewed as a contract requirement as opposed to an essential part of the project staff. In those instances where the CQCS program was successful, the CQCS staff performed as an integral part of the Contractor's job site team and was fully involved in the planning and execution of the work.

WMATA attempted to motivate Contractors to have a more positive attitude towards the CQCS program by introducing a Quality Awareness Program. The program included payments to the contractor for implementing an effective CQCS. The value of the program equaled 1% of the bid items and was included in the total bid price. Programmatic payments were made monthly if the CQCS was effective. Payments withheld because of an ineffective CQCS were forfeited and the value of the contract was reduced accordingly.

The contract included specific conditions that had to be met in order for a programmatic payment to be made. The conditions were mandatory and not up to the discretion of the Resident Engineer. Programmatic payments were not paid in those months according to the following conditions:

- Payment was denied for a portion of the work that was determined to be deficient and non-compliant.
- The Engineer had determined that the contractor had installed unapproved or unsatisfactory material, components, or equipment.
- The Engineer had notified the contractor of deviations from the contract requirements for work in progress that resulted in the stoppage of the production of the work activity.
- The Engineer had written one or more stop work orders because work in progress was not in compliance with the contract requirements.
- The Engineer has provided more than three written notices, for work performed within the payment period, to initiate corrective action on construction work, procedures, or operations that do not meet the contract requirements.
- The Contracting Officer had determined that one or more of the Engineer's written corrective action or deviation notices demonstrate the severity, repetitive nature, or criticality of circumstances that the CQCS staff and/or procedures were not effectively controlling the quality of construction.
- The CQCS had been without the service of the approved full-time CQCS Manager and/or staff except where absences were for bona fide emergencies and the Contractor took appropriate steps, in the Engineer's judgment, to

continue effective control of the quality.

WMATA anticipated that the program would motivate contractors possessing a marginal or ineffective CQCS to raise performance to an acceptable level. The program was introduced as a trial on a single contract in 1990. The contractor had previously performed work for WMATA and was familiar with the CQCS requirements. The contractor initially proposed a CQCS Manager who was unacceptable to WMATA. However, the second proposed candidate was found to be acceptable and was approved. The CQCS Manager proved to be an effective member of the project team and was recognized by the contractor as an asset to the project organization. An effective CQCS was implemented and the full programmatic payment was made. The program did appear to motivate the contractor to have an effective CQCS although the trial itself was not conclusive.

The program was included in some subsequent contracts. Multiple programmatic payments were withheld on two separate contracts with little or no improvement in CQCS effectiveness. One of the two contractors who had programmatic payments withheld had also been awarded a

Quality Case Study #9

Charlotte Area Transit System Blue Line Extension (BLE) Project

Delivery Methods:	Design-Build, Systems Integration Testing, Risk Assessment Process
Program Description:	This is the OP26 Lessons Learned Report for the CATS Blue Line Extension (BLE) Project. Over the duration of the oversight period the PMOC identified and developed twenty-seven (27) mini-lessons learned. The lessons learned were identified by phase (i.e. construction), category (i.e. third-party agreements) and subject. The PMOC shared these lessons learned with the FTA and CATS during monthly and quarterly meetings and kept a register of the mini lessons learned as part of monthly and quarterly reports. The PMOC also held two workshops over the course of the Project to discuss, review and evaluate the lessons learned developed both by the PMOC and a separate lesson learned register developed by CATS. The CATS lessons learned register includes approximately 100 lessons learned. The PMOC mini-lessons learned and the CATS lessons learned registers are separate documents. As a result of review of the lessons learned registers, discussions internally amongst the PMOC, CATS and the FTA regarding the most recurring and impactful lessons learned, and with consideration of identifying lessons learned that serve as a benefit, the PMOC proposed the following two Project Lessons learned: Planning and Organization for Systems Integration Testing (SIT) The CATS BLE Risk Assessment and Process The Planning and Organizing for Systems Integration Testing Lesson Learned addresses the various causes for delays in starting and completing systems integration testing which were largely due to lack of advance planning to develop the plan and qualified resources to prepare the plan. The Risk Assessment Process Lesson Learned addresses the BLE Risk Assessment Process and the benefits how conducting a comprehensive systematic scope, schedule, cost and risk review resulted in identifying additional risks, establishing the Full Funding Grant Agreement (FFGA) date 12 months beyond the CATS RSD, and recommending identification and phased implementation of secondary mitigations should they become necessary. The results of the

	process also included developing a mitigation and monitoring plan for the Project. The extension of the FFGA date by one was proved to be necessary. It is the PMOC's opinion that these two Lessons Learned for this Project will benefit the transit industry and FTA for future federally assisted projects and particularly for new Project Sponsors.
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Lessons Learned:

Lessons Learned No. 1: Planning and Organization for Systems Integration Testing (SIT)

Date: September 2018

Project Name: CATS Blue Line Extension Project

Abstract: *Systems Integration Testing (SIT) on the CATS BLE Project encountered issues as the Project moved from completion of the Construction Phase to system testing and pre-revenue operations.*

Project Phase: Construction through Start-up

Category: Project Management and Scheduling

Background:

The CATS BLE Project (the Project) extends the existing Blue Line approximately 9.3 miles from Uptown Charlotte (Central Business District) to the University of North Carolina Charlotte (UNCC) campus. The Project includes eleven (11) light rail stations, with approximately 3,200 parking spaces at four (4) stations with parking facilities. The Project also includes twenty-two (22) new Light Rail Vehicles (LRVs), a storage yard and support facility, and improvements to the existing Vehicle Maintenance Facility to support the additional fleet.

There was a total of twelve (12) major Consultant and Construction Contracts awarded throughout the phases of the Project from Project Development through Revenue Service. The summary of the type of Contracts are shown below:

- Design Consultant
- Construction Management Consultant
- Vehicle Consultant
- Two (2) Civil Construction Contractors
- North Yard Facility
- South Boulevard Light Rail Facility Upfits
- Station Finishes Contractor
- Three (3) Parking Garage Contractors

- Track and Systems Contractor
- Fare Collection Contractor
- Vehicle Manufacturer

The Track and Systems Contractor was responsible for the design, manufacture, installation and testing of the track and systems elements for the entire Project. The Contractor had a number of subcontractors responsible for the various elements, including: track, train control (signals) traction power, communications, and the Rail Operations Control Center.

To ensure that all the system elements provided by the Track and Systems Contractor and their subcontractors functioned safely and in accordance with design requirements, Systems Integration Testing (SIT) was critical.

The Lesson:

Condition, Cause and Effect

One of the most significant issues regarding SIT was the development of the SIT Plan. There were two (2) separate SIT Plans developed for the BLE Project. One (1) of the SIT Plans was developed by the Track and Systems Contractor¹ and the other was developed by the Construction Management Consultant. Both SIT Plans went through a significant number of iterations before they were finally approved which ultimately impacted the start of SIT. There were instances where some of the SITs were conducted while the SIT Plan was still unapproved.

With two (2) separate organizations generating two (2) separate documents, there were two (2) different organization charts developed with overlaps in responsibilities claimed and confusion regarding whom owned responsibility for specific tests. Neither SIT Plan acknowledged that the Grantee was ultimately in charge.

Another concern was that the SIT Plan was developed and executed by the Contractor. The organization of the tests was initially confusing in that the tests were organized into “Levels”, “Types”, “Breakout Points”, “System Elements” and “Geographic Areas”.

Due to delays in the completion of systems element installation and Stand-Alone Testing, and to try to make up lost time, the SITs were conducted at times in a sporadic manner – performing tests whenever and wherever possible. Complete “end-to-end” testing from the field locations through to the Control Center resulted in delays due to some of the signal houses being delayed in their design and installation.

¹ The SIT Plan was actually developed by a subcontractor to the Track and Systems Contractor.

Remedy, Solution

There are several proposed remedies and solutions related to the SIT Plan from the BLE Project:

- Complete the SIT Plan at least one year in advance of the construction completion date. This will allow a viable SIT schedule to be developed.
- Develop one comprehensive SIT Plan for the Project to direct contractor testing. This will result in better coordination and adjustment of testing activities and more clarity as to responsibilities.
- Develop a detailed schedule for all SIT that are included in the SIT Plan and incorporate it in the overall Project Schedule early enough so time is provided to conduct the testing in a logical, systematic and straightforward manner.
- Develop a detailed organization chart for the testing process that include the grantee, consultants and contractors and clearly outline roles and responsibilities.
- Verify qualified people are involved in the development and writing of the SIT Plan including experience in testing traction power, signaling, communications and Supervisory Control and Data Acquisition Systems and the integration of these systems and developing test objectives, plans and step by step procedures and resources needed.
- In the specifications for the contractor and consultants, define the overall responsibilities and goals of all parties involved (i.e., grantee, consultants, contractors). This will allow for better coordination of activities and clarity in directing contractor progress.
- In the specifications, define the requirements in detail for timing of submittals and consequences if they are not timely submitted. This will allow for a more effective means of ensuring that the contractor will be able to maintain a schedule or accrue penalties.
- Due to quantity of tests, and that many of them are required to be conducted in numerous locations along the alignment, a matrix should be developed to track the status of all testing. This will allow for a comprehensive method of tracking the overall progress so that no tests are inadvertently omitted.

