

California High-Speed Rail Program



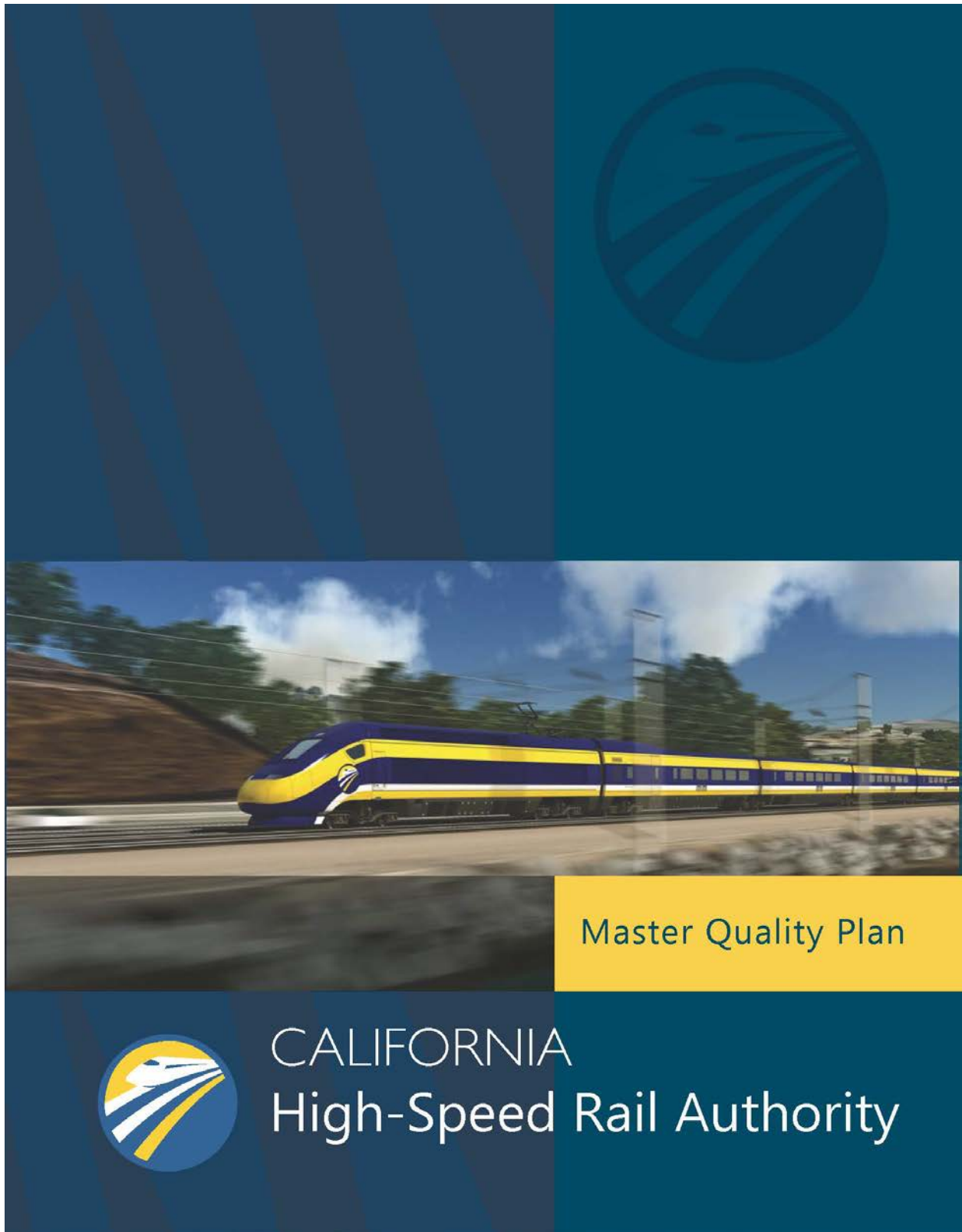
RFP No.: HSR 13-57

Request for Proposal for Design-Build Services for Construction Package 2-3

Book IV, Part D.2 – Master Quality Plan

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California High Speed Rail Program



Master Quality Plan

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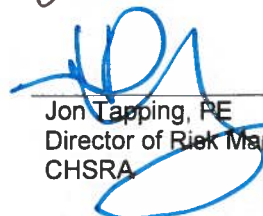
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Quality Policy

The Authority serves the public by delivering the California High-Speed Rail Program with a quality and safety that meets or exceeds acceptable industry and government standards, on schedule, and at the lowest possible cost. The Authority follows internationally accepted standards for quality on every phase of the Program, starting at project planning, preliminary and final engineering, system construction, equipment procurement and testing, and culminating in revenue service.

The California High Speed Rail Authority and its partners are implementing a Quality Program with the following requirements:

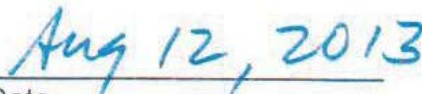
- ANSI/ISO/ASQ Q9001:2008 Quality Management Systems
- U.S. Department of Transportation, Federal Transit Administration, *Quality Management System Guidelines*, December 2012, and
- CHSR Project and Construction Management Guidelines.

To assure the Quality Management Systems (QMS) remain effective and current throughout the Program, the Authority is committing to a program wide implementation, monitoring, review and improvement process as the CHSR Program grows and moves forward.

The commitment to quality, as stated in this Quality Policy Statement, is the basis for the Program's QMS. All managers, supervisors, and employees participating in the CHSR are urged to participate and establish quality objectives in their areas of responsibilities. These will help shape effective quality procedures and plans that then can then be communicated and implemented within the CHSR program.



Chief Executive Officer
Jeff Morales
California High Speed Rail Authority



Date

Acronyms

Acronym	Acronym Definition
AAR	Association of American Railroads
AASHTO	American Association of State Highway and Transportation Officials
ACI	American Concrete Institute
AISC	American Institute of Steel Construction
AREMA	American Railway Engineering and Maintenance-of-Way Association
ASQ	American Society for Quality
ASTM	American Society of Testing and Materials
ANSI	American National Standards Institute
AWS	American Welding Society
CADD	Computer Aided Drafting and Design
CAR	Corrective Action Request
Caltrans	California Department of Transportation
CHSR	California High Speed Rail
CHSRA	California High Speed Rail Authority (aka Authority)
CHSRP	California High Speed Rail Program
DBB	Design Bid Build
DB	Design Build
FHWA	Federal Highway Administration
FRA	Federal Railroad Administration

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Acronym	Acronym Definition
FTA	Federal Transit Administration
IEEE	Institute of Electrical and Electronic Engineers
IGA	Intergovernmental Agreement
ILA	Interlocal Agreement
IOS	Initial Operating Segment
ISO	International Organization for Standardization
MIS	Major Investment Study
MQP	Master Quality Plan
MOU	Memorandum of Understanding
NEPA	National Environmental Policy Act
PCI	Precast/Prestressed Concrete Institute
PCM	Project and Construction Management
PMO	Project Management Oversight
PMP	Project Management Plan, Program Management Plan
PMT	Program Management Team
QAM	Quality Assurance Manager
QMP	Quality Management Plan
QMS	Quality Management System
RC	Regional Consultants
RFP	Request for Proposal
ROW	Right of Way
TM	Technical Memorandum

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Acronym	Acronym Definition
U.S. DOT	United States Department of Transportation
WBS	Work Breakdown Structure

Definitions

As-Built - Documented data or drawings that describe the final product.

Contractor - A generic term used within this document to refer to planning and design consultants, construction contractors, material suppliers, and design-builders that deliver works to CHSRA.

Constructability Review - An analysis to confirm that a product can be properly constructed or installed.

Due Diligence - The effective demonstration to others that the expected level of care and attention has been applied.

Functional Elements - Groups within the CHSRA that have a common purpose. Functional elements are the higher level groupings within the Authority organizational chart. See Figure 2.2.2.

Major Capital Projects - A project that involves the construction of a new fixed guideway or extension of an existing guideway; the rehabilitation or modernization of an existing fixed guideway with a total project cost in excess of \$100 million; or the Administrator determining that the project management oversight program for the project will benefit, specifically the agency or the recipient.

Master Quality Plan - The main document used in concert with the CHSRA Program Management Plan for developing and implementing the QMS. The Quality Plan contains the Quality Policy, Quality Objectives, and outlines the framework and processes for the program functional elements to develop their own Quality Procedures.

Non-conformance/Noncompliance - Non-fulfillment of a requirement. NOTE: these terms are used interchangeably within this document.

Non-Technical Contract Requirements – Contract Requirements that do not meet the criteria of Technical Contract Requirements, such as Project Management, Commercial, Legal or other Contract Requirements.

Program Management Plan – A document that summarizes the management approach, structure and processes used by the CHSRA to deliver the Program.

Quality Assurance - QA emphasizes actions at a management level that directly improve the chances that QC actions 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 Control - Techniques that are used to assure that a product or service meets requirements and that the work meets the product or service goals. QC is the act of taking measurements, testing, and inspecting a process or product to assure that it meets specification. 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 Elements - Elements used as a good management practice to ensure quality of design, manufacturing, and construction services, as well as other transit agency functions such as operations and maintenance. Quality elements are developed based on the ANSI/ISO/ASQ Q9001:2008.

Quality Management - The application of the quality management system in managing a process to achieve maximum customer satisfaction at the lowest overall cost to the public while continuing to improve the process.

Quality Management System - A formalized system that documents the structure, responsibilities, and procedures required to achieve effective quality management.

Quality Management Oversight - General supervision performed by the CHSRA. Quality Management Oversight verifies the execution of the Quality Program.

Quality Objectives - Objectives or goals, related to quality. Objectives should be measurable and consistent with the Quality Policy.

Quality Policy - The overall quality intentions and direction of the CHSRA with regard to quality. The Quality Policy provides a framework for establishing quality with the entire program.

Quality Procedures - Written instructions for implementing various elements of the QMS. Procedures identify what is to be done; who should do it; and when it should be done.

Quality Program - The coordinated execution of applicable Quality Plans and activities for a project.

Self-Certification - Certification by the Contractor that the contract submittals conform to Contract Requirements and as reasonably inferred therefrom.

Technical Contract Submittals - Contract submittals that address the technical contract requirements.

Technical Contract Requirements - Contract requirements specifying the characteristics of the final infrastructure deliverable, including related final design, construction, inspection, testing, and acceptance requirements.

Tier 1 Deliverables - Requirements with a defined deliverable due to an entity outside the CHSRA.

Tier 2 Deliverables - Specific deliverables identified in the procedures, quality procedures, and work instructions that remain internal to the CHSR program.

Validation - Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use have been fulfilled.

Verification - Confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled.

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1.1 Purpose

The purpose of this document is to develop and satisfy the requirement for a Master Quality Plan as set forth in the U.S. Department of Transportation, Federal Rail Administration, Grant/Cooperative Agreement¹.

1.2 Background

The quality management system, as described in the Quality Policy, is prepared for the California High-Speed Rail Authority (CHSRA) and follows the requirements of the U.S. Department of Transportation, Federal Rail Administration (FRA), Grant/Cooperative Agreement¹. The CHSRA is advancing the program under the American Recovery and Reinvestment Act, and therefore has entered into an agreement with the FRA to meet specific quality requirements and deliverables. FRA maintains oversight for the grants that it awards, but assigns the grant administration and management responsibilities to the CHSRA.

The job of project management is to manage scope, schedule, budget, safety, and quality. While delivering a project in accordance with a defined scope and a given budget and schedule, the Authority/Grantee requires an acceptable quality. While acceptable quality may have several

¹US Department of Transportation, Federal Rail Administration, Grant/Cooperative Agreement, Ad. 5 - FR-HSR-0009-10-01-05.

definitions, and stakeholders may have different expectations for quality, the necessary objective management structure is required, and an effective and objective quality management system needs to be developed.

1.3 Developing the Quality Management System

The CHSR quality management system establishes and documents the organizational structure, responsibilities, procedures, processes, and resources needed to meet the quality policy and objectives of the program while keeping the project on scope, on schedule, and on budget. This Master Quality Plan (MQP) serves as the main document used in developing and implementing the quality management system (QMS) for the CHSR. The MQP is developed hand-in-hand with the Program Management Plan (PMP).

The CHSRA is an evolving organization that will continue to progress the way it does business. The QMS will continually seek to improve the products and services being delivered by CHSR and the corresponding delivery processes used by the organization.² As such, the CHSR Master Quality Plan and the established QMS are living documents and should be revised to amend procedures for continual improvement of the CHSR program.

The Master Quality Plan and the overall QMS were developed based on ANSI/ISO/ASQ Q9001:2008 and the *Federal Transit Administration Quality Management System Guidelines* published in December of 2012. These two documents will be referenced in major capital projects³ for the CHSR program.

The quality management system consists of the Quality Policy, the Master Quality Plan (Parts 1 and 2), and the associated program and project Quality Management Plans, procedures, work instructions, and quality records. All of these documents and processes, collectively, make up the CHSR Quality Management System as illustrated in Figure 1.3.1.

² U.S. Department of Transportation, Federal Transit Administration, *Quality Management System Guidelines*, December 2012.

³ "Project Management Oversight." 49 CFR 633.5. 2013.

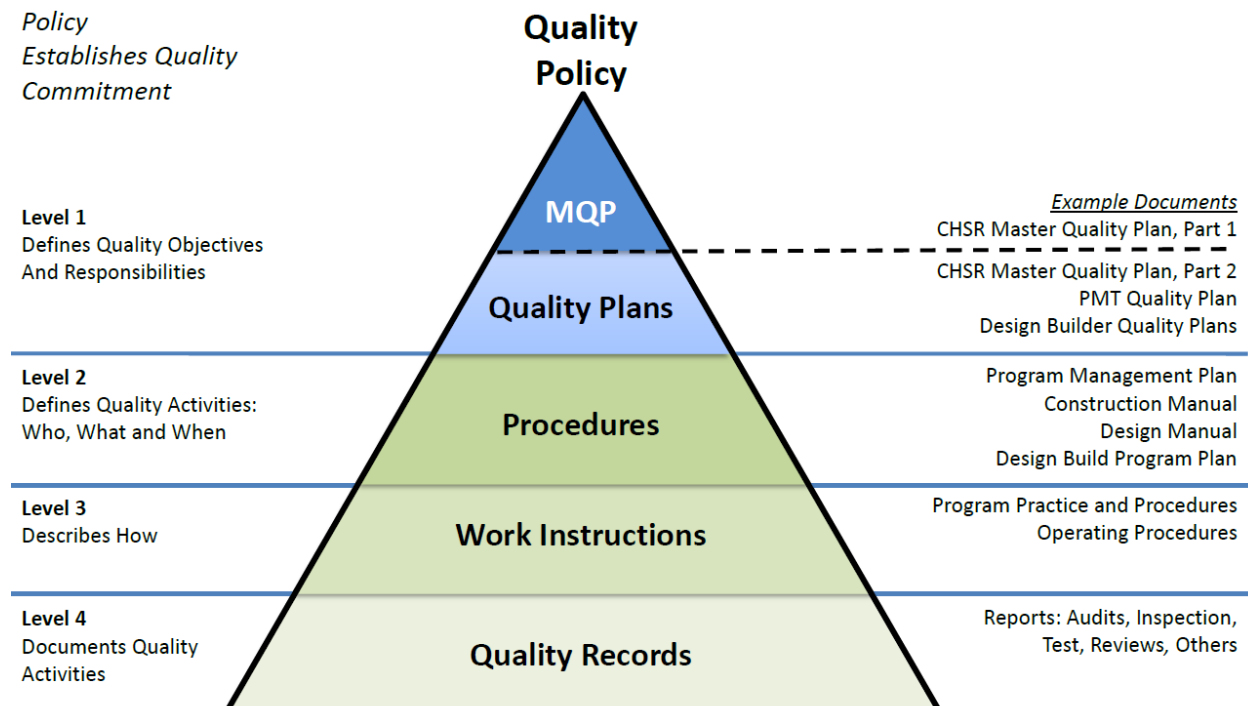


Figure 1.3.1: The QMS Pyramid illustrates the CHSR QMS which consists of all of the program and project quality management plans, procedures, work instructions, and quality records.

