

# Quality Management Plan (Rev 0) Globeville Landing Outfall Project

## Vasquez Boulevard/Interstate 70 Site, Operable Unit #2 Removal Action

Prepared for:

**City and County of Denver  
Environmental Quality Division  
200 West 14th Ave, Suite 310  
Denver, Colorado 80204**

Prepared by:

**Engineering Management Support, Inc.  
7220 West Jefferson Avenue, Suite 406  
Lakewood, CO 80235**

February 2016 – January 2017

Approved by:

USEPA Remedial Project Manager

\_\_\_\_\_  
Dania Zinner

\_\_\_\_\_  
Date

USEPA Region 8 QA Manager

\_\_\_\_\_  
Linda Himmelbauer

\_\_\_\_\_  
Date

Engineering Management Support, Inc.

  
\_\_\_\_\_  
Paul V. Rosasco, P.E.  
President

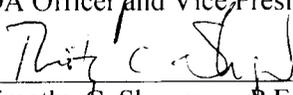
2-22-16  
Date

Engineering Management Support, Inc.

  
\_\_\_\_\_  
Robert T. Jelnek, P.E.  
QA Officer and Vice President

2-22-16  
Date

Engineering Management Support, Inc.

  
\_\_\_\_\_  
Timothy C. Shangraw, P.E.  
Vice President

2/22/16  
Date

## TABLE OF CONTENTS

1	INTRODUCTION .....	1
1.1	Commitment to Quality.....	1
1.2	QA Program Principles .....	1
1.2.1	Client Satisfaction.....	1
1.2.2	Employee Participation.....	2
1.2.3	Problem Prevention.....	2
1.2.4	Continuous Quality Improvement.....	2
1.3	Quality Assurance Program Components .....	3
1.4	QMP Objectives .....	3
1.5	QMP Scope and Organization.....	4
2	QUALITY MANAGEMENT SYSTEM .....	5
2.1	General .....	5
2.2	Management Commitment.....	5
2.3	Management Organization and Responsibilities.....	6
2.3.1	President.....	6
2.3.2	Quality Assurance Officer .....	6
2.3.3	Project Manager.....	7
2.3.4	Project Quality Control Review.....	8
2.3.5	Task Manager.....	9
2.4	Personnel Qualifications, Development, and Training .....	9
2.4.1	Internal Programs.....	9
2.4.2	External Programs.....	10
2.5	Project Management.....	10
2.6	Subcontractor Management.....	11
2.7	Document Control and Records Management .....	12
2.8	Computer Hardware and Software Systems.....	12
2.9	Work Processes and Systems .....	13
2.10	Quality Control Review .....	14
2.10.1	Project Scope and Objectives.....	15
2.10.2	Report Outline.....	16
2.10.3	Data Collection Rationale .....	16
2.10.4	Data Collection Methods .....	16
2.10.5	Factual Conclusions/Findings .....	16
2.10.6	Opinions and Recommendations .....	17
2.10.7	Technical Reviews and Professional Registrations .....	17
2.10.8	Standard of Practice .....	17
2.10.9	The Client's Perspective.....	17
2.11	Management Assessment .....	17
2.11.1	Quality Assurance Audits .....	18
2.11.2	Corrective Actions .....	19
3	DATA ACQUISITION AND MANAGEMENT .....	20
3.1	General .....	20
3.2	Planning and Scoping.....	20