Applicability:

The lessons are applicable to Project Sponsors with rail projects that require Systems Integration Test Plans and especially with integration into an existing rail system.

Lessons Learned No. 2: BLE Risk Assessment Process

Date: October 2018

Project Name: CATS Blue Line Extension Project

Abstract: *An effective Risk Assessment Workshop resulted in effective cost and schedule controls to achieve the FFGA revenue service date (RSD).*

Project Phase: Engineering, Procurement, Construction, Startup Phases

Category: Management, Scope, Schedule, Cost, Risk

Background:

The CATS BLE Project (the Project) extends the existing Blue Line approximately 9.3 miles from Uptown Charlotte (Central Business District) to the University of North Carolina Charlotte (UNCC) campus. The Project includes eleven (11) light rail stations, with approximately 3,200 parking spaces at four (4) stations with parking facilities. The Project also includes twenty-two (22) new Light Rail Vehicles (LRVs), a storage yard, support facility, and improvements to the existing Vehicle Maintenance Facility to support the additional fleet.

The Lesson:

Condition, Cause and Effect

Leading up to the Risk Assessment Process a Scope, Schedule and Cost review was performed which is briefly addressed below:

Scope: The Project Scope was evaluated by standard cost category (SCC) and sub-SCC elements. The review included the evaluation of the potential schedule and cost increase attributes associated with elements of the Project scope for all relevant phases of the Project. The Project scope was further evaluated for constructability issues, stakeholder impacts, project compliance requirements and market forces that could affect schedule and cost. Example scope issues identified included:

- High fills damaging culverts needing to be replaced or upgraded
- Laydown areas for continuous welded rail
- Greater likelihood of more hazardous material removal due to large amounts of excavations.
- Lack of design detail for Grade crossings

Schedule: The Project Schedule review included a summary and characterization of the level of detail in the schedule, activity durations compared to industry, schedule assumptions for right of way acquisition and utility relocation and stakeholder influences. Example schedule issues identified included consideration of additional time for the following activities or schedule elements:

- Fabrication of special steel girders

- Special testing and removal of Hazardous materials
- Separate testing of the Signaling Systems and interlockings
- Additional float time for Stand-alone and Systems Integration testing

Cost: The Project Cost Reviews included a summary and characterization of the level of detail of the cost estimate, evaluations comparisons of historical bid prices, evaluation of construction cost activity and overhead and management related costs and inflations rates. Example cost issues included consideration of additional cost for the following items or cost elements:

- Special fabrication of steel girders not considered
- Testing and removal of hazardous material
- Discrete level testing of Systems Equipment commensurate with the design detail
- Carrying forward all discrete Systems cost to the build main and identifying communications and central control room discrete costs under the correct Sub SCCs

Risk: The Risk Review included a review and update of the risk register, a cost risk review and evaluation, schedule modeling activity, and development of risk and contingency management, mitigation and monitoring plans.

Cost risk review and evaluation included adjusting the baseline cost by adding the additional PMOC cost recommendations. The baseline cost estimate was then modeled to develop a minimum, likely and maximum costs.

As a result of this process the PMOC recommended a final project cost range between \$1,099 million and \$1,239 million and determined that the \$1,160 million dollar budget should provide adequate contingency against risks. The PMOC also recommend CATS identify \$25 million in secondary mitigations and phased implementation of the mitigations should they become necessary.

The Schedule Risk Modeling activity included adjusting the schedule baseline based on the PMOC schedule recommendations and establishing probable durations for schedule activity using 10% below the baseline schedule as a minimum duration and 25% above the baseline schedule as a maximum duration. Schedule simulations were run with substituting a range of optimistic, mostly likely and pessimistic durations using 1000 iterations. The results of this process generated finish dates based on 50%, 80%, 85% and 100% probabilities of meeting the RSD date with the 100% probability being 12 months past the CATS RSD.

As a result of the schedule risk modeling activity the PMOC recommended a schedule contingency of twelve (12) months. Based on the risk assessment and several rounds of discussions among the FTA, CATS and the PMOC, it was agreed to establish the FFGA RSD as twelve (12) months beyond the CATS RSD.

A risk mitigation and monitoring plan was developed out of this process. The plan included development, completion and updates of plans, studies and reports during the final design stage. The plan also included identification of top 10 risks, monitoring of schedule and cost contingency usage and secondary cost mitigations to correspond with milestones.