The QMS Pyramid in Figure 1.3.1 begins with the CHSR Quality Policy, which is documented in the Master Quality Plan, Part 1. The MQP also documents the Level 1 activities of the pyramid. It defines the CHSR Quality Objectives and Responsibilities and provides the framework for the functional elements within the Authority to develop their own quality objectives and quality related activities.

Level 2 of the QMS Pyramid begins with the procedures each of the functional elements will follow to meet the deliverables defined in the Grant / Cooperative Agreement. These procedures will also define Quality Objectives and Quality Related Activities for each of the functional elements. The Quality Objectives should be measureable, separate from operational activities, and consistent with the CHSR Quality Policy. These procedures should describe the quality activities, in terms of **who**, **what**, and **when** needed to ensure that the CHSR program meets the requirements specified in the Grant / Cooperative Agreements. Functional elements should utilize the framework and processes detailed in Chapter 3 of this manual to develop these quality activities.

The Level 3 activities of the QMS Pyramid include the work instructions developed by each of the functional elements to provide detailed, step-by-step guidelines for implementing the procedures and quality related activities established in Level 2. The CHSRA also utilizes these work instructions to develop Part 2 (to be developed) of the Master Quality Plan which outlines **how** the Authority verifies the execution of the CHSR Quality Program through Quality Oversight activities.

Finally, Level 4 of the QMS Pyramid includes the documentation of the quality activities of the functional elements as well as the Authority's Quality Oversight. The documentation requirements are also described in Part 2 (to be developed) of the MQP.

This Master Quality Plan (MQP) serves as the main document used in developing and implementing the QMS. The objectives of this Master Quality Plan are as follows:

- Provide the framework for the CHSRA to develop an effective quality management system
- Define the roles, responsibilities, organizational structures, and procedures needed to establish and implement the CHSR QMS
- Coordinate the execution and appraisal of the quality policies, plans, and procedures

1.4 Quality Goals & Objectives

1.4.1 Quality Goals

The Authority establishes the following Quality Goals:

- Improve planning and programming of the CHSR program
- Improve project design estimates
- Establish clear responsibilities and requirements to plan and execute deliverables in accordance with CHSRA goals and industry or government standards
- Secure all available federal funds
- Ensure that the system initiated into revenue service is safe and secure for passengers, employees, emergency response personnel, and the general public

1.4.2 Quality Objectives

The Authority establishes the following Quality Objectives:

- Contracts will be planned and executed efficiently to accomplish 100% on time delivery of CHSR projects.
- Total project delivery costs are within budget.
- Each functional element of the CHSR program will establish and implement written procedures describing how they will meet the deliverables established in the core grant agreement.
- All available federal funds are fully satisfied by delivering the program per the timelines specified in the FRA Grant / Cooperative Agreement.
- All entities shall promote safety by performing work for the CHSR program in conformance with the CHSR program Safety and Security Management Plan and their individual contract safety requirements.

1.5 Involvement

The CHSR QMS applies to the entire CHSR program. The requirements and objectives set by this MQP apply to all participants within the program including the Authority, PMT, PCM, DB team, and other contractors, consultants, suppliers, and subcontractors/subconsultants.

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2.1 Responsibilities

The Authority Chief Executive Officer (CEO) is responsible for the following:

1. Adopting the QMS and issuing the Quality Policy
2. Responsible for the work of the CHSRA Quality Manager, including providing guidance and direction on Quality Policy matters

The CHSRA Quality Manager (QM) is responsible for planning, implementing, evaluating, and maintaining an effective quality management system. The CHSRA Quality Manager's responsibilities include the following:

1. Developing and implementing the QMS
2. Reviewing and approving quality plans submitted by program participants
3. Reporting to the Authority Executive Officer for quality oversight and auditing of the program consultants and construction contractors

The CHSRA Program Management Team is responsible for the development of the CHSR program, implementation, monitoring, and progress reporting. The Program Management Team comprises of consultant staff together with CHSRA staff. This team has responsibility for the following quality requirements:

1. Establishing the Quality Policy and Quality Objectives for the program
2. Communicating to program stakeholders the importance of meeting quality requirements
3. Conducting management quality reviews and quality oversight
4. Providing the necessary resources to implement the QMS

2.2 Organization

The *CHSRA Program Management Plan* outlines the management approach, organizational structure, and processes used by the California High-Speed Rail Authority to deliver the California High-Speed Rail System. The organizational structure from the PMP of the Authority is illustrated below in Figure 2.2.1.

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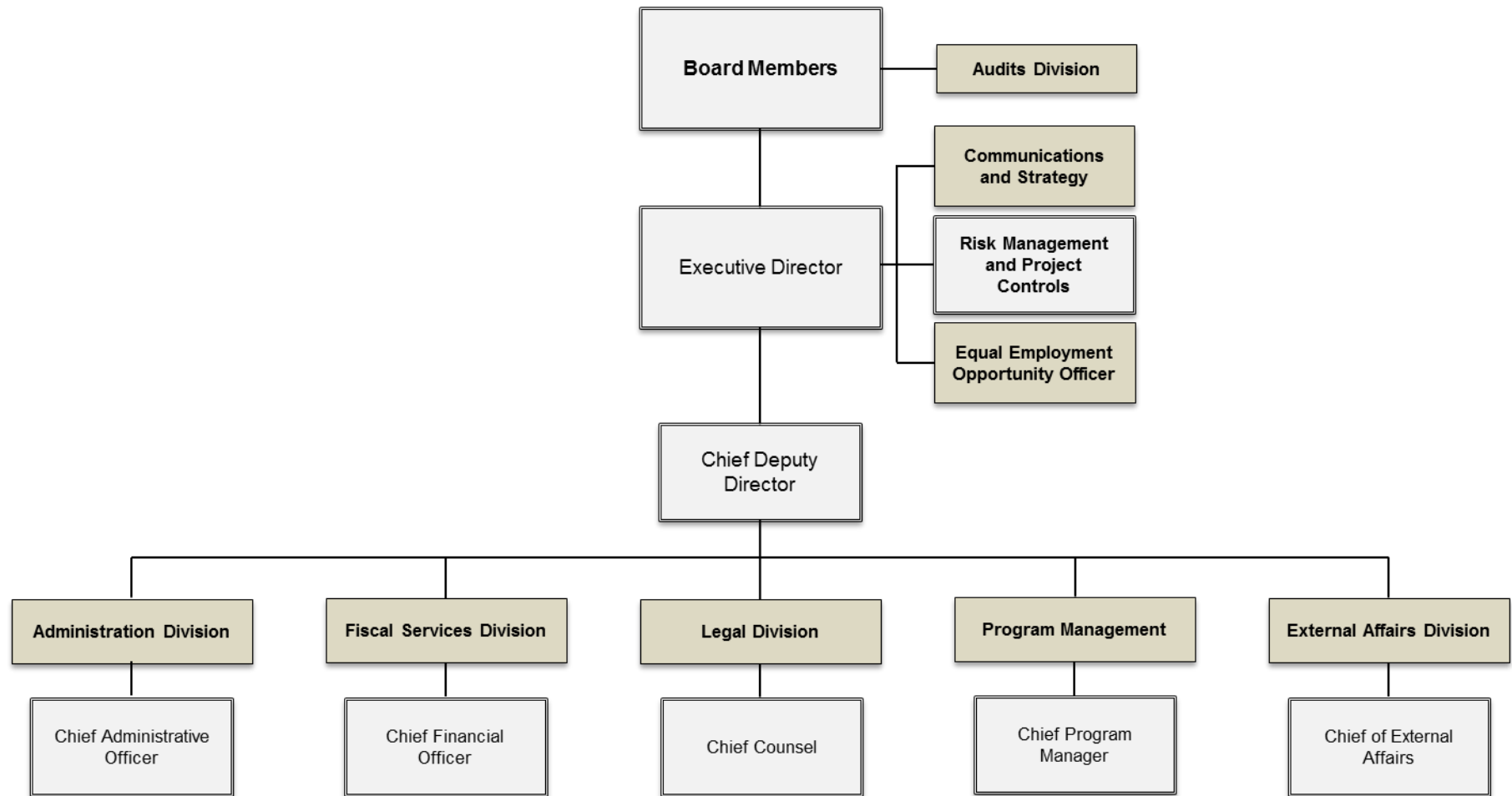


Figure 2.2.1: The CHSR Organizational Structure⁴

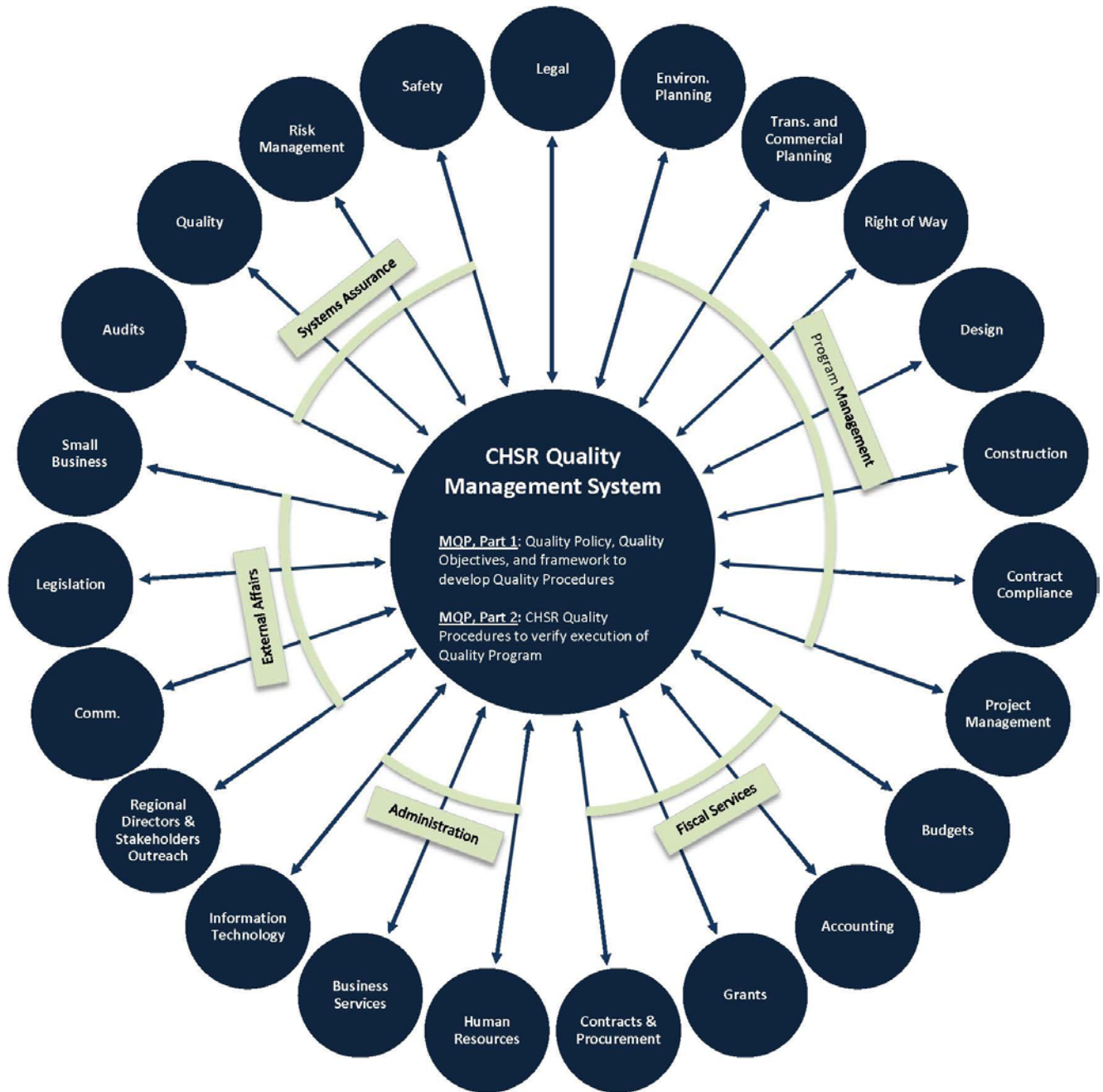
⁴ California High Speed Rail Authority Board Meeting, Item 4 Attachment, December 5, 2013.

The CHSRA organizational chart goes on to further organize the structure and processes of the Authority around the following functional elements:

1. Legal
2. Environmental Planning
3. Transportation and Commercial Planning
4. Right-of-Way
5. Design
6. Construction
7. Contract Compliance
8. Project Management
9. Budgets
10. Accounting
11. Grants
12. Contracts and Procurement
13. Human Relations
14. Business Services
15. Information Technology
16. Regional Directors and Stakeholders Outreach
17. Communications
18. Legislation
19. Small Business
20. Audits
21. Quality
22. Risk Management
23. Safety

Each of the individuals in charge of the above elements is responsible for developing procedures for the CHSRA to follow in order to meet the deliverables defined in the Grant / Cooperative Agreement(s).

As discussed in Chapter 1, the MQP serves as the main document used in developing and implementing the QMS for the CHSRP. Figure 2.2.2 provides an overview of how Part 1 and Part 2 (to be developed) coordinate the execution of the each functional element's quality procedures, work instructions, and documentation of quality records.



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Figure 2.2.2: “Starburst” Diagram - Part 1 and Part 2 of the CHSR Master Quality Plan coordinate the execution of each functional element’s quality procedures, work instructions, and documentation of quality records.