3.3	Data Collection Systems Design .....	22
3.4	Planning Documents .....	23
3.4.1	Work Plan .....	23
3.4.2	Field Sampling Plan (FSP) .....	24
3.4.3	Quality Assurance Project Plan .....	24
3.4.4	Health and Safety Plan (HASP) .....	25
3.5	Implementation of Data Acquisition Activities .....	25
3.5.1	Sample Custody .....	26
3.5.2	Calibration Procedures .....	26
3.5.3	Internal Quality Control Procedures .....	26
3.5.4	Preventive Maintenance .....	27
3.5.5	Procurement Control .....	27
3.5.6	Geospatial Data .....	27
3.6	Assessment of Data Usability .....	28
3.6.1	Data Reduction .....	28
3.6.2	Data Validation .....	29
3.6.3	Data Reporting .....	30
3.6.4	Data Assessment .....	30
3.7	Performance and System Audits .....	30
3.8	Corrective Actions .....	32
4	DESIGN, CONSTRUCTION, OPERATION OF ENGINEERED SYSTEMS .....	33
4.1	Project Planning and Scoping .....	33
4.2	Project Organization .....	34
4.3	Design Phase Quality Control Reviews .....	34
4.3.1	Design Document QC Checking .....	35
4.3.2	Quality Control Reviews .....	35
4.3.3	Value Engineering Reviews .....	36
4.3.4	Constructibility/Biddability Reviews .....	36
4.4	Construction Phase Quality Control Reviews .....	37
4.5	Operations and Maintenance Procedures .....	37
4.6.1	Procedures/Responsibilities for Inspection and Acceptance Testing .....	39
4.6.2	Procedures for Tracking Inspection and Acceptance Test Results .....	39
4.6.3	Tracking Deficiencies .....	40
4.6.4	Field Reporting System .....	40
4.6.5	Testing Procedures .....	40
4.6.6	Calibration and Control of Measuring and Testing Equipment .....	41
4.7	Corrective Actions .....	41
5	REFERENCES .....	43

## LIST OF TABLES

Table 1 - Comparison between QMP and EPA Requirements for Quality Management Plans

## LIST OF FIGURES

Figure 1 - Functional Organization Structure

## APPENDIX A – STANDARD OPERATING PROCEDURES

Document Control Procedures

Control of External Documents

General Checking and Review Procedure

## APPENDIX B

Form B-1: Project Planning and Scoping Checklist

Form B-2: Quality Control Review Checklist

Form B-3: Quality Assurance Audit Checklist

Form B-4: Quality Assurance Audit Form

## LIST OF ACRONYMS

ANSI	American National Standards Institute
ASQC	American Society for Quality Control
ASTM	American Society for Testing and Materials
CQAP	Construction Quality Assurance Plan
DQO	Data Quality Objective
EPA	U.S. Environmental Protection Agency
FSP	Field Sampling Plan
HASP	Health and Safety Plan
EMSI	Engineering Management Support
O&M	Operation and maintenance
PARCC	Precision, accuracy, representativeness, comparability, and completeness
PPM	Project Procedures Memorandum
QA	Quality Assurance
QMP	Quality Management Plan
QAPP	Quality Assurance Project Plan
QC	Quality Control
SAP	Sampling and Analysis Plan
SOP	Standard Operating Procedure
UST	Underground storage tank

# 1 INTRODUCTION

## 1.1 Commitment to Quality

Since its founding in 1994, Engineering Management Support (EMSI) has had a strong commitment to quality. EMSI is dedicated to the achieving technical and management excellence and to delivering professional environmental and engineering services that meet or exceed our clients' needs. Our Quality Assurance (QA) Program has evolved in response to client needs, an evolving state of the practice, and concerns regarding liability.

This Quality Management Plan (QMP) describes EMSI's QA Program, which is based on four principles: client satisfaction, employee participation, problem prevention, and continuous quality improvement. These principles are discussed below and embodied in our corporate quality vision, which states:

*Commitment to client needs and expectations,  
from all EMSI team members,  
provides technically competent, timely and  
cost-effective solutions.*

## 1.2 QA Program Principles

EMSI's QA Program establishes minimum quality standards for performance and procedures for assuring that our clients receive quality service. EMSI's QA Program requires the participation of employees at every level. It encourages Project Managers and technical staff to take pride in their work and responsibility for ensuring that the work is done correctly the first time. The program is designed to reduce the incidence of problems related to quality and result in implementation, where necessary, of corrective actions and modification of work procedures, where necessary, to reduce the incidence of future problems.

### 1.2.1 Client Satisfaction

Client satisfaction is achieved when EMSI meets or exceeds the expectations of the client. Quality standards are typically established for each project based on the client's industry or business practice, regulatory requirements affecting the industry and project, and the professional standard of care. In addition to the technical aspects of a project, EMSI Project Managers concentrate their management efforts on responsiveness, timely delivery, and cost effectiveness.