Remedy, Solution

Holding a comprehensive and systematic Risk Assessment Process helps to uncover additional Project risks, better determine the weight of risks and uncover additional project cost and schedule activities. The process can also uncover reductions for the same. The results of this process also help to establish more effective mitigation and monitoring plans tailored for the Project. The implementation of these plans helped to achieve the FFGA RSD before the established date.

Applicability:

The lesson is applicable to Project Sponsors engaging in a major FTA New Starts Projects involving multiple Construction Contractors requiring to interface with each other.

Appendix A: List of Acronyms

BLE	Blue Line Extension
BY	Base Year
CATS	Charlotte Area Transit System
City	The City of Charlotte
FFGA	Full Funding Grant Agreement
FTA	Federal Transit Administration
LRV	Light Rail Vehicle
OP	Oversight Procedure
PMO	Project Management Oversight
PMOC	Project Management Oversight Contractor
Project	CATS BLE Project
RSD	Revenue Service Date
SCC	Standard Cost Category
SIT	Systems Integration Testing
TO	Task Order
UNCC	University of North Carolina Charlotte
WO	Work Order
YOE	Year of Expenditure

Quality Case Study #10

Regional Transportation District of Denver FasTracks Plan

Delivery Methods:

CM/GC, Design-Build, DBFOM

Program Description:

The *FasTracks Plan* consists of nine rail lines (new or extended), two Bus Rapid Transit (BRT) lines, redevelopment of Denver Union Station, a new Commuter Rail Maintenance Facility, and an expanded light rail maintenance facility. The Plan adds approximately 64 miles of commuter rail (East Rail, Gold Line, North Metro Rail, and Northwest Rail – Phase 1 and 2); approximately 28 miles of light rail (Southeast Rail and Southwest Rail Line Extensions, Central Rail Line Extension, I-225, and West Rail Line); Park-n-Ride improvements and/or relocations at existing Park-n-Ride lots along US 36 (US 36 BRT – Phase 1), and up to 80 miles of BRT (US 36 BRT – Phase 2 and Northwest Corridor BRT).

Lessons Learned:

Chapter 5.

Overview

On RTD's larger capital projects that are delivered through a best-value procurement (CM/GC, Design-Build, DBFOM), RTD places full responsibility for Quality Assurance (QA) of the work on the Contractor. This includes managing all required materials testing in accordance with the construction specifications. However, as a quality oversight activity, RTD employs a verification testing program to validate the results of contractor managed acceptance testing.

Lesson 1: Limit variation

If a discrepancy occurs between the Owners Verification Testing (OVT) technician's results and those of the Contractor's QA technician, an investigation of the following sources of variation should be done:

- Is the equipment of the same make and model, precision, and calibration frequency?
- Are the calibrations traceable to a national standard?
- Are the calibrations current, and completed by qualified personnel?
- Are there inherent and repeatable differences between OVT equipment and QA equipment that can be addressed through a correction factor?

- Are there differences in the way OVT and QA conduct a procedure (i.e., different types of molds, different curing procedures, different proctors, different rock corrections, etc.)?

Limiting these sources of variation should result in reproducible results that add value to the testing program.

Lesson 2: Employ a split-sampling approach

Another way to limit variation is to test the same materials, in the same location, at the same time. This can be done through an approach known as split-sampling, whereby the OVT and QA technicians test the same sample of materials independently, and compare the results. RTD utilizes a table of pre-set tolerances for split-test results that are derived from the Colorado Department of Transportation's Field Materials Manual. The goal of OVT testing under this regime is not to determine if the material passes or fails, but rather to validate the results obtained through QA acceptance testing, within the established tolerances, regardless of whether the material passes or fails. The QA results determine if the material is conforming.

Lesson 3: Supplement split testing with process audits

While split-testing provides for direct comparisons of actual test results, a robust program of process audits should be used to supplement the split-testing protocol. In addition to auditing the field-testing process against the governing standard, the audit scope can include equipment calibrations, personnel credentials, laboratory accreditation, and laboratory procedures. Resolving noncompliances in any of these areas could be a preventive measure against nonconforming work.

Lesson 4: Utilize a common database

RTD utilizes a common database for all materials test results, which is accessible via the internet to all firms conducting materials testing on RTD projects. Within the database, failed tests can be linked to retests, QA tests can be linked to the corresponding OVT split-tests, and trend analysis can be conducted by project, time period, test type, etc.

Lesson 5: Conduct root cause analysis for systemic problems

In 2014, RTD experienced a series of failing concrete strength results. This occurred across projects, and with multiple mix designs. RTD's OVT team was able to work with the different contract QA teams, and concrete suppliers to identify a root cause: inconsistent fly ash supply. A Corrective Action Plan was implemented to address this and other contributing factors, leading to improved concrete quality.