2.3 Implementation

The purpose of this section is to describe the steps the Authority will use in implementing the QMS using this Master Quality Plan.

Step 1

The first step in implementing the MQP is documenting the functional element responsible for each of the Tier 1 deliverables defined in the FRA Grant / Cooperative Agreement, Legislation, and state and federal requirements. Tier 1 deliverables are requirements with a defined deliverable due to an entity outside the CHSRA. The responsibility matrix that details the responsible element and source of the requirement in the Grant / Cooperative Agreement is maintained on the program SharePoint site.

Step 2

Each functional element documents the procedures the CHSRA will follow to meet their respective deliverables defined in the Grant / Cooperative Agreement and responsibility matrix.

Step 3

Each functional element develops quality procedures. These quality procedures should define Quality Objectives and Quality Related Activities the functional elements will use to ensure that the Authority meets the requirements specified in the Grant / Cooperative Agreements. The Quality Objectives should be measureable, separate from operational activities, and consistent with the CHSRA Quality Policy. These procedures should identify **what** is to be done; **who** should do it; and **when** it should be done. Functional elements should utilize the framework and processes detailed in Chapter 3 of this manual to develop these quality activities.

Step 4

The functional elements develop work instructions to provide guidelines for **how** the quality procedures and quality related activities established in Step 3 will be implemented.

Step 5

The Quality Manager identifies secondary deliverables (Tier 2) specified in the quality procedures and work instructions of each of the functional elements. Tier 2 deliverables are specific deliverables identified in the procedures (Step 2), quality procedures (Step 3), and work instructions (Step 4) that remain internal to the CHSRA program.

Step 6

The CHSRA utilizes the quality procedures, work instructions, and deliverables from each functional element to identify efficiencies and develop the Authority's quality procedures and work instructions. These quality procedures and work instructions will be documented in Part 2 of the Master Quality Plan, which will outline how the Authority will verify the execution of the CHSRA Quality Program. These procedures will coordinate the execution of each functional element's quality procedures, work instructions, and documentation of quality records.

Step 7

The CHSRA will revise their quality procedures and work instructions as appropriate during the different stages of construction.

Step 8

CHSRA verifies the execution of the quality management system by performing Quality Oversight of the program. Such oversight will include verifying the quality records of each of the functional elements. These procedures will be outlined in the Part 2 of the MQP and will include reports summarizing any audits, inspections, tests, and/or reviews completed.

2.4 Project Delivery Systems

For preparing this QMS, the Design-Build method of project delivery is used for modeling. The Authority may consider alternate delivery methods, including design/bid/build, design/build/operate/maintain (DBOM), or design/build/operate/maintain/finance (DBOMF), in which case the QMS will need to be modified. The management structure and responsibilities for each of the methods of project delivery will vary and may affect the quality plans prepared for each model. In addition, each contract with the Authority is unique and provisions will vary. Figure 2.4.1 illustrates the responsibilities of the Authority and the Design-Build team for a current contract. Each contract contains a Verification, Validation and Self-Certification specification detailing responsibilities for ensuring work is in compliance with the Contract Requirements.

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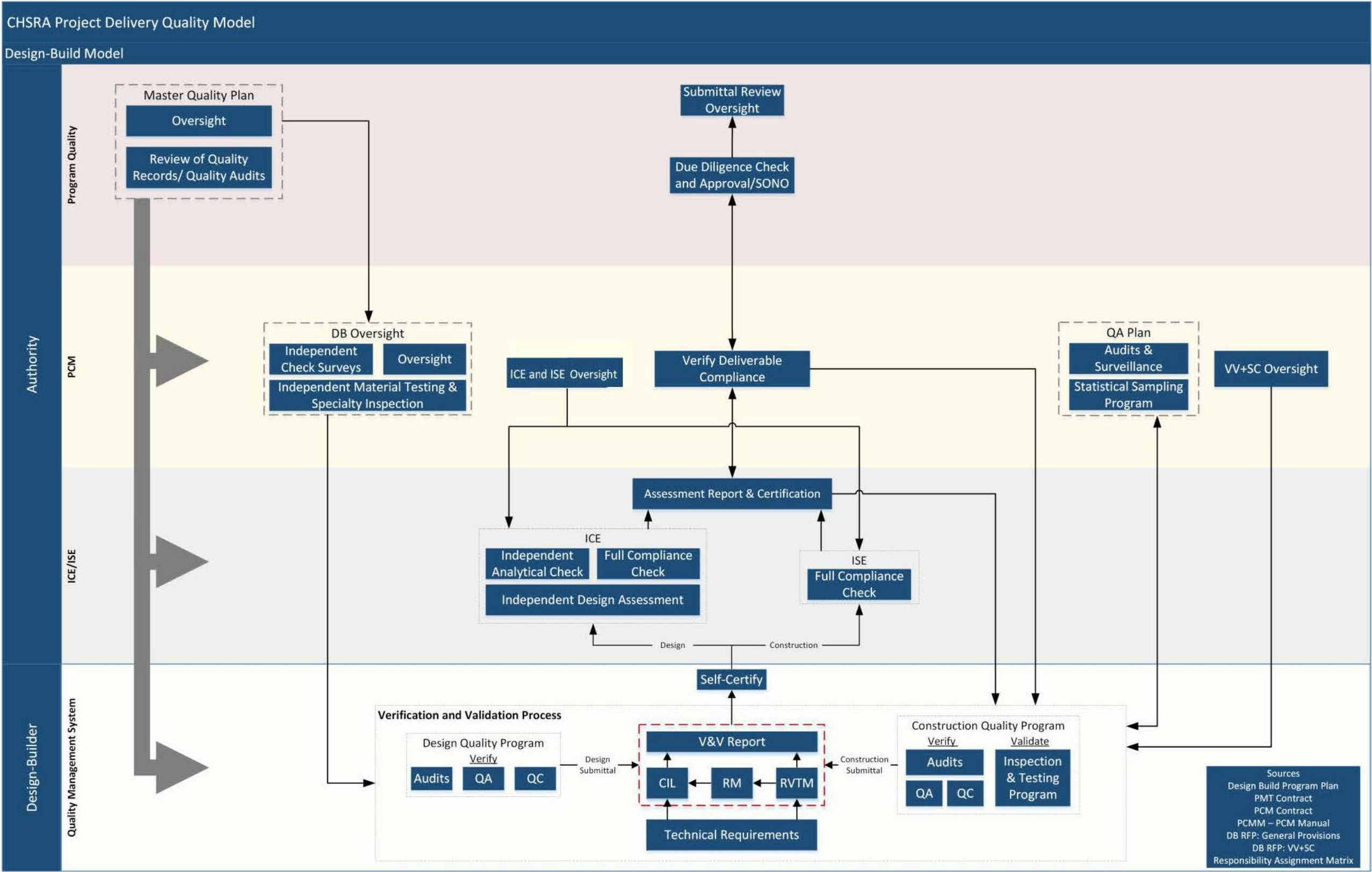


Figure 2.4.1: Separation of quality responsibilities in a DB project within the CHSR program

2.5 The QMS throughout the Program Lifecycle

A QMS, regardless of the project delivery method used, is expected to have unique quality objectives and defined quality activities throughout its program/project lifecycles. An effective QMS represents the situation whereby acceptable products and services are delivered at every stage, and at the same time seeks to continuously improve the products and services being delivered. The quality activities developed in each stage meet its prescribed objectives, and the quality must be maintained or improved in every stage of the lifecycle. This quality process and its continuous improvements are illustrated in Figure 2.5.1. To facilitate continuous improvements of the CHSRP, all entities shall develop and document a “lessons-learned” program that is integrated within their quality procedures and tailored to their respective functions.

The QMS will grow with the program at every stage of the lifecycle, seeking improvements every step of the way. Quality is involved in all stages of the project design and implementation. It is constant, like safety, and remains at the core of any project phase during the lifecycle.

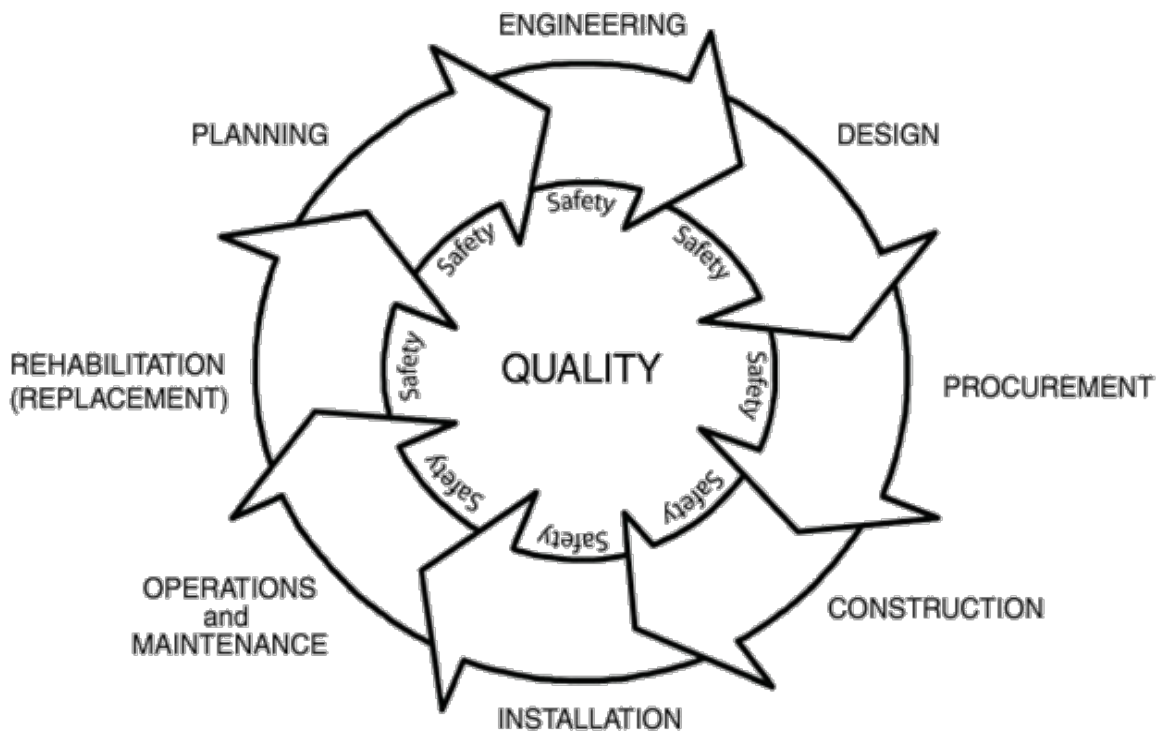


Figure 2.5.1: Quality in the Project Lifecycle⁵

⁵ U.S. Department of Transportation, Federal Transit Administration, *Quality Management System Guidelines*, December 2012.

2.6 Evolution of the Master Quality Plan throughout the Program Lifecycle

2.6.1 Project Planning

Project planning phase for the CHSRP commenced with the development of the PMP. The MQP is a stand-alone document required as part of the PMP. The 15 basic quality elements summarized in Chapter 3 and throughout this document are described in general descriptions and will be developed in Part 2 of the Master Quality Plan as the CHSRA evolves.

The development of the draft MQP and Quality Plans for each of the functional elements at this stage is important to set overall expectations, objectives, and direction for quality for the CHSRP.

2.6.2 Preliminary Engineering and Final Design

During the preliminary engineering phase, the design is developed to provide more accurate estimates of project costs and impacts. The financial and technical information from this effort is used for subsequent funding and decision processes. During the final design phase, the plans and specifications and final bid documents (RFP documents) required for awarding construction packages are distributed to prospective bidders. Managing the preliminary engineering and Design-Build bid packages is the responsibility of the CHSRA, while consultants perform the general design/engineering packages. For early procurements, the practice of the CHSRA is to retain a consultant PMT firm to supervise and manage the work of firms retained to design sections of the project. Preliminary engineering for procurement is performed by Regional Consultants, charged with preparing the preliminary design and environmental documents for a lengthy stretch of future track. Final design is performed by design-build teams responsible for smaller pieces of the system. Each design-build bid package has an individual PCM consultant team in charge of managing that contract. As the PMP is updated to reflect changes in the organizational structure of the CHSRA and the PMT, it will be necessary to update the MQP to reflect these actions. The MQP should begin to answer questions of who is responsible and when quality activities and deliverables take place.

2.6.3 Construction and Equipment Procurement

Once the procurement phase has started, contractors, subcontractors, fabricators, suppliers, and CHSRA personnel and consultant support staff will be involved at all levels of the construction work. During this phase, the MQP may be updated to guide all stakeholders in appropriate QA, QC, and quality oversight procedures.

The process for early procurements includes pre-qualification of prospective DB contractors by way of a publicly advertised RFQ/SOQ process, followed by submission of formal proposals in response to a formal RFP process. In the specifications of the procurement contract, the DB contractors assume responsibility for their quality programs and become accountable for specific quality activities, including all materials and work incorporated into the project. The RFP details the requirements for QC, QA, and the specified quality oversight procedures for the contractors' Verification, Validation, and Self-Certification process.

For the CHSRA, the appropriate quality oversight requirements⁶ are provided in part through the Project & Construction Management (PCM) team working on site with the contractors. Technical Contract Submittals are independently reviewed by the Independent Checking Engineer (for design submittals) and by the Independent Site Engineer (for construction submittals). The Authority team also implements independent survey, material testing, and specialty inspection as described in the Independent Assurance Plan. Additional quality oversight requirements are outlined in this MQP.