A proactive approach to the client's needs and expectations is the key to client satisfaction. The Project Manager is the primary point of contact: EMSI's Project Managers are urged to work closely with their clients to assess client needs and receive feedback on project performance.

### 1.2.2 Employee Participation

EMSI recognizes the value of having its employees at all levels participate in the QA program. Opportunities are continuously sought for encouraging employees to improve the quality of their work. EMSI's President encourages participative management by soliciting input from project managers and staff before issuing company policies and procedures.

### 1.2.3 Problem Prevention

Through its QA Program, EMSI reduces the potential for problems to occur. The procedures in EMSI's QA Program are, therefore, based on the principles of problem prevention, liability reduction, risk management, and loss prevention.

The steps necessary to assure the quality of EMSI work products and services are summarized below:

- Make sure the work performed will satisfy the client's objectives;
- Perform work correctly the first time;
- Have all work checked;
- Correct errors where they occur;
- Modify work processes to reduce or eliminate future errors; and
- Demonstrate that the QC procedures have been followed through QC review signatures and QA audits.

### 1.2.4 Continuous Quality Improvement

The final principle of EMSI's QA Program is continuous quality improvement. The QA Program advocates systematic planning, implementing, assessing, and correcting in an incremental process that results in a net long-term improvement. Continuous implementation of activities designed to achieve this principle results in higher value to our clients over time.

### 1.3 Quality Assurance Program Components

EMSI's QA Program consists of the following related components, summarized below:

- **Assignment of Responsibilities** - The Company designates personnel with the responsibility and authority to implement the QA Program. Roles and authorities are clearly defined. All staff levels have responsibilities under the program.
- **Training and Development** - Quality awareness seminars are part of the EMSI employee training program. Topics covered include project planning, QC procedures, client relationships, liability issues, and loss prevention. In addition, training on the fundamentals of project management problem/loss prevention is available to Project Managers.
- **Written Policies and Guidance** - The company maintains written guidance including procedures for many commonly performed work activities. These documents serve to assist project managers and staff to provide a quality of service that meets or exceeds the standard of practice.
- **Quality Control Review** - EMSI projects are assigned a QC reviewer responsible for assuring that project processes and documents have been properly reviewed by qualified professionals. Problems are communicated to the Project Manager and corrected.
- **Quality Assurance Audits** - EMSI projects are subject to unannounced audits to assure project procedures including QC review are followed at all times.
- **Work Process Analysis** - Where a need for improvement is identified, EMSI staff will analyze the problem and develop ways to improve EMSI management and project systems. Efforts to simplify work processes, while maintaining high quality standards, are ongoing.
- **Change Management** - Recommended quality improvement measures identified by work process analysis are communicated to EMSI staff.

### 1.4 QMP Objectives

The QA Program described in this QMP is designed to monitor the effectiveness of EMSI's engineering and environmental data collection operations; report preparation; and the design, construction, operation, and monitoring of engineered systems. Where necessary, the QA Program is designed to correct situations where corrective actions are required.

This QMP was developed to achieve three primary objectives.

- It defines EMSI's QA Program. The QMP is designed to be responsive to federal government agency quality standards, while addressing industry standards. See Table 1 for a comparison between this QMP and EPA Requirements for Quality Management Plans (EPA QA/R-2). The EMSI QA Program will be consistent with EPA Order 2105 (Mandatory Agency-Wide Quality System), EPA 2105P (EPA Quality Manual), EPA Order 2106 (Quality Policy) and QA/R-2 (EPA Requirements for Quality Management Plans). These documents are referenced as the foundation for implementing quality assurance for the Vasquez Boulevard I-70 Operable Unit 2 project.
- It is a “bridging document” between EMSI’s QA policy, our procedures and guidelines, standard operating procedures (SOPs), and project Quality Control (QC) procedures.
- It establishes a framework for planning and implementing EMSI projects so that quality standards of the client and relevant regulatory agencies are met.

To assure that EMSI’s QA Program remains adequate for the type of work being performed by EMSI, this QMP and attached QA documents will be reviewed annually by EMSI’s QA Manager.