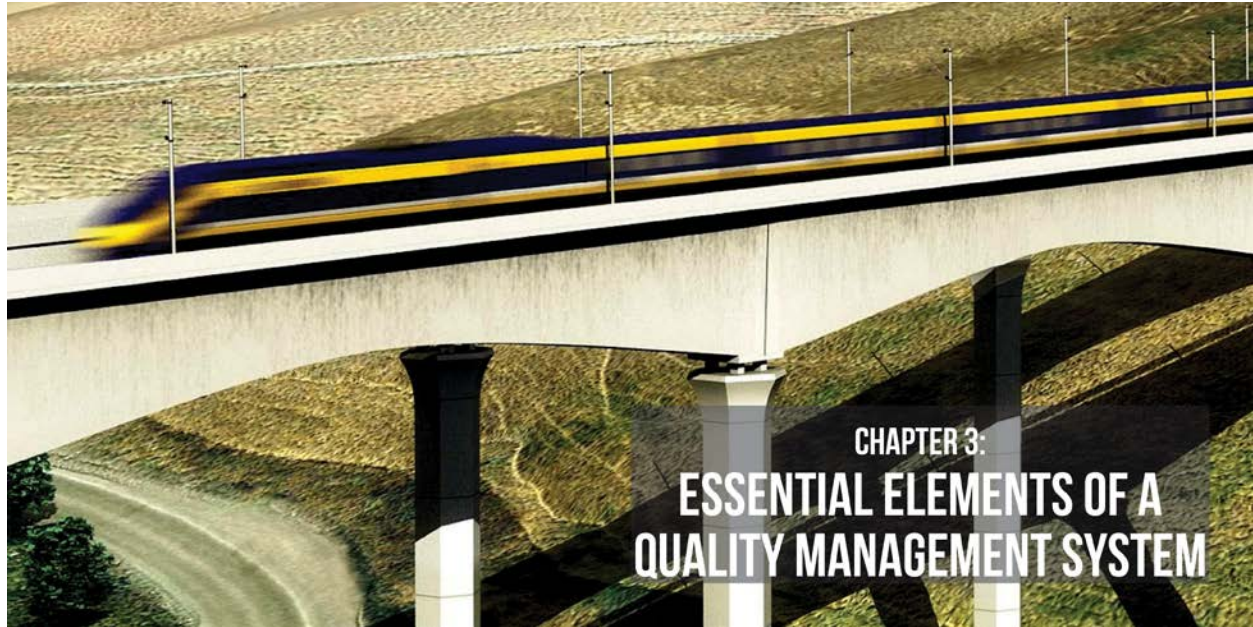
Key quality control and assurance elements are specified in detail in the construction contracts (and in Part 2 (under development) of this MQP). Procedures for non-conformances and corrective actions and for handling stop-work orders, including approvals required and any restrictions need to be well considered, formalized, and written down.

2.6.4 Testing and Acceptance

Testing and acceptance follow the construction phase and precede start-up of revenue service on the CHSR system. The purpose of this phase is to receive and accept track systems, rolling stock equipment, energy and communication systems, and more. This phase includes integration testing of the operating system prior to start-up.

The Verification and Validation requirements in the early construction contracts will integrate with future procurements and systems. However, prior to the transfer of facilities and equipment from the construction phase to the operating phase, more testing is required. This portion of the MQP will be developed and/or modified later, but prior to the testing and start-up phase. Assurance of the testing program, training of personnel, and maintaining the facilities will be the responsibility of the entity responsible for operating the system.

⁶ Details of Oversight Requirement by CHSRA under development. The Authority's role in providing quality oversight for the program will be described in Part 2 of this MQP, including monitoring and audit activities.



This chapter discusses the fifteen quality elements as identified by the FTA that should be considered in the development of a quality plan and quality procedures. The requirements of a quality management system are applicable to all entities providing goods and services to the CHSR program including, but not limited to contractors, consultants, subcontractors, subconsultants, and suppliers/vendors. The CHSRA recognizes that not all fifteen quality elements may be applicable to an entity depending upon their scope of work.

The fifteen quality elements 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. Non-conformance

- 12. Corrective Action
- 13. Quality Records
- 14. Quality Audits
- 15. Training

3.1 Element 1: Management Responsibility

3.1.1 Management Commitment

Executive management has demonstrated its commitment to the program by setting quality goals and objectives outlined in Section 1.4. Executive level commitment is further demonstrated through establishment of the Executive Oversight Committee. The CHSRA Chief Executive Officer (CEO), who oversees the program, has established a program-wide quality policy.

To continue to provide leadership and show evidence of its commitment to the improvement of the QMS, the executive management will do the following:

- Communicate to all employees the importance of meeting customer, statutory, and regulatory requirements through training, staff meetings, and other communication methods
- Establish and promote the Quality Policy
- Establish and promote quality objectives in the Authority and all its contractors and consultants
- Conduct regular management reviews
- Ensure the availability of resources

The contractors' Quality Management Plans shall be endorsed by their quality assurance manager, project manager, and principal in charge to provide evidence of their management commitment.

3.1.2 Customer Focus

CHSRA executive management will ensure that customer needs and expectations, as determined during the planning/major investment studies and environmental studies, will be continually addressed throughout the program. Environmental studies result in locally preferred alternatives for development of new transportation infrastructure and are developed with considerable public input. Figure 3.1.1 illustrates that the CHSRA solicits customer input at the beginning of each project segment development. As such, these documents define CHSRA customer requirements, and form a basis for design and construction.

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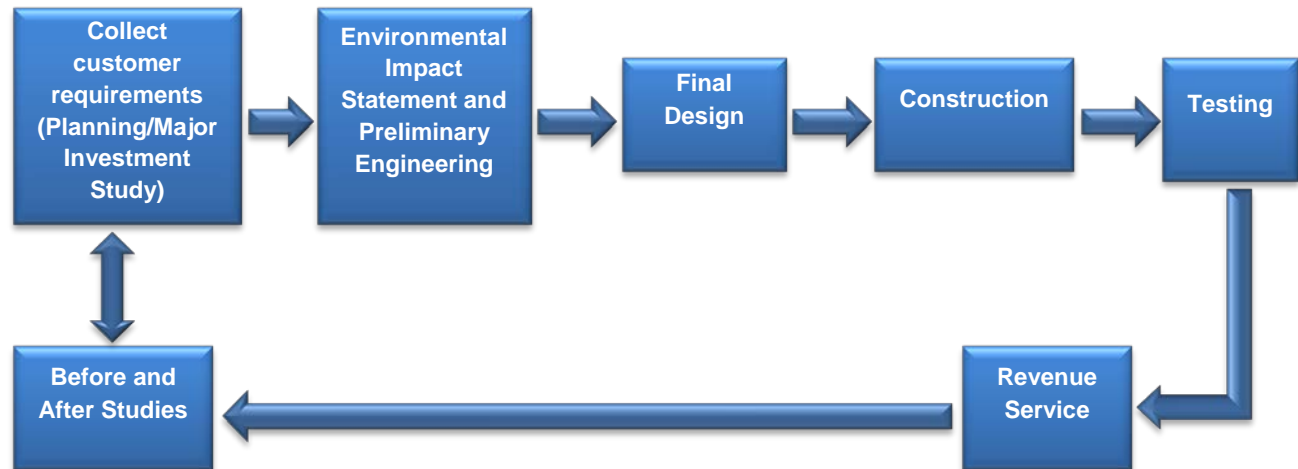


Figure 3.1.1: CHSRA Customer Input during Project Development

The CHSRA has a dedicated the External Affairs Division to continually address customer concerns and to provide outreach to various businesses, community, government, and media interests represented in California. Additionally, the CHSRA seeks partnerships with community groups to help ensure that the program diversity goals are met.

The CHSRP management may identify additional customer feedback projects during management review, lessons learned activities, and other staff meetings. Management can assign responsibility for such projects as needed. Such projects may include:

- Focus group meetings
- Direct customer communication
- Satisfaction surveys or studies
- Project hearings or informational meetings
- Other methods identified by management

Contractors may be required to provide a public information function for their respective project.

3.1.3 Quality Policy

The CHSRA has established a quality policy for the delivery of the CHSRP (see page vi).

Management ensures that the Quality Policy is communicated to all CHSRA staff as well as all its consultants and contractor employees through various means, such as newsletters, memos, and staff meetings to encourage and maintain high standards within the program. The Policy shall also be included in new employee training and training on the QMS.

Management reviews the Quality Policy at least annually to determine the Policy's continuing suitability for the CHSRP. The management review team evaluates the continuing suitability and

effectiveness of the QMS in satisfying the applicable requirements, including those of the FRA and ISO 9001:2008. Management reviews also identify possible improvements to the system and provide the framework for establishing regular reviews of the quality objectives.

Contractors should include their corporate or project quality policy within their project Quality Management Plans.

3.1.4 Planning

3.1.4.1 Program Goal and Objectives

Separate from the Quality Goals and Objectives, CHSRA Executive Management and Board of Directors have established the following program goal and objectives:

“The Authority’s statutory mandate is to plan, design, build, operate, and maintain a High Speed Train (HST) system that is coordinated with California’s existing transportation network, particularly intercity rail and bus lines, commuter rail lines, urban rail transit lines, highways, and airports. Within this overall goal, there are objectives with respect to Quality, Safety, Cost, Timeliness, Public Trust, and Public Outreach and Communications.”⁷

Following are detailed descriptions of the Authority’s objectives that are integral with the program goal:

Quality

The objective is to provide a high-speed rail system that is consistent with the performance requirements of the system as determined in California Streets and Highway Code, Section 2704. This includes top-level system requirements such as capability for 220+ MPH high-speed train operations, non-stop service travel times, station locations, impacts to communities and the environment, as well as system reliability, availability, and maintenance requirements. Technical performance requirements for the system are included in TM 0.3 – Basis for Design Policy, which is further discussed in the Design Program Section of the CHSRA Program Management Plan.

The Authority serves the public by delivering the CHSRP with a quality that meets or exceeds acceptable industry and government standards, on schedule, and at the lowest possible cost. The Authority’s Master Quality Plan and overall quality management system are developed based on ANSI/ISO/ASQ Q9001:2008 and the Federal Transit Administration Quality Management System Guidelines published in December of 2012 for quality for each phase of the program, starting with project planning and finishing in revenue service. Program Quality Goals and Objectives are defined in Section 1.4 of MQP. Individual functional elements of the CHSRA shall develop and implement their respective quality goals and objectives. The Quality

⁷ California High Speed Rail Program Management Team, California High Speed Rail Program, *CHSRA Program Management Plan*, June 2013.

Manager of the CHSRA shall oversee the implementation of quality goals and objectives within the program and each functional element as well as in consultants and contractors of the Authority.

Safety

The objective is to provide a high speed rail system that achieves or exceeds a level of operational safety consistent with similar high-speed systems currently operating in Asia and Europe, as well as provide for a safe working environment during all phases of the Project including construction. Measurement for safety is defined and monitored with the System Safety Management Plan (SSMP). The SSMP defines the safety and security activities of the project and methods for identifying, evaluating, and resolving potential safety hazards and security vulnerabilities of the CHSR system, and establishes responsibility and accountability for safety and security during lifecycle of the project.

Costs

The objective is to deliver the operational phases of the program consistent with the budget, as presented in the Authority's *Business Plan*.

Timeliness

The objective is to deliver the Operational Phases of the program consistent with the schedule as presented in the Authority's *Business Plan*.

Public Trust

The objective is to establish and maintain a high level of public trust and support for the program.

Public Outreach and Communications

The objective is to provide a mechanism to inform the public and stakeholders on the status of the program. The Authority maintains an active outreach program which includes press releases, public hearings, brochures, and electronic communications and feedback – as well as a process for receiving and recording feedback from the public and stakeholders.

Contractors should describe their own project goals within their Quality Management Plans in alignment with the CHSRA goals.

3.1.4.2 Quality Management System Planning

Each project, under the CHSRP, will be managed in accordance with the CHSRA Program Management Plan (PMP). The PMP, along with this MQP, will define the approaches and processes the CHSRA will use to ensure project delivery.

All RFPs will include quality control/quality assurance requirements applicable to that particular project. Contractors shall develop Quality Manuals based on the CHSRA requirements. These plans shall be submitted to CHSRA for review and approval prior to beginning work on that project. Additional requirements will be based on the specific scope of work, and may include industry standards such as IEEE, PCI, ASTM, etc. In the event that a prime contractor subcontracts all or any portion of the work, accountability for the quality program remains with the prime contractor.

3.1.5 Responsibility, Authority, and Communication

3.1.5.1 Responsibility and Authority

The CHSRA Chief Executive Officer (CEO) provides strategic guidance and executive level commitment to the CHSRA Program Management Team. The Chief Program Manager has overall responsibility for implementing the CHSRA program to achieve quality, budget, safety, and schedule objectives

The Regional Directors have responsibility for stakeholder engagement and coordination for all program work within their respective regions.

The CHSRA Quality Manager is the individual responsible for implementation of the QMS. Within the CHSRA, the Quality Manager reports to the CEO. In addition to the responsibility for administration of the overall quality management program, the Quality Manager is delegated the authority to provide complete organizational freedom to investigate quality-related activities in all areas of the CHSRP. The Quality Manager also has the authority to identify, evaluate, and ensure resolution of quality-related issues. The responsibilities of the CHSRA Quality Manager include, but are not limited to:

- Reviewing CHSRA contracts for appropriate QA/QC program requirements
- Reviewing and approving contractors' Quality Management Plans
- Providing coordination of the quality auditing program
- Identifying quality issues and trends to management
- Monitoring contractor quality assurance and quality control programs
- Conducting quality audits as needed
- Developing quality programs and procedures
- Interfacing with FRA officials on quality issues
- Interfacing with contractor QA/QC staff to resolve quality issues
- Interfacing with CHSRA project managers on quality issues

Every member of the CHSRP will perform a quality oversight role for their specific function(s). See Figure 2.4.1 for the CHSRA Quality Management System Organization Chart.

Contractors will have primary responsibility for quality management within their respective scope of work. The Contractor, who has primary responsibility for day-to-day project implementation of planning, design, construction, testing, etc., has the greatest impact on overall quality within their scope of their work. Assigning the responsibility for quality management to the individual contractors emphasizes that the contractor is not only responsible for meeting the contract requirements, but also for taking measures to provide confidence to the CHSRA that the requirements have been met.

The structure for any organization performing the work on the CHSRP is that organization's responsibility, within the limits of the MQP. The organizations responsible for quality assurance shall have sufficient authority, access to work areas, and organizational freedom to:

- Identify quality problems
- Verify implementation of solutions
- Assure that further processing, delivery, or installation is controlled until proper disposition of a deficiency, non-conformance, or unsatisfactory condition has occurred

Those functions that perform quality verification shall report to a level of management that provides sufficient authority and organizational freedom to ensure that appropriate actions are taken to resolve conditions adverse to quality.

Contractors, sub-contractors, and suppliers shall be structured in such a manner that:

- **Quality is achieved and maintained by those responsible for performing the work.**
- **Quality achievement is verified by persons or organizations not directly responsible for performance of the work.**

Contractors shall describe their organizational reporting structure within their Quality Manuals clearly defining the relationship between the Project Manager, the Quality Manager, and other key managers. In addition, their Quality Manual shall describe the responsibilities and authorities of these managers as it relates to product or service quality.

Although certain QA/QC responsibilities may be assigned to subcontractors, overall accountability remains with the prime contractor.

3.1.5.2 Management Representative

The CHSRA Quality Manager shall serve as the management representative for external and internal quality-related interfaces.

Contractors' Quality Manuals shall identify the Quality Manager as serving as the management representative for all quality related matters.

3.1.5.3 Quality Resources

The CHSRA Quality Manager, in consultation with the CEO and the Program Manager, shall identify resource requirements needed for implementation of the Quality Management Program. This effort will include all functional elements as well as consultant work plans.

Contractors are responsible for addressing their own resource needs based on requirements within their respective contracts. Adequate resources for quality assurance/quality control activities shall be budgeted for each project and be included in the contractor's bid.