## 1.5 QMP Scope and Organization

The scope of the plan encompasses the QA aspects of EMSI's science and engineering operations. The manual follows a three-part format used by ANSI/ASQ-E 2014 for Quality Assurance of Environmental Programs:

- Quality Management System - Common QA Program elements, regardless of the type of project, are described in Section 2.
- Data Acquisition and Management Program elements related to planning, implementing, and assessing operations to collect, analyze, and evaluate physical, chemical, biological, geological, ecological, and engineering data, are described in Section 3.
- Design, Construction, and Operation of Engineered Systems Program elements that pertain to the design, construction, and operation of engineered processes or systems are described in Section 4.

## 2 QUALITY MANAGEMENT SYSTEM

### 2.1 General

Implementation of any quality program requires a management system available to all Project Managers, regardless of the client, project type or phase of project operations. Elements of this system include:

- Management commitment;
- Management organization;
- Written policies, procedures, and guidance;
- Personnel qualifications, development, and training;
- Project management;
- Subcontractor management;
- Document control and records management;
- Computer hardware and software systems;
- Work processes and systems;
- Quality control review; and
- Management assessment.

This section describes these key elements of EMSI's Quality Management System. Some of these elements are addressed in more detail in Sections 3 and 4 as they pertain to project execution.

### 2.2 Management Commitment

EMSI management is committed to the principles and practices of its QA Program at the highest level. Senior management recognizes and accepts its responsibility to identify the quality requirements that will meet client needs and expectations and create the business and professional environment where all employees take responsibility for the quality of their work. EMSI's QA Program focuses on preventing quality problems.

## 2.3 Management Organization and Responsibilities

The QA management system is independent of EMSI administrative and project management systems: it receives its authority directly from the President.

An organization chart showing key QA positions is presented on Figure 1. The following sections describe QA personnel roles and responsibilities.

### 2.3.1 President

The President is ultimately responsible for all quality-related functions. The President's QA responsibilities are to:

- Authorize the issuance of the QA Policy;
- Direct the implementation of QA objectives, plans, and policies;
- Approve the issuance of this QMP;
- Appoint the Quality Assurance Officer who directs the QA Program; and
- Approve the QA implementation strategy.

### 2.3.2 Quality Assurance Officer

The QA Officer manages the QA Program and is responsible for the technical quality of all work products in the company and the development and maintenance of a sufficient level of technical resources to support the company's quality objectives. The QA Officer reports to the President and has the authority to halt the transmittal of any work product that in his or her opinion is not consistent with the Company's quality or loss prevention standards. The QA Officer's primary duties are to:

- Provide a central point of responsibility for assessing company-wide technical strengths, needs and direction in order to maintain a consistent Company-wide quality of work that meets or exceeds the current standard of practice;
- Develop the Company-wide QA Policy and QMP;
- Coordinate QA training;
- Provide guidance to the QC Reviewers in carrying out QC-related functions;

- Inform project personnel of QA policies, procedures, and other guidance documents;
- Schedule and/or conduct quality awareness seminars for project personnel;
- Assist in preparation of Quality Assurance Project Plans (QAPPs) or review QAPPs, to become familiar with the QA activities at the project level and to understand the lines of communication between the QC Reviewer (described below), the QA officer, and the Project Manager (described below). These lines of communication are necessary for the QA Officer to be informed of the project's QC activities and to effectively work with the QC reviewer to address QA concerns in a timely manner;
- Audit selected EMSI projects and monitor general compliance with the QA Policy;
- Advise Project Managers of deficiencies based on peer reviews or audits and identify corrective action needs. Review the effectiveness of the QA Program with the President; and
- Maintain corporate/office QA files, including any audit and QA Program progress reports.

### 2.3.3 Project Manager

Each EMSI project is directed by a Project Manager who has overall responsibility for the project, including client liaison, planning document preparation, technical quality of work performed, data acquisition, report preparation, and presentations, as well as budget and schedule management. The Project Manager is also responsible for determining that staff assigned to the project understand and comply with the QC procedures that apply to their activities. The Project Manager's QA-related responsibilities are to:

- Review and approve project controlling documents, including QAPPs, Work Plans, Sampling Plans, standard operating procedures (SOPs), and contract documents;
- Select additional technical reviewers with the project QC Reviewer, if needed;
- Communicate project scope requirements to project team members;
- Communicate with the client for feedback on service satisfaction;
- Ensure that project deliverables and activities are in accordance with project controlling documents;

- Respond to corrective action requests and assure that deficiencies are corrected in a timely manner; and
- Communicate with the project QC Reviewer on quality issues.

#### 2.3.4 Project Quality Control Reviewer

At a minimum, a QC Reviewer is assigned to each project. The QC Reviewer has overall responsibility for all project QA issues. The QC Reviewer reports to the Project Manager, but also maintains a direct communication link and reporting relationship with the QA Officer on quality-related matters. Any audits performed by the QC Reviewer are circulated to the Project Manager and QA Officer. As well, any non-conformance with QC procedures identified by the QC Reviewer are reported to the Project Manager and QA Officer, along with recommended corrective measures and timeframes for implementation. Progress on resolving a non-conformance is shared with the Project Manager and QA Officer. The QC Reviewer's responsibilities are to:

- Work with the Project Manager to select additional QC reviewers or qualified professionals to check design documents, as appropriate, to assure compliance with all applicable Standard Operating Procedures listed in Appendix A;
- Review validation of field and subcontractor laboratory data with respect to QC criteria;
- Review and approve all project QA documents;
- Conduct project QA audits of field operations and subcontracted laboratories;
- Review project documents;
- Communicate review comments to project team members;
- Develop, with the Project Manager, corrective actions when appropriate; and
- Follow up to assure planned corrective actions have been completed.

Standard Operating Procedures that are applicable to the VB/I70 project are PRO-QA-004 (Document Control Procedures and Control of External Documents) and PRO-QA-012 (General Checking and Review Procedures). They are presented in Appendix A. If the project becomes sufficiently large or complex, QC Reviewers may be assigned to specific portions of the project and the EMSI QA Officer may be assigned to the project to have overall responsibility for all project QA issues and the coordination of all project QC Reviewers.

### 2.3.5 Task Manager

A Task Manager is a professional responsible for a particular project task. The Task Manager's responsibilities are to:

- Prepare project technical memoranda for the project task(s);
- Oversee data collection and analysis and determine that appropriate procedures are employed;
- Prepare reports or report sections related to the project task(s);
- Ensure that all task deliverables are in accordance with project controlling documents;
- Correct deficiencies and nonconformities identified for the project task(s);
- Keep the Project Manager and QC Reviewer informed of project requirements and changes in requirements; and
- Coordinate technical review requirements with the Project Manager and QC Reviewer.

## 2.4 Personnel Qualifications, Development, and Training

All EMSI employees must meet a minimum requirement of a master's degree for education, have 15 years of relevant professional experience, and have professional registration(s) where appropriate. EMSI's project managers are responsible for assigning only qualified personnel to project activities.

EMSI provides for and encourages professional development through professional development and training programs. These activities are planned and monitored by EMSI's President and can include internal and external programs.

### 2.4.1 Internal Programs

- **Quality Awareness Seminars:** Seminars and informal presentations on the scope and implementation of EMSI's QA Program and other quality management topics.
- **Health and Safety Training:** Training required to meet federal statutes for employees performing work under specific conditions.

- Project Management Training: Training workshops, focused seminars, and continuing education for EMSI's Project Managers.
- Loss Prevention Training: Seminars and training workshops for all EMSI staff.
- Technical Training: On-the-job training for specific job responsibilities, seminars on specific technical subjects, workshops focused on specific service areas.

#### 2.4.2 External Programs

- Continuing Education: Funding of college level course work;
- Seminars/Short Courses: Selectively funded by EMSI for individuals requiring or desiring specific technical training through a non-degreed program;
- Publications: EMSI encourages its staff to publish articles in peer-reviewed journals and trade magazines and to prepare and present technical papers at technical conferences;
- Membership in Professional Societies/Organizations: EMSI encourages membership in relevant professional societies and provides professional fees for membership; and
- Professional Licenses: EMSI pays for professional licenses for individuals based on the requirements of our clients, projects, or the states within which we operate.