3.1.5.4 Internal Communication

CHSRA will make maximum use of its electronic tools to communicate vital information both internally and externally. All team members will have access to the web site, as well as email and telephone/voicemail. Formal and informal meetings will be used to coordinate various activities and assist in the decision making process. Communication will be facilitated throughout the program by co-locating members of the CHSRA PMT from the various entities involved. The CHSRA team will utilize a partnering approach to resolve issues at the lowest possible level.

Contractors shall describe their internal communication protocols within their Quality Management Plans. Specifically, contractors shall address how information is shared between the production and quality assurance functions.

3.1.6 Management Review

3.1.6.1 General

The adequacy and effectiveness of the quality management system shall be regularly assessed by the management of the respective organization. Within the CHSRA, the Quality Manager will schedule quarterly quality management reviews with the CHSRA executive management. NOTE: Refer to the CHSRA Program Management Plan for a description of the executive management.

These quarterly reviews will provide a forum for the CHSRA managers to review the quality program with respect to established goals, document lessons learned, and develop action plans for improvement if necessary. The reviews assess the QMS suitability, adequacy, and effectiveness in identifying opportunities for improvement and needed changes. Records are maintained for each management review meeting by the CHSRA Quality Manager.

Contractors shall describe within their Quality Manuals the process by which their quality program results are reviewed by management, how action plans are generated and tracked, and how often this occurs. In addition, Contractors shall describe how their Quality Manuals are reviewed and updated. NOTE: Revisions to Quality Manuals shall be submitted to the CHSRA for approval.

3.1.6.2 Review Input

Assessment of the QMS is based on a review of information provided to management for review. These inputs include the following:

- Results of audits
- Customer feedback
- Process performance and product/service conformity
- Status of preventive and corrective actions
- Follow-up actions from previous management reviews
- Changes that could affect the quality management system
- Recommendations for improvement

All required inputs are reviewed quarterly during management reviews.

3.1.6.3 Review Output

Output from the management review will include any decisions and actions related to:

- Improvement of the effectiveness of the quality management system and its processes
- Improvement of product or service related to customer requirements
- Resource needs

Responsibility for required actions is assigned to members of the management review team. Any decisions made during the meeting, assigned actions, and their due dates are recorded in the minutes of management review. These records are maintained by the Quality Manager.

3.2 Element 2: Documented Quality Management System

3.2.1 General

The CHSRA, through the development and issuance of this MQP, has established a quality management system for the CHSRP. All quality objectives, organizational structures, policies, and procedures are documented or referenced in the QMS and incorporated as part of the

quality management system. The quality management system shall detail the procedure to be updated and continually improve the quality program and its documents.

3.2.2 Quality Manuals

The CHSRA's QMS defines the Authority's structure for managing the quality of the CHSRP. It also defines a hierarchal system of documented procedures, starting with this MQP as the top-level document. Additional procedures are added, as necessary, as the program evolves through the continuous improvement process.

Prime contractors shall submit Quality Manuals for CHSRA approval, based on requirements of the respective contracts and this MQP. Contractor manuals shall clearly state that the provisions within the plan will flow down to its subcontractors.

3.2.3 Developing the Quality Management System

For contractors, the Quality Manual is a detailed document, which specifies the quality oversight procedures for their scope of work to comply with their contractual requirements. At a minimum, it should address:

- Quality Policy
- Quality Planning
- Quality Management
- Quality System Procedures
- Records to provide objective evidence that the system is being followed, including plan review comments
- Instructions at the job or task level
- Planning or Design review processes
- Internal quality audit process
- Requirement Management process
- Procedures for preparation, control, and distribution of the Quality Manual
- Procedures for executive management review of the Quality Manual

3.2.4 Involvement

The requirements and objectives set forth in the CHSR MQP apply to the entire CHSR program including the Authority, PMT, PCMs, DB teams, and other contractors, consultants, suppliers, and their subcontractors.

Each Authority functional element or contractor providing management, design, construction, consulting, or other services to the program will develop, adopt, and implement a quality plan appropriate to the service being provided that defines the administrative and control measures to achieve the quality requirements of the QMS. These plans must define quality goals and objectives, specify quality-related activities through documented procedures, and assign responsibilities for conducting the activities and verifying that the objectives are met. The specific quality plan requirements will be implemented as appropriate to cover each contract's scope of services. These requirements will be included in the specifications and bid documents for engineering, procurement, construction, construction management, and other services.

3.2.5 Control of Records

Quality records will be collected, stored, and preserved in a manner which precludes damage, loss, or deterioration in accordance with storage requirements defined in the various contracts and specifications.

Changes made to the quality records must receive the same level of review and approval as the original document. Quality records are valid only if stamped, signed, and dated as required by authorized personnel. Please also see Section 3.4 Element 4: Document Control for further details.

Contractors/suppliers should safeguard quality records during design, construction, assembly, installation, and testing. Quality records shall be submitted to CHSRA for review and archival in accordance with the contract submittal requirements.

Contractors shall maintain quality records in a manner that is readily retrievable. At all times throughout the contract, quality records shall be available upon request, and may be subject to review by the CHSRA quality assurance auditors.

3.3 Element 3: Design Control

This section defines the requirements for control of design and development planning to be included in project quality plans used in the program. For most project design work, CHSRA will solicit the services of planning and engineering contractors. Specific regional requirements and general CHSRA requirements will be stated in the contract scope of work.

Design control is implemented to verify design documents meet the program and project requirements. Design documents include but are not limited to design criteria, calculations, drawings, technical reports, specifications, and bid documents.

3.3.1 Design Quality Planning and Control

All contractors performing design activities are responsible for establishing, implementing, and maintaining a Quality Management Plan to control, verify, and validate the design for their projects. (Sub-contractors may either produce their own Quality Management Plan or officially adopt the Plan of the contractor they are performing work for.) They are also responsible for the following:

- Planning the design and development processes and identifying responsibilities for design, development, and verification activities.
- Assigning design, development, and verification activities to qualified staff equipped with adequate resources. Design work will be performed by qualified personnel and will comply with the documented procedures.
- Design control and review processes will be conducted to verify design integrity, reliability, safety, constructability, operability, and economic maintainability.
- Design change (revisions) will be subject to checking, coordination, and design review to the same level as the original design. Design changes documents must be approved and processed in accordance with project configuration management procedures. Documentation of the design change will be in accordance with Document Control section (Section 3.4) of this MQP.
- Managing design interfaces with other program projects and third parties. Each contractor's Quality Manager will audit internal and external design and development activities to verify that design control procedures are being implemented.
- An individual of equal or higher qualification than that of the designer will perform an independent verification of design documents. The Quality Manager will assess the qualifications and responsibilities of design reviewers.
- Use of appropriate computer programs in design activities is of special importance. In this regard:
- Describe the methods for documenting the use of industry standard computer programs for design and analysis.
 - Describe the methods for verifying custom or non-industry standard programs used for design and analysis.
 - Describe methods for documenting input to computer programs used for design and analysis.

The Quality Manual for all contractors will be submitted in a timeline consistent with their contract.

Contractors will prepare written procedures consistent with the processes described above and in conformance with the requirements of the contract. The procedures should include, but not be limited to, the following as appropriate:

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- Procedures to control and verify the design, including provisions for configuration management activities to be performed by contractors
- Procedures to determine if appropriate quality standards have been specified for the intended use, and that parts, materials, equipment, and processes specified are appropriate to the application
- Document control procedures including procedures for document issuance, approval, and revision
- Procedures to notify all affected parties of a design change. To expedite design changes, parties affected by changes should be promptly notified
- Procedures for the identification and, where required by contract, the traceability of deliverable items, such as plan reports, NEPA documentation, drawings, specifications, and design inputs
- Procedures for verification and validation of the design
- Procedures for control of nonconforming products
- Procedures for corrective/preventive actions
- Procedures for verification and control of computer programs and spreadsheets used in design
- Training procedures

The CHSRA Quality Manager will verify implementation of the QMS requirements for design control within each project.

3.3.2 Design and Development Inputs

Design criteria will consist of written guidelines and directives. When required by the contract, design criteria will be developed and/or completed by the consultant or design contractor. Design criteria, while not a code, will conform to the jurisdictional codes and provide guidance and standards where existing codes are lacking. Design quality objectives are critical input elements. Additionally, design criteria should consider applicable industry standards and specifications such as AAR, AASHTO, AREMA, ASTM, AISC, ACI, ASCE, AWS, PCI, and IEEE. Solicitation processes as well as design review processes may provide additional input.

The basis of design will:

- Identify, document, and verify design input requirements, including Authority, contractual, and regulatory requirements relating to the project
- Identify organizational and technical interfaces with input into the design process, and establish processes for transmitting and reviewing interface requirements
- Establish acceptance criteria for the adequacy of design solutions in satisfying design input requirements

- Identify, review, and approve inputs to the design basis prior to use
- Ensure that the design basis is issued internally and approved by PCM and/or CHSRA before beginning preliminary or final design activities

Contractors should identify design input requirements relating to the product, including applicable statutory and regulatory requirements. Additionally, design contractors shall perform ongoing adequacy reviews of the selected regulatory requirements. Contractors should resolve incomplete, ambiguous, or conflicting requirements with the applicable entity. Contractors should take the following steps:

- Identify what information is needed and the available sources of information
- Review all pertinent information sources of information
- Ensure that there is sufficient information to carry out the assignment

Where pertinent, resolve any actual or apparent conflicts with CHSRA, planning, and NEPA commitments, and/or other appropriate authorities

3.3.3 Design and Development Outputs

The output from the design and development processes includes completed design criteria and the preliminary engineering for procurement or 100% system design documents as applicable. The design criteria will form the basis of the product design and will be reviewed and approved prior to use for system design. The submittal review process for DB contractor is described in Chapter 5 of the Project & Construction Management Manual. For design consultants, the submittal and review process is described in their respective contracts.

Design and development outputs may include the following per the contractual requirements:

Drawing Preparation and Approval

Describe the methods and requirements for planning, identifying, preparing, checking, reviewing, controlling, approving, and documenting engineering drawings.

Technical Reports

Describe the methods and requirements for preparing, checking, reviewing, and approving technical reports that document design input or are used as a basis for making decisions on the project.

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Specifications

Describe the methods and requirements for preparing, checking, reviewing, and approving specifications prepared during design to identify requirements for procurement and construction. Specifications should be well-written and complete and include all applicable quality requirements.

Cost Estimates

Describe the methods for preparing and reviewing estimates of probable construction costs in conjunction with design.

Design Documents Prepared by Others

Any activity carried out by a subcontractor or supplier should be conducted in accordance with a quality plan and supporting procedures that meet the QMS requirements.

Describe the methods for acknowledging, reviewing, accepting, and documenting engineering design inputs prepared by other organizations before incorporation into the design basis or design output.

Design Changes

Describe methods for identifying, documenting, appropriately reviewing and approving changes, and modifications to the design basis, drawings, specifications, cost, or schedule.

Design changes are controlled and authorized and should only be by personnel designated in the PMP.

Project Record “As Built” Documents

Describe methods to verify that as-built drawings, specifications, calculations, and reports reflect completed project configuration.

Describe methods to verify that final record documents are in accordance with contract requirements.

The CHSRA Quality Manager will be responsible for oversight of design quality processes to ensure all quality objectives are met. By applying a continuous improvement process, design quality objectives may also be revised and constitute additional output.

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Design contractors should provide high quality engineering documents in accordance with the CHSRA approved design criteria and good engineering practices. Design output documents may be reviewed for compliance with contractual requirements by the CHSRA, and should be sealed by a licensed engineer or architect as required by California state laws. The design should be cross-referenced to design input requirements to demonstrate completion of the requirement.

The contractor's design output should be documented and expressed in terms that can be verified and validated. Design output should:

- Be in full accord with the design output requirements.
- Delineate acceptance criteria.
- Delineate the design characteristics crucial to the safe and proper functioning of the product (i.e., operating, storage, handling, maintenance, and disposal requirements).

The control of all design documentation outputs, including drawings, reports, and specifications, shall be an integral part of the design contractor's document control process).

3.3.4 Design and Development Review

Design contractors will be used for preliminary and final design of the system.

CHSRA will record and track the results of the design reviews per the relevant contract procedures.

Specific requirements for design review will be included in the contract scope of work and documented in the design contractor's Quality Manual. Examples of various types of design reviews include:

- Design Initiation: A formal and scheduled meeting between the contractor, ICE, and CHSRA to review design status, including any changes to the basic configuration of the project. There may be no formal design submittal concurrent with the design initiation meeting. Meeting minutes are kept by the contractor and a copy is submitted to the ICE and the CHSRA.
- Design Progress Meetings: Scheduled design (by discipline) coordination meetings held by the contractor, with the ICE and the CHSRA representatives present, to discuss design-related critical issues that arise. Meeting minutes kept by the contractor and formally submitted to the ICE and the CHSRA.

- Released for Construction: In the case of design-build contracts, the contractor is allowed to initiate construction prior to final design acceptance by CHSRA.
- Design Submittal: All elements within the design documents are to be completed to the level expected for that submittal, including resolution of prior reviews/audits/outstanding comments. The ICE and CHSRA will not accept the design until contractors have addressed, resolved, and incorporated all review comments. The formal design submittal may include but not limited to all design plans, calculations, reports, specifications, estimated quantities, and electronic CADD files specified in the contract. A set of check prints will be developed for formal design submittals to demonstrate that every design feature on each drawing has been checked for completeness, correctness, coordination, and compliance with applicable laws and specifications. As a QC measure, all work will be checked by someone other than the individual who performed the work but with equivalent or higher qualifications prior to the formal design package being submitted to the ICE.
- As-Built: Submitted to the PCM and CHSRA in both hard copy and electronic copy for review to ensure completion and compliance with the contract requirements prior to final project acceptance.

Design review may consist of the following activities:

- Describing the methods for reviewing design documents to verify that they are adequate and back-checked in accordance with approved project design criteria and generally accepted design and engineering practice, including:
 - Coordination between disciplines
 - Physical coordination with adjoining projects
 - Verification that all Authority comments and directives have been addressed
 - Cost checks
 - Value engineering
- Ensuring that design reviews incorporate requirements from other interfacing projects
- Ensuring that additional reviews are held and documented as appropriate, including:
 - Bidability reviews
 - Constructability reviews
 - Risk assessments

Design reviews shall be included in the contractors' Quality Manual, and should be conducted by the contractor with ICE, CHSRA, and local agency participation at specified milestones. They should conduct their own internal reviews, prior to submitting design product to the ICE for formal review. Internal reviews and ICE milestone reviews should be described in the Quality Manual.

3.3.5 Design and Development Verification

Design reviews, checks, alternate calculations, performance tests, and other means used to verify the design prior to submittal to the PMT or the ICE should be performed and documented by personnel other than those who originated the design, but with similar or higher qualifications.