#### 2.5 Project Management

The Project Manager is the primary link between EMSI and its clients and is responsible for furnishing the client a work product or service that meets the functional, technical, cost, and schedule requirements of the project. The Project Manager is assisted by technical staff, the designated QC Reviewer, and other Technical Reviewers.

EMSI recognizes the importance of strong project management skills and their applications. EMSI's project management training activities provide Project Managers with tools to help perform effectively through all stages of a project. The training is designed to hone their interpersonal, time management, business, and communication skills, help them be responsive to clients, manage budgets and schedules, lead project teams, and meet the desired quality standards of the work.

## 2.6 Subcontractor Management

Requirements to ensure adequate quality of subcontractor products or services are included or referenced in EMSI's procurement documents; these include bid requests, purchase orders, and contracts. Changes to a procurement document are subject to the degree of control used in preparing the original document.

Procurement documents state applicable requirements for technical performance, quality, acceptability, and documentation, as follows:

Technical Performance:

- General requirements (scope of work);
- Appropriate codes and standards;
- Material composition, or physical/chemical requirements;
- Quantity and scheduling requirements;
- Work procedures;
- Testing and calibration requirements;
- Performance and accept/reject criteria; and
- Reporting requirements.

**Quality.** Quality requirements that a subcontractor must satisfy depend on the purpose of the procurement, the degree of contractor independence, and client requirements. The right to stop work for significant quality problems should be clearly stated in all contract documents. The control of purchased items and services will include procurement source evaluation and selection and subcontractor performance control, including inspections and audits where appropriate.

**Acceptability.** Purchased items or services are controlled by invoking appropriate quality-related requirements and elements of this QMP. To verify acceptability, the procurement documents will provide for EMSI access to subcontractor facilities, work areas, and records.

**Documentation.** The contract should specify EMSI rights and procedures the subcontractor must follow for preparation, control, and retention of documentation. Subcontractor submittals of nonconformance, work progress, and results will be specified in the procurement documents.

## 2.7 Document Control and Records Management

Documents developed and used by EMSI personnel, subcontractors, and vendors to describe work processes and/or specify EMSI work activities are controlled in accordance with the PRO-QA-004 (Document Control Procedures), PRO-QA-005 (Control of External Documents), and PRO-QA-012 (General Checking and Review Procedures) in Appendix A. These policies and procedures address general requirements for the preparation, review and approval, and issuance and revision of documents. Project-specific procedures for preparing and approving documents are established by Project Managers and distributed to all project personnel.

A document is considered a completed record when it has finished full processing and is logged into the project file index. Completed project records should be maintained in a secure location to facilitate retrievability and provide protection from deterioration. Documents to be controlled include those documents and/or computer-generated records that specify project requirements such as:

- Proposals;
- Contracts and subcontracts;
- Purchase orders;
- Cost estimates;
- Work plans, instructions and procedures;
- Calculations;
- Data quality standards;
- Technical reports;
- Drawings and specifications;
- Inspection and test reports;
- Correspondence; and
- Invoices and related backup.

The Project Manager is responsible for project document control. This responsibility includes establishing a records management system to control both printed paper copies and documents and data stored in electronic media. The records management system should address procedures and responsibilities for the preparation, review and approval, collection, custody and control, indexing, filing, distribution, safe storage, maintenance, retrieval, and retention/destruction of company and project records. Written records management and document control procedures should also be furnished by EMSI subconsultants, subcontractors, and vendors.

## 2.8 Computer Hardware and Software Systems

All computer hardware used for the storage and manipulation of scientific or engineering data shall be selected considering its intended use. Modifications or additions to

computer hardware will be controlled and evaluated to confirm that the modifications will not affect computer system performance or in any way alter the stored files.

Software used for data storage and manipulation, including all Geographic Information Systems (GIS) [e.g., esri ArcGIS] and mapping (e.g., AutoCAD Map 3D) software, should be validated, verified, and documented considering its intended use in accordance with PRO-GE-015 (Verification and Validation of Computer Software Programs) in Appendix A. Where possible, EMSI technical staff should use public domain software that has been qualified, peer-reviewed, validated, and verified. Documentation for the software used will be current.

Where software that is not considered public domain is used, the source of the software will be specified and documented. EMSI project personnel will validate and verify the software before its use on EMSI projects. Where EMSI project personnel develop project-specific software, the code will be independently benchmarked, validated, and verified prior to use. In addition, documentation of the code will be available and maintained with the project file.

Modifications to software will be controlled, documented, and assessed to assure that performance is not unacceptably altered.

## 2.9 Work Processes and Systems

EMSI projects are planned, implemented, and monitored following procedures described in this QMP.

Project planning is conducted using established project management procedures and, where applicable, the Data Quality Objective (DQO) process as defined by EPA and interpreted by Project Managers. Planning procedures are designed to ensure that the project scope of work will achieve the client's objective. Planning will be performed by the EMSI Project Manager and Technical Reviewer before detailed work plans are developed. This planning effort will determine the type and quality of data needed to characterize environmental processes or conditions. Planning will include the development of design criteria prior to design of any engineered system. The DQO process is used where appropriate to identify specific data or interpretive requirements and the level of QA commensurate with the intended use of the data.

Form B-1 (Appendix B) is a Project Planning and Scoping Checklist. This checklist can be used to assist Project Managers, Technical Reviewers, or Task Managers to assure that a comprehensive planning and scoping effort has been performed.

EMSI projects shall be implemented in accordance with written project documents (work plan, plans, procedures, specifications, drawings) and the contract and implemented in a sequence consistent with the project schedule.

SOPs are available or are developed and implemented for some routine, standardized, or specialized operations that are repetitive and require consistent controls. The Project Manager will assure that requisite project SOPs are established prior to initiation of field or design work, and that these SOPs are followed. SOPs that specify technical requirements will be reviewed for adequacy by technically qualified personnel prior to use.

The work process will be monitored using: inspections, tests, QC reviews, peer reviews, and audits. Persons conducting QC reviews should be technically qualified and should have previously received training to perform QC reviews. The QC reviewer must:

- Identify quality problems where present;
- Propose corrective actions as appropriate;
- Confirm that corrective actions have been implemented as necessary;
- Report to management (Project Manager and QA Officer) the nature of quality problems, proposed corrective action(s), and the effectiveness of solution implemented; and
- Control nonconforming or deficient work until quality problems are resolved and provide information to all EMSI employees to assure future studies/investigations, designs, or construction projects are satisfactorily performed.

## 2.10 Quality Control Review

All EMSI work products are required to undergo formal QC review in accordance with EMSI's General Checking and Review Procedure SOP (Appendix A). Each QC review should address:

- Project scope and objectives;
- Report outline;
- Data collection rationale;
- Data collection methods;
- Factual conclusions/findings;
- Opinions and recommendations;
- Technical reviews and professional registrations;

- Standard of practice; and
- The client's perspective.

Although these review elements were developed for report review, many also apply to other EMSI work products. Form B-2 (Appendix B) is a Quality Control Review Checklist designed to facilitate the QC review process. QC reviews of design engineering documents should follow the general approach described in Section 4.

#### 2.10.1 Project Scope and Objectives

The report should clearly state the project scope and objectives, as defined in the original proposal, work plan, and *contract*. If the scope or objectives were modified during the course of the project, the rationale for modification must be explained. A written record that the client has acknowledged the changes must be part of the project file.

### 2.10.2 Report Outline

The report should adhere to a logical outline, for example:

- Introduction;
- Methods;
- Data Presentation;
- Interpretations/Analyses;
- Conclusions; and
- Recommendations.

Reviewing the outline will provide the first assessment of whether the project includes the necessary steps to fulfill the scope and achieve the project objectives.

### 2.10.3 Data Collection Rationale

Is the rationale used to establish data collection points, sampling intervals/frequencies, and chemical analyses easily understood and well documented? Early establishment of DQOs will aid in this documentation. For example, do the data need to be of sufficient quality to estimate the size of an excavation for removal of an underground storage tank (UST) or to establish human health risks to sensitive populations in support of litigation?