Design contractors will develop and record appropriate methods for verifying that design outputs satisfy the design input requirements, including the following:

- Planning for and conducting design reviews
- Determining when a review must be performed by an independent or outside entity
- Undertaking qualification tests
- Carrying out alternative calculations, as appropriate
- Comparing the new design with a similar proven design, if available

The CHSRA will also perform periodic reviews at specified milestones (such as 60% and 90% design) to ensure that the contractors' designs meet contractual requirements.

Design contractors should describe methods of design and development verification within their Quality Manual.

3.3.6 Design and Development Validation

Peer reviews, simulations, constructability reviews, and other methods of validation should be considered by the design contractor when developing quality plans. Validation efforts may be integrated within planned design reviews. Other aspects of the design to be analyzed during design reviews include usability, reliability, maintainability, availability of materials, operability, safety, cost, aesthetics, and sociological factors. Any computer software used to perform design calculations must be validated before use, and the validation documentation should be maintained with the quality records. CHSRA project managers may supplement the review staff, as needed, with representatives from operations and maintenance.

Design contractors should describe methods of design and development validation within their Quality Manual.

3.3.7 Control of Design and Development Changes

Design changes should be checked, coordinated, documented, and reviewed to the same level as the original design. Superseded design documents should be marked and retained for information only. Design contractors will establish procedures within quality plans, describing how design changes will be initiated, reviewed, approved, implemented, and recorded in order to maintain configuration control. Such changes may originate from the CHSRA, the designer, site or field personnel (in case of design-build), regulatory agencies, or community inputs.

Personnel authorized to approve changes will be identified in the quality manuals. Also, the contractor should maintain a master list of currently accepted design changes. If post-design changes are required, these changes should be communicated to the PCM, the CHSRA, and the construction site on a timely basis. Construction staff should not perform work without incorporation of all approved design changes.

Design contractors should describe methods of design and development change control within their quality plans.

3.4 Element 4: Document Control

CHSRA staff will comply with the CHSRA Document Control Plan. These procedures describe the filing system and archival requirements for program and project documents and data. Contractors and suppliers are responsible for developing and implementing project-specific document and data control procedures that meet overall program requirements for their scope of work.

The CHSRA Quality Manager is responsible for reviewing and assessing that document control procedures are effective in meeting the requirements as stated here and detailed in respective quality plans. The contractor's Quality Manager is responsible for reviewing and assessing that the project document control procedures are effective in meeting the requirements of the program QMS. It is the responsibility of all contractor personnel producing, using, or revising any document or data that falls within the scope of controlled documentation to perform these activities in accordance with the document control procedures.

Contractor documents and data will undergo a review, and will be approved by authorized personnel prior to release, in accordance with the project-specific document and data control procedures. Document Control will establish and maintain a database of all controlled documents for use in revision and distribution tracking. Further control measures will ensure that:

- Appropriate documents are available for those performing the work.
- Obsolete documents are either removed, or marked accordingly, to safeguard against unintended use.
- Obsolete documents, retained for legal and reference purposes, are identified accordingly and filed as per the CHSRA Document Control Plan.
- The distribution of project documents is recorded and, in designated cases, controlled.
- A master list of all documents, indicating current authorized versions, is maintained.
- Quality records are maintained and retained in accordance with project procedures.

Incoming and outgoing correspondence will be filed in accordance with the CHSRA Document Control Plan. This system will ensure that project documents are secured, maintained, and readily retrievable for use when needed.

Changes to all controlled documents should be reviewed and approved by the same functions/personnel that approved the original document. Designated functions/personnel will have access to pertinent background information, on which to base their review and approval. Where practical, changes will be identified within the document. For more information, refer to the CHSRA Document Control Plan.

Contractors should describe their own document control procedures within their quality manuals, based on requirements from their respective

3.5 Element 5: Purchasing

3.5.1 Purchasing Process

This section defines the requirements for the preparation, review, approval, and control of CHSR program procurement activities for services or products. These requirements will provide for, as appropriate, the following:

- Inclusion of quality, program control, and procedural requirements in procurement documents
- Source evaluation
- Objective evidence of quality furnished by the consultant, contractor, or supplier
- Inspection or audit at the source
- Evaluation of items upon delivery to verify conformance of products to procurement and contract document requirements

Numerous regulatory and administrative controls at the federal, state, and local level govern CHSRA procurement practices. In addition, the CHSRA CEO issues Administrative Policies/Procedures, which impact the procurement process. The overall procurement process for CHSRA generally has three distinct phases:

- Pre-solicitation – Request for Proposals
- Solicitation-award – evaluation of proposals, selection of contractor, and notice to proceed
- Post award – contractor management and oversight

The selection process for CHSRA contracts varies. Design contracts will typically be qualification based; and construction contracts will typically be based on the lowest bid. Many professional service and procurement type contracts will be based on a best value determination. For best value determinations, an initial evaluation is conducted on a pass/fail basis to determine responsiveness (the degree to which the proposal addresses the RFP requirements) and responsibility (the degree to which the proposer is resourced for meeting the RFP requirements). Non-responsive and/or non-responsible proposals are rejected. In certain cases, the CHSRA reserves the right to proceed directly with discussions with the proposers, followed by a request for Best and Final Offer (BAFO), or cancel the solicitation. However, in

most cases, the CHSRA will proceed with performance of an integrated assessment of price and technical factors, with the highest ranked proposal considered as the best value. For additional information, refer to the CHSRA for specific procurement policies and procedures.

3.5.2 Purchasing Information

RFPs or RFQs will include Instructions to Proposers which detail how the proposal packages are to be assembled, and how the evaluation will take place. Additional documentation which may be included in the RFP includes copies of the following:

- Certification requirements
- Technical specifications (including QA/QC program, safety program, personnel qualifications, etc.)
- Applicable standards
- Contract drawings
- Reference documents

The requirement to develop and implement design or construction quality plans that meet QMS requirements will be included in all requests for bids or proposals. Prior to being issued, purchasing and contract packages are prepared, reviewed, and processed in accordance with approved procedures. Purchasing and contract packages checklists will be used to verify that the packages address the following issues at a minimum:

- Design, technical, and quality requirements by reference to design standards, specifications, drawings, and reference documents
- Required source inspections, surveillance requirements, independent laboratory inspection, or witness or hold points, as necessary.
- Specific shipping, handling, storage, and safety requirements, as necessary.
- Specific quality program, control, or procedural requirements, by inclusion or reference
- Any required certifications of conformance or compliance
- The purchasing function is carried out in accordance with the standards and methods defined in the program procedures
- The CHSRA's guaranteed right-of-entry to contractor or supplier facilities to perform quality audits to verify compliance by the contractor and their suppliers with the quality program requirements and to ascertain the following:
 - Existence and subsequent evaluation of a documented quality system
 - Ability of that organization to meet the program's procurement and quality requirements
 - Ability of that organization to adequately ensure that the program's products are controlled, handled, shipped, and stored to ensure acceptable quality of items and services

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- Periodic audits from the CHSRA to verify proper execution of these procedures

3.5.3 Verification of Purchased Product

The CHSRA shall implement appropriate compliance auditing and/or inspection processes that provide adequate confidence throughout the duration of the contracts to verify that contractual requirements are met, including those related to quality control and quality assurance.

As a recipient of Federal funds, certain projects within the CHSRP are subject to oversight by the FHWA and the FRA. Representatives of the FRA (to include the PMOC if applicable) shall have the right to carry out verification of CHSRA quality oversight activities on location and within corridors, or at any of the supplier locations for which Federal funds have been used. Such audits should not be used by CHSRA as a substitute for their own quality oversight activities, nor should they preclude subsequent rejection by the FRA.

3.6 Element 6: Product Identification and Traceability

This section defines the requirements for product identification and traceability controls for material and equipment used in the program. These controls ensure that only correct and acceptable items are used or installed and prevent the use of incorrect or defective items.

Product identification and traceability needs to take place during all the various production phases from the receipt of raw materials and components through the manufacturing process to the delivery of final products or systems. The Quality Management Plan, created by the supplier of the material or product, establishes the process for traceability so that at every stage of fabrication all pertinent information is maintained and traceable.

Raw materials should be traceable back to a particular batch or lot number and should be accompanied by applicable test data sheets and material certifications. Assemblies in production should be traceable to their subcomponents. Final assemblies should be clearly marked with project numbers, model numbers, serial numbers, bar codes, and/or similar information so that all pertinent information regarding that assembly may be retrieved.

The contractor or supplier will establish procedures for control of materials, parts, components, equipment and products, including works in progress, and will provide for identification and traceability of those materials. Procedures will provide for such activities as receipt of materials, storage of materials, and incorporation of materials into the work.

Control of individual products will be accomplished by the use of physical identification, separation into lots, or other appropriate means. Contractor or supplier inspection personnel will verify and document that items are identified properly. Product identification will be provided by means such as:

- Project or contract number
- Supplier name and location
- Batch or lot number

- Item serial number
- Unique item description number

Authority-furnished materials, if any, will be listed or described in the contract documents.

Contractors, suppliers, fabricators, and manufacturers are responsible for assuring control of materials, identification, and traceability and will need to establish quality control plans and procedures to ensure proper control, identification, and traceability of items. Their QC and QA inspection personnel will verify and document that items are identified and traced properly. Design-Build contractors will be the ultimate responsible party to ensure material identification and traceability for their scope of work, including work which is subcontracted. Records of identification and traceability activities are considered quality records and should be retained.

The Authority will perform verification reviews or audits to ensure requirements for control, identification, and traceability are contained in contract documents and procurement specifications. The Authority will also monitor the contractor's or supplier's procedures through the use of inspections and/or audits to confirm that materials have full traceability throughout the life of the item.

Contractors should establish and maintain documented procedures for identifying and controlling products delivered for use in construction/installation. Quality Manuals should describe traceability procedures for materials, parts, equipment, and services important to the function of safety related systems and subsystems. Instructions relating to testing and inspection should include requirements to verify and record the identification of items and for tracking test/retest status.

3.7 Element 7: Process Control

This section defines the requirements for identifying and controlling special processes. Special process and control instructions may be specified for critical, high-value, or high risk operations, or when the specified performance cannot be verified upon completion or installation. Design contractors are responsible for identifying work that requires special process instructions and for establishing workmanship standards. These special requirements will be included in the specifications. Construction contractors are responsible for performing work in accordance with the instructions and workmanship standards indicated in the special process instructions and specifications. The CHSRA Quality Manager will monitor and verify conformance with documented procedures required for special processes. Examples include welding, non-destructive examination, heat treatment, and special coatings. Specifications shall describe the required performance and quality of the work products. Where the specified performance cannot be verified upon completion or installation, special process and control instructions may be specified.

The CHSRA Quality Manager will verify that special process instructions have been included in the specifications and contract documents and that the instructions are properly implemented.

3.7.1 Work environment

The work environment should be conducive to positive two-way communication between the contractor's and CHSRA's project staff; and within the CHSRA team itself. It should be designed in such a way as to allow the CHSRA team to exercise due diligence in overseeing the work of the contractor. Specific requirements will be included within the contract requirements and provided to the contractors. To the extent possible, co-location will be utilized to facilitate effective communication. A partnering program will be used to measure the effectiveness of communications and cooperation within the teams and to resolve issues.

3.7.2 Control of Production and Service Provision

Contractors must obtain CHSRA acceptance of work-related submittals (plans, procedures, reports, shop drawings, etc.) in accordance with the submittals section of their respective contracts. Documented work instructions will define the manner of production and installation where the absence of such instructions could adversely affect quality. These work instructions may be required to adhere to applicable standards, such as welding specifications, non-destructive examination, heat treatment requirements, or special coating specifications.

All special processes performed by contractors or inspection and test laboratories will be identified, planned, and conducted under the required and applicable controlled conditions as specified in the contract documents. Before any special process begins, the qualified processes, equipment, and personnel involved will be documented by the contractors, and the documentation submitted to and approved by the Authority per contract requirements.

Contractors shall provide inspection of their work in accordance with the approved Quality Manual. Inspection of critical work that will be hidden by subsequent construction/installation activities will be documented by the contractor quality control staff.

Prior to beginning any definable segment of construction/installation work, contractor(s) will conduct a preparatory meeting to review the contract requirements, approved shop drawings, and other submittal data. Contractor(s) will also provide assurance that the required quality control testing will be provided, materials and equipment conform to approved shop drawings and submittal data, and all required preliminary work has been completed. These meetings should include members of the PCM and CHSRA staff, a member of the contractor's quality control staff assigned to inspect the work, the supervisor in charge of the work, and the individual(s) responsible for accomplishing the work.

3.7.3 Validation of Processes for Production and Service Provision

Special processes must be controlled and accomplished by qualified personnel using approved procedures and/or instructions in accordance with applicable codes, standards or specifications, and contractual requirements. Records of procedure and personnel qualification/certification shall be maintained in the project files.

When special processes are in use, contractor quality assurance personnel will verify personnel qualifications and the use of approved procedures through personal witness and through review and audit documentation. Records of verification will be maintained in the project files. Records

will be maintained for qualified processes, equipment, and personnel used. Monitoring of these processes and product characteristics may be performed through the use of surveillance, hold point inspections, report reviews, or audits as appropriate.

Quality managers should perform planned and systematic reviews or audits of processes and procedural compliance, where results of processes cannot be fully verified by subsequent inspection or testing of the product.

Contractors should identify special processes within the test plan portion of their Quality Manual. Controls, such as hold points that should be identified in the test plan.

3.7.4 Customer Property

When public and/or private property is placed under custody of the Authority or its contractors, then measures will be taken to assure such property is adequately protected during construction activities. Examples of such properties include existing utilities, railroad property, existing pavement and structures, corporate and private property, streams, lakes, natural areas, wetlands, and endangered and threatened species. CHSRA may find it necessary to enter into Intergovernmental Agreements (IGA), Interlocal Agreements (ILA), or Memorandums of Understanding (MOU) in order to obtain easements or products for work on state, county, city, or privately owned property adjacent to the project. Such arrangements, to include access control and maintenance and protection of this property, will be clearly defined within the AIG/ILA/MOU and passed on to the construction contractors.

Contractors' Quality Manuals should describe controls used to protect public and/or private property while in their possession.

3.7.5 Preservation of Property

Condition of materials, equipment, and other elements of the work in storage will be assessed at regular and appropriate intervals. Contractors will control the packaging, preservation, and marking processes (including material used) to the extent necessary to ensure conformance with the applicable requirements. Identification, preservation, and segregation of materials, equipment, and other elements of the work will extend from the time of final source inspection or receipt, until incorporation into the work.

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Construction contractors should establish and maintain written procedures for handling, storage, packing, and delivery of materials, equipment, and other elements of the work.

Contractors should prevent damage or deterioration of materials, equipment, and other elements of the work pending delivery, use, or incorporation into the work. Appropriate methods for authorizing receipt and the release to and from such areas will be stipulated in the Quality Manuals.

3.8 Element 8: Product Inspection and Testing

This section defines the requirements for inspection and test activities during receiving inspection and testing, in-process inspection and testing, final inspection and testing, and start-up testing. These requirements will be included in construction plans used in the program.

Contractors should submit a detailed test plan to meet contractual requirements, as described in their respective contracts.

3.8.1 Inspection and Test Plan

Contractors are responsible for identifying inspection and testing requirements and including them in the specifications. Contractors are also responsible for reviewing and recommending approval of startup and commissioning test results. Each contractor or supplier is responsible for providing an Inspection and Test Plan in its quality plan. The Inspection and Test Plan should address the following at a minimum:

- Identification of the individuals, group, or test laboratory responsible for performing the inspection or test
- Procedure for performing in-process inspections and testing of items to verify conformance to quality requirements throughout the duration of the process
- Procedure for source inspections at supplier or subcontractor plants
- Location of the inspection or test (e.g., on-site or off-site)
- Item to be inspected and characteristics and activities to be inspected or tested
- Description of the method of inspection or test including identification of required procedures, drawings, and specifications
- Acceptance (i.e., pass/fail) criteria
- Frequency of the required inspections or tests:
 - Where a sample is used to verify acceptability for a group of items, the sampling procedure shall be based on approved sampling practice

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- Inspection or test hold points, where work should not proceed without the specific consent of the appropriate quality representative, should be identified in the plan
- Procedure for performing first article inspections on the first production unit of all major components and systems to ensure compliance with the contract, requirements. Inspections should include engineering tests and physical examinations, and be performed , prior to delivery,

The CHSRA Quality Manager is responsible for reviewing and approving the contractors' quality plans, monitoring and verifying quality plan implementation, and all inspection and test activities.

The CHSRA shall implement appropriate compliance for auditing and/or inspections procedures that provide adequate confidence throughout the duration of the contracts to verify that contractual requirements are met, including those related to quality control and quality assurance. This also involves independent material inspection and testing, which is described in the Independent Assurance Plan.

As a recipient of Federal funds, certain projects within the CHSRP are subject to oversight by the FHWA and the FRA. Representatives of these agencies (including the PMOC if applicable) shall have the right to carry out verification of the CHSRA quality oversight activities on location and within corridors, or at any of the supplier locations for which Federal funds have been used. These audits shall not be used by the CHSRA as a substitute for their own quality oversight activities; nor shall they preclude subsequent rejection by the agencies used.

Contractors should establish and maintain documented procedures for identifying and controlling products delivered for use in construction/installation. Instructions relating to testing and inspection should include requirements to verify and record the identification of items, and for tracking test/retest status.

3.8.2 Monitoring and Measurement of Product

Testing will include qualification tests, factory tests, installation verification tests, material tests, demonstration tests, systems integration tests, and pre-operation tests. The CHSRA will provide oversight throughout the process.

Each individual who conducts an inspection or engineering analysis for or on behalf of the CHSRA will compile a detailed report. The details include date, location, type of inspection or service, and any other relevant information such as weather. Daily inspection reports will be reviewed by a supervisor to ensure accuracy. Records will be filed for a minimum of five years, or as required by the contract.

The inspection and testing personnel who verify conformance of work activities for the purposes of acceptance shall not be the same personnel who performed the work being inspected or tested. Inspection and testing personnel shall be qualified as necessary to perform the assigned inspection or testing task.

For certain types of work, contractors shall retain the services of an independent testing laboratory, qualified to conduct the types of testing required. The CHSRA will monitor the work through verification testing activities conducted by its own inspectors and qualified testing laboratory; however, this will not relieve contractors of their responsibility to provide for their own inspection and testing.

The CHSRA will verify whether final inspections identified in the contracts and the contractors' Quality Manuals are satisfactorily completed as projects progress and prior to project close-out and final payment.

Inspection and testing of workmanship, materials, and products that are verified for conformance to specified requirements shall be in accordance with the contract documents, quality control plan, documented procedures, and referenced industry standard procedures. Both inspection and process monitoring methods should be utilized as necessary to ensure that the specified requirements for the control of work process and the quality of the item are being achieved throughout the duration of the work.

Upon completion of work or fabrication of a product, final inspection and testing shall be carried out and properly documented. The extent of final inspections can vary with the amount of in-process inspection, safety criticality of the product, and confidence in the quality history of the supplier. Final inspection and testing shall ensure that all specified inspections and tests, including those specified for intermediate fabrication stages, have been carried out and that the product or workmanship meets acceptance criteria, as stated in relevant specifications.

Records of the various inspections and tests must be maintained to provide traceability and evidence that the product has passed inspections and/or tests using defined acceptance criteria.

Testing requirements should be included in the specifications, including references to testing standards and procedures, frequency and location, requirements for witnessing of tests, and whether source inspection and/or testing is required prior to shipping.

Appropriate forms shall be developed and used to record all measurements and observations for each material inspection. When required, certifications are to be attached to these forms. Final acceptance of the product and/or workmanship should be recorded by the QC department and endorsed by the contractor's Quality Manager prior to incorporation into the work.

Quality control units of contractors, suppliers, fabricators, and manufacturers will be responsible for coordinating and/or performing inspection and testing, as specified by contract documents. The Design Build contractor will be the ultimate responsible party to ensure adequate inspection and testing has been performed for their scope of work. The Quality Manager of each entity will verify and document that items are inspected and tested properly. Documentation of all inspection and testing activities is to be retained as quality records.

The Authority will perform document verification reviews to ensure adequate requirements for inspection and testing are contained in contract documents and procurement specifications. In addition, the Authority, at its discretion, may perform independent verification inspection and

testing and may monitor the contractor's or supplier's testing and inspection activities for the project.

Prior to incorporating materials or products into the work, it is the responsibility of the contractors to verify that the products are in conformance with the requirements. Verification shall be in accordance with the contract documents, quality control plans, and/or documented procedures as applicable.

The CHSRA Quality Manager will conduct oversight monitoring to verify that appropriate examinations, tests, measurements, and inspections are being properly performed and documented by the contractors, independent testing laboratory, and Resident Engineer or inspector.

The results of the oversight monitoring will be documented in accordance with the program QMS requirements.

Where products or materials fail to meet any design criteria or contractually imposed specification during inspection or testing, the procedures for non-conformances will apply. Details of non-conformance control are described in Element 11 of the MQP.

Manufacturers and construction contractors should submit certified inspection and testing reports to the CHSRA and (or) their designees for review and archival in the project files. These reports shall be numbered sequentially and traceable to the contract, location, lot, part, and retest number (as applicable).

3.9 Element 9: Inspection, Measuring, and Test Equipment

This section defines requirements for calibration of inspection and testing equipment used in the CHSR program.

Prime contractors should require their subcontractors to implement equivalent procedures to adopt the prime contractor's procedures. Contractors will control, calibrate, and maintain inspection, measuring, and test equipment to ensure conformance of equipment with industry standards and other applicable requirements. Inspection, measuring, and test equipment used by the contractors should be of a quality and capacity, which ensures that measurements made are to acceptable levels of accuracy and precision. Contractors should, at a minimum:

- Identify the measurements to be made, determine the accuracy required, and select the appropriate inspection, measuring, and test equipment.
- Identify, calibrate, and adjust all inspection, measuring, and testing equipment and devices that can affect product quality, at prescribed intervals and prior to use. The equipment and devices shall be tested against certified equipment and measurement standards of the National Institute of Standards and Technology or other similar recognized technical standards customarily accepted in the industry. Where no standard exists, the basis for

calibration will be developed in writing based upon the best-available information and technology.

- Establish, document, and maintain calibration procedures, including details of equipment type, identification number, location, frequency of checks, checking methods, acceptance criteria, and action to be taken when results are unsatisfactory.
- Ensure that inspection, measuring, and test equipment is capable of and regularly calibrated to obtain the required levels of accuracy and precision.
- Identify inspection, measuring, and testing equipment with a suitable indicator or approved identification record to show the calibration status.
- Maintain current calibration records for inspection, measuring, and test equipment.
- Assess and document the validity of previous measurements, inspections, and test results when inspection, measuring, and test equipment is found to be out of calibration.
- Ensure that environmental conditions are suitable for the calibrations, inspections, measurements, and tests being carried out.
- Ensure that the handling, preservation, and storage of inspection, measuring, and test equipment is such that the accuracy and fitness for use is maintained.
- Safeguard inspection, measuring, and test equipment and facilities, including both test hardware and test software, from adjustments, which would invalidate the calibration setting.

Where test hardware, such as jigs, fixtures, templates, patterns, or test software, are used for inspection and testing purposes, they should be checked to establish they are capable of verifying acceptability, prior to release for use, and should be rechecked at regular and prescribed intervals, as required. Contractors will establish, in accordance with good industry practices, the extent and frequency of such checks and maintain records as evidence of control. Measurement data should be made available, where required by the designer, for verification that the design is functionally adequate.

The CHSRA Quality Manager will monitor contractors' and suppliers' calibration and control processes of inspection, measuring, and testing equipment for compliance with the contract specifications, the Independent Assurance Plan, the contractors' and suppliers' approved quality plans.

Construction contractors should document their procedures for identification, control, calibration, and maintenance of inspection, measuring, and test equipment within their Quality Manuals submitted to the PCM and the CHSRA for approval.

3.10 Element 10: Inspection and Test Status

Requirements for maintaining status of inspection and testing of workmanship, materials, and products shall be included, where applicable in contract documents. In order to accomplish

those requirements, an adequate inspection and test plan will need to be developed by the entity performing the work and approved by the Authority. The plan is to describe the work item and all applicable tests and inspections and is to be in accordance with contract requirements. Individuals authorized to perform inspections and tests should have their qualifications included in the plan.

During the course of project execution, inspection and testing will be carried out in accordance with contract documents, applicable quality plans, inspection and test plan, and any referenced standards. The extent of final inspections and testing, which may vary with factors such as the amount of in-process inspection and safety criticality of the product, is addressed in Section 3.8.

The test and inspection status should be identified by suitable means such as physical markings, attached tags, etc. The status identification indicates the conformance or non-conformance with regard to inspections and tests performed. Nonconforming materials, products, or constructed works should be recorded with their location noted on inspection reports or non-conformance reports as applicable. The status of in-process, completed, tested, and inspected items should be maintained as quality records.

Contractor surveillance and inspection personnel should verify and document that items are as identified in applicable certifications, approved shop drawings, and reports (qualification and functional test reports, data reports, nondestructive examination reports, etc.). Additionally, all correspondence between the CHSRP and the contractors will be traceable to the contract number.

Contractors and suppliers will establish procedures for identifying the inspection and test status of materials, parts, components, equipment, and products during production and installation to ensure that only work that has passed inspections and tests is incorporated into the project. These procedures, as described in specific contract documents, will be submitted to the Authority for review and approval.

Identification of inspection and test status will be the responsibility of the entity inspecting or testing the particular work element. However, the Design-Build contractor is the ultimate responsible party to ensure proper recording of inspection and test status at all stages of production and installation for their scope of work.

The Authority will perform verification reviews to ensure adequate requirements for inspection and test status are contained in contract documents and procurement specifications. Additionally, the Authority may monitor the contractor's or supplier's testing and inspection activities for the project to ensure proper maintenance of inspection and test status by the contractors and all parties involved.

3.11 Element 11: Non-conformance

This section defines the requirements for controlling design, workmanship, materials, parts, or components that do not conform to specified requirements. The intent is to ensure that nonconforming items are identified, documented, segregated, and dispositioned to prevent use

or installation. When appropriate, a preventive action (see Section 3.12) may be required to prevent recurrence of the non-conformance.

Nonconforming items, whether identified by contractors or the CHSRA, will be dispositioned as follows:

- **REJECT:** The item is unsuitable for its intended use and economically or physically incapable of being repaired or reworked.
- **REWORK:** The item can be brought into conformance with the original requirements.
- **REPAIR:** The item can be made acceptable for its intended purpose; however, it will not meet all requirements.
- **USE-AS-IS:** The item can be used without modifications and will continue to meet all engineering functional requirements for safety, performance, and fit.

Contractors will develop procedures for correcting non-conformances issued as REJECT or REWORK. Any recommendation for REPAIR or USE-AS-IS may require concurrence of the Designer of Record, with analysis:

1. Confirming that the work will meet its original intent with no detriment to public safety.
2. Identifying any long term durability issues.
3. Proposing an equitable adjustment for acceptance of the nonconforming work. Regardless of the contractor's recommendation, final acceptance of nonconforming work is at the sole discretion of the CHSRA.

Items that have the disposition of REWORK or REPAIR will be inspected and verified by the contractor's QA/QC staff the CHSRA prior to close out.

When practicable, nonconforming work should be segregated. When segregation is not practicable, the nonconforming work should be clearly identified as such.

Nonconforming conditions, whether they are materials, products, or actions, should be documented, and the CHSRA should be notified at the earliest opportunity. The non-conformance report (NCR) must include details of the root cause of the non-conformance and the actions that will be taken to prevent recurrence. Every entity providing products or services to the CHSR program shall keep a log of nonconforming conditions, with traceability to the original findings, disposition, corrective action, and engineering evaluations as applicable.

Entities providing services or products to the CHSR program are responsible for developing a set of non-conformance procedures in accordance with this document.

The CHSRA may also identify non-conformances to the contract. . When this occurs, the CHSRA will document non-conformances through the use of a database. A hardcopy of the non-conformance report will be forwarded to the CHSR Document Control for internal recordkeeping, and the original forwarded to the contractor for recommended disposition. The CHSRA retains authority for final acceptance of the recommended disposition.

The Quality Manager of the entity responsible for the non-conformance is responsible for proposing the disposition of non-conformances. If the disposition of the non-conformance is “repair” or “use as-is,” the disposition should be approved by the CHSRA Quality Manager, with concurrence from the Quality Manager of the prime contractor/consultant and the Engineer of Record. The Quality Manager of the prime contractor/consultant is responsible for approving any disposition proposal and submitting it to the Authority. The CHSRA Quality Manager is responsible for the review and final approval of the non-conformance resolution. The CHSRA Quality Manager also monitors the contractor and supplier quality control procedures for controlling and processing non-conformances, and ensures that they are properly discovered, addressed, and documented.

Contractors should establish and maintain procedures within their Quality Manual for uniform reporting, controlling, and disposition of non-conformances. Procedures should be established to prevent the use or installation of nonconforming material, equipment, or other elements of the work. Control procedures should provide for identification, evaluation, segregation, and, when practical, disposition of nonconforming material, equipment, or other elements of the work; and for notification to the contractor’s Project Manager, CHSRA, and all personnel involved in the affected work. Contractors will provide access to original copies of all reports dealing with nonconforming items for review by the CHSRA.

3.12 Element 12: Corrective Action

The CHSRA will implement corrective action procedures and preventative action procedures to address deficiencies, level of risk, and the Authority’s interest. Additionally, when opportunities for improvement within the program are identified through internal audits, third party audits, documented lessons learned, or other means, the CHSRA will initiate an “Improvement Action” plan. This will require the responsible party to investigate the matter and propose a solution. Improvement Actions will require follow-up to determine the effectiveness of the proposed approach. If necessary, alternative approaches will be implemented to achieve acceptable results.

3.12.1 Corrective Action

All contractor and supplier quality plans shall include provisions to implement corrective actions, as appropriate, when non-conformances are identified. Such action should include an investigation by the consultants or contractors to determine what caused the deficiency or non-conformance, and what will be done to prevent its reoccurrence. Root cause analysis should be used by management to identify trends, based on analysis of non-conformances and audit findings. Corrective actions shall be tracked in the NCR database for proper disposition, closure, and use for additional preventive actions.

In the event of a non-conformance, existing work procedures need to be evaluated for potential revisions to prevent recurrence of the nonconforming cause. Furthermore, those procedure revisions should include preventive actions to eliminate other potential causes of future non-conformance or for improving processes. The procedures will be detailed in order to address the following:

- Root causes of the non-conformance
- Disposition of the specific non-conformance at hand
- Methods or provisions to prevent recurrence of the issue
- Implementation of the corrective action
- Monitoring of the effectiveness of the corrective action

If the CHSRA Quality Manager determines that a breakdown has occurred in the implementation of contractor's quality management system that could have adverse impact on project quality, CHSRA Project Managers may initiate a non-conformance report (NCR). The NCR shall be forwarded to the contractors, with copies sent to document control. The consultants or contractors will investigate the case and will implement corrective actions subject to approval by the CHSRA Quality Manager.

If the corrective action proves ineffective, disciplinary measures may be invoked in accordance with the contract.

Contractors should describe their corrective action procedures within their Quality Manuals submitted to CHSRA.

3.12.2 Preventive Action

Preventive actions consist of steps taken, prior to or after award of a contract, to eliminate the causes of potential non-conformances in order to prevent their occurrence. Such steps may include evaluation of quality programs prior to contract award, improvement of testing and inspection programs, regular quality meetings, quality audits, improved designs, lessons learned action plans, and additional certifications for personnel and subcontractors performing special processes. A preventive action may include the following:

- Determining potential non-conformances and their causes
- Evaluating the need for action to prevent occurrence of non-conformances
- Determining and implementing action needed
- Records of results of action taken
- Reviewing the effectiveness of the preventive action taken

Opportunities for improvement are best identified through internal and external quality audits, effective testing and inspection programs, and regular quality meetings.

Contractors should describe their preventive measures within their Quality Manuals submitted to the CHSRA.

3.12.3 Improvement Responsibility

The Quality Manager of the entity performing work is responsible for proposing and subsequently implementing the appropriate improvement, corrective, and (or) preventive actions in response to the deficiency or lessons learned.

The prime contractor/consultant is the responsible party to approve the corrective or preventive action. In addition, the prime contractor's Quality Manager will ensure that any corrective or preventive action is properly documented and adequate changes in work procedures are implemented to prevent recurrence of similar non-conformance. Findings from root cause analyses will be used for continual improvement initiatives.

The CHSRA Quality Manager will verify proper implementation of corrective/preventive action to eliminate the potential causes of non-conformances.

Each entity is responsible for maintaining a log of all non-conformance cases with status of each case clearly identified. The log will include description of each case, status of the root cause analyses, disposition of affected work, and steps taken to prevent recurrence in the future. On a monthly basis, the prime contractor will provide a log of all non-conformances and corrective and preventive actions to the CHSRA.

3.13 Element 13: Quality Records

3.13.1 Control of Quality Records

Quality records constitute documents that demonstrate evidence of compliance of goods and services to specified acceptance criteria and approved procedures. Entities shall identify quality records by title, contract number, revision, and activity description.

Typical quality records include but are not limited to:

- Audit reports and audit finding reports
- Approved shop drawings
- As-built drawings
- Certificates of compliance
- Certifications (process, equipment, personnel, and material)
- Change orders
- Contract specifications
- Contractor submittals
- Concrete pour records

- Corrective action reports
- Cost estimates
- Daily inspection reports
- Diaries
- Design procedures and manuals
- Design criteria
- Design review reports
- Design deviations and changes
- Design calculations and checks
- Design submittals
- Drawings (design, shop fabrication, as-built)
- Field test reports
- Laboratory test records
- Lessons-learned action plans
- Logs
- NEPA documentation
- Non-conformance notices
- Official correspondence (project)
- Planning reports
- Procurement documents
- Quality plans and manuals
- Quantity take-off check prints
- Release for shipment notices
- Safety certification documentation
- Supplier quality verification records
- Surveillance inspection reports
- Test witness reports
- Project photographs and videos

Quality records will be validated through means such as stamps, initials, or signatures of the appropriate personnel. All quality records shall be dated. If corrections/revisions to quality

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records are necessary, they should be subject to the same review and approval requirements as the original document.

Quality records shall be identified, collected, and stored in an easily retrievable manner. The CHSRA design review/audit/inspection results will be stored in an approved database, accessible through the internet.

Records in electronic format should be regularly backed up and stored to ensure their safety from deterioration and damage. Storage facilities should be protected from environmental hazards, including fire and moisture. Retention requirements for the quality records should be specified in contract documents. The Authority retains the right to inspect quality records at any time.

Contractors/suppliers should safeguard quality records during design, construction, assembly, installation, and testing. Quality records shall be submitted to the CHSRA for review and archival in accordance with the Contract submittal requirements.

Contractors should maintain quality records that are readily retrievable. At all times throughout the contract, quality records should be available upon request, and may be subject to review by the CHSRA quality assurance

3.13.2 Management of Quality Records

The Quality Manager of the entity responsible for the work should be responsible for quality assurance of the quality records.

Unless otherwise stated in the contract, Quality Records should be turned over to the CHSRA as work progresses. Entities shall retain copies of the records for specified periods. The Authority will retain these records for a retention period as required.

3.14 Element 14: Quality Audits

The CHSR program shall establish a program of documented internal and external quality audits to verify that quality activities being performed by and for the program to meet the commitments of the QMS. These audits shall be used to provide feedback on the implementation and effectiveness of the QMS and confirm that discrepant conditions are addressed by comprehensive and verifiable corrective action. The CHSR program Quality Manager will perform or oversee the audit activities.

Quality audits will verify the effectiveness of the implementation of the quality program and overall compliance with contractual requirements and the approved quality plan.

Audits will consist of thorough reviews of documentation, procedures, and policies included in the quality plan. Quality audits will be scheduled at frequencies appropriate to the status and importance of the activity. Those schedules will be distributed to all participating entities in

advance of the audit. A checklist describing the scope of the audit will be provided to the entity prior to the audit.

Initial findings of the audit will be provided to the auditees at a debriefing meeting. The auditee will have the opportunity to clarify/refute the findings at this time. Audit findings may be classified as either deficiencies that require action to be taken or recommendations for continuous improvement. An audit report shall be written summarizing the issues. The lead auditor will sign and submit the final audit report to the entity's Quality Manager for approval. A follow-up audit shall be conducted to evaluate the implementation of the resolutions of the initial audit's findings.

An entity's audit unit is in charge of conducting audits. In the absence of an audit unit in an entity's organizational structure, the Quality Manager will be responsible for audits to be conducted. Entities are responsible for conducting audits of organizations under contract to them. Entities are also responsible for conducting internal audits of their own quality program.

A lead auditor will be assigned by the entity conducting the audit. The lead auditor assigned is responsible for all elements of the audit, including audit schedules, plans, reports, and checklists, as applicable. The lead auditor will schedule follow-up audits. The lead auditor will ensure audit records are maintained as quality records. Audit records will include audit schedules, checklists for quality audits, audit reports, written replies to the report and the record of completion of corrective action.

Audit product may be report or summary letter at discretion of the lead auditor.

3.14.1 Internal Audits

The CHSRA will monitor its key management processes through an internal quality audit program established with the assistance of its Program Management Team (PMT). Results from these audits will be analyzed during program reviews in an effort towards continuous improvement.

CHSRA's key management processes are typically those described within the CHSRA Program Management Plan, and supporting documentation. Examples include design, construction, procurement, contract management, project controls, quality management, public information, and inter-agency coordination.

Contractors should describe their own internal auditing procedures within their Quality Manual for the respective project.

3.14.2 External Audits

In preparation for a contractor or supplier audit, auditors shall review the relevant contractual and technical documents used in the execution of the contract and the results of previous audits, if applicable. From this document review, a checklist will be developed to ensure that a comprehensive audit is accomplished. The relevant documents may include the following:

- Quality assurance and quality control plans
- Project procedures and instructions
- Drawings, specifications, and calculations
- Industry standards (e.g., ASTM, ACI, Caltrans, etc.)

Prior to the execution of an external audit, the contractors or suppliers are notified of the time, duration, and scope of the audit. The audit will include an entry meeting held to familiarize the project team with the audit process, a follow-up meeting to discuss the draft audit report, and an exit meeting to summarize the findings and the steps forward. The contractors are ultimately responsible for notifying subcontractors and suppliers about the audit requirements.

Following completion of an audit, an audit report will be written by the participating QA auditor or technical specialist. The audit report will identify the scope of the audit, audit results, and corrective action, and will include a quantitative and qualitative assessment of the effectiveness of the auditee's quality program. The audit report will be prepared and issued after the audit exit meeting. The audit report will be provided to the audit unit, the CHSRA Quality Manager, and contractors or suppliers having responsibility in the audited area. The audited organization will have one month to respond to the audit report.

Follow-up verification that corrective action has taken place will occur if the audited organization does not provide objective evidence with its response to the audit finding.

Contractors should describe its production and management process monitoring tools, including the use of statistical techniques when applicable, within their quality plans.

3.14.3 Analysis of Data

The CHSRA will maintain a database of all audit and inspection findings that will allow analysis of trends and verification of closure for all non-conformances. Based on this data, frequency of compliance audits and/or inspections for various contractor activities may be increased or decreased.

Contractors should describe their data analysis procedures within their respective Quality Manuals.

3.15 Element 15: Training

All personnel performing activities affecting quality should be qualified on the basis of appropriate education, training, and/or experience, as applicable to their scope of work and as determined by the contract documents.

Training needed to maintain professional certifications and credentials shall be evaluated and approved by the individual entities in accordance with federal and state regulations.

All organizations within the program shall establish and maintain procedures to assess qualification and competence of their staff, to identify training needs, and to provide for the training of all personnel performing activities affecting quality of the Program. Those procedures should ensure that personnel performing the work have the appropriate qualifications.

The effectiveness of training should be evaluated by the Quality Manager of the individual entities. Training and qualification records are considered quality records and are subject to the requirements found in Section 3.13.

The CHSRA will ensure that specific qualification and training requirements for personnel are included in relevant contracts. The CHSRA Quality Manager will perform verification reviews to ensure the appropriate personnel qualification and training requirements are included in procurement contracts.

The Quality Manager of each entity will verify that the training and qualification procedures are established and implemented.

Resumes for QA staff should be included within the contractors' Quality Manuals, as well as qualifications for personnel who check the work of others.

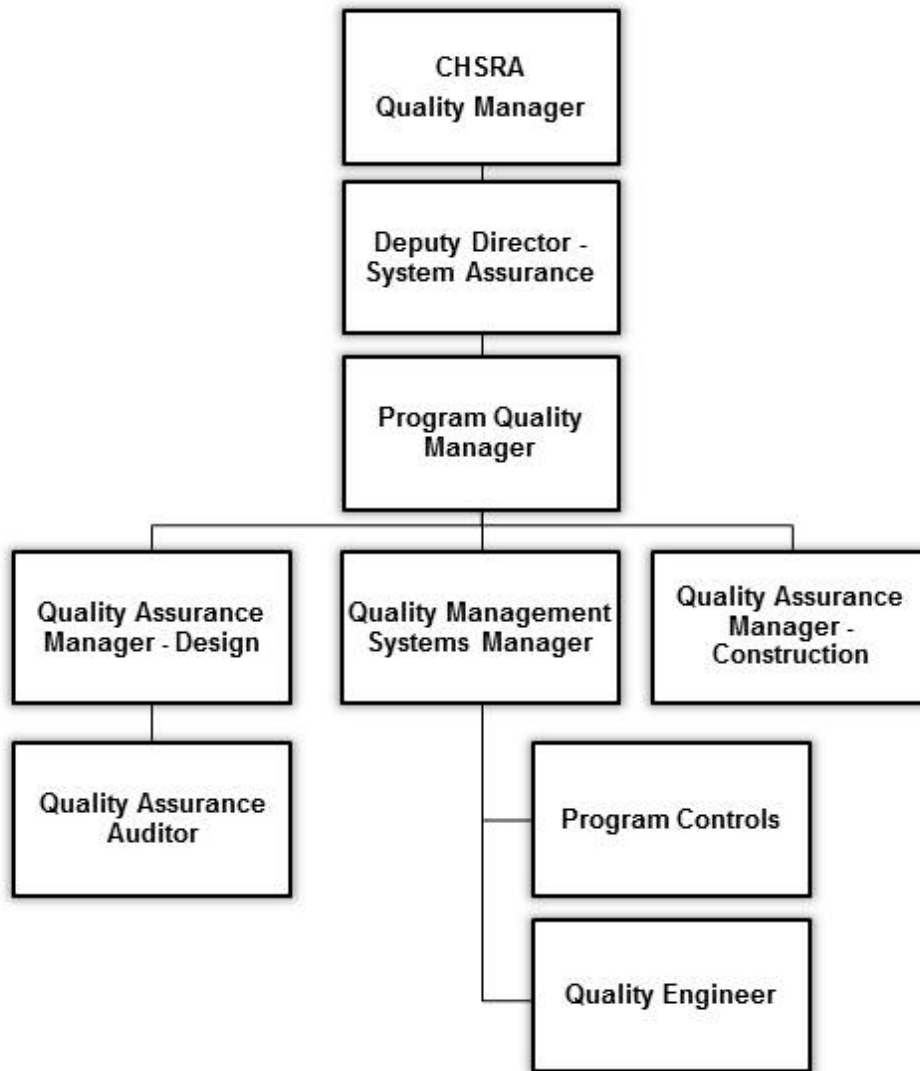
Contractors should describe their methods for providing and documenting training on project QA procedures and standards for all personnel assigned to the project (including subcontractors).

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Appendices

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Appendix A – CHSRA Quality Management Organization Chart



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