### 2.10.4 Data Collection Methods

The data collection methods should be sufficiently documented to allow a qualified professional to repeat them. Methods need not be completely documented in a final report if they are described in a previous document (e.g., a Sampling and Analysis Plan, Remedial Action Plan, or Operations and Maintenance Plan). However, deviations from methods referenced in previous documents should be clearly explained.

### 2.10.5 Factual Conclusions/Findings

Independent reviewers should be able to follow the logical progress from project plan through execution and analysis or interpretation so that, using scientific or engineering judgment and independent thought, they can reach the same conclusions, which should be clearly stated in the report.

#### 2.10.6 Opinions and Recommendations

Our clients pay us as consultants to formulate opinions and make recommendations based on professional judgment. These opinions should be supported by the data. The reviewer should assess whether the recommendations are reasonable and if other reasonable solutions have been overlooked. Opinions and recommendations should not be interspersed throughout the report, but should be confined to a section clearly identified as containing opinions and recommendations.

#### 2.10.7 Technical Reviews and Professional Registrations

The QC Reviewer should confirm that the technical aspects of the project have been checked or reviewed by technical personnel qualified in the appropriate disciplines. A QC Reviewer is not expected to review the work of all scientific and engineering disciplines, but is responsible for certifying that the proper technical reviews have been performed. Appropriate registrations should be held by individuals signing reports or stamping/sealing drawings.

#### 2.10.8 Standard of Practice

Data collection and interpretive techniques should conform with the standard of practice and applicable regulatory requirements. It is important to recognize that the standard of practice is *the ordinary skill and competence exercised by members of a profession in good standing in the community at the time the work is undertaken*. This is not to be confused with the state of the art or an individual's perception of "excellence." Necessary deviations from the standard of practice should be explained.

#### 2.10.9 The Client's Perspective

Before completing any QC review, the reviewer should question whether the report meets the client's needs or provided a solution to the client's problem. The magnitude of the solution should be in line with the magnitude of the problem. The QC Reviewer should discuss any concerns with the Project Manager.

#### 2.11 Management Assessment

The management assessment process is a combination of client service assessments, QA audits, management self-appraisals, and, where necessary, corrective actions. The management assessment process is designed to identify quality problems, appropriate response actions, and permanent changes to the practice that will improve quality.

EMSI's President and QA Officer are responsible for regularly reviewing, documenting, and where necessary correcting compliance with the QA Policy and this QMP. Elements to be reviewed include:

- The organizational structure, including the qualifications and commitment of personnel and resources;
- The degree to which EMSI's QA Program is being implemented and the effectiveness of established management controls; and
- The results of QA audits, and peer reviews.

At a minimum, Management Assessments will be conducted annually if this QMP extends beyond one year.

#### 2.11.1 Quality Assurance Audits

Project QA audits may be performed to determine the degree to which a project is in compliance with EMSI's QA Policy and procedures. Audits can be initiated by the President, the Project Manager, or QA personnel. Audits may be performed by the QA Officer or senior technical staff with training in performing project audits.

Typical steps in an audit include:

- Notify the Project Manager of the intent to perform an audit as well as the objective and scope of the audit;
- Audit work processes;
- Review project files and deliverables;
- Interview the Project Manager and other key technical staff;
- Prepare a draft audit report for the Project Manager;
- Debrief the Project Manager and President; and
- Finalize the audit report with input from the Project Manager and President.

Audits may be conducted at EMSI office, project field sites, or at a subcontractor's or vendor's location. Auditors usually use the QA Audit Checklist (Form B-3 in Appendix B) and summarize results on the QA Audit Form (Form B-4 in Appendix B). Audit reports are to be completed by the auditor within one week after completion of the audit and be distributed to the Project Manager, QA Officer, and President. The President will

ensure that corrective actions identified by the audits are implemented and documented. The QA Officer and President will monitor the effectiveness of corrective actions.

#### 2.11.2 Corrective Actions

Conditions identified during QC reviews or QA audits as needing corrective action should be addressed promptly. The President will follow up to verify that appropriate and effective response actions were taken and that operating procedures, work processes, or organizational responsibilities were modified, if necessary, to correct the concern.

### 3 DATA ACQUISITION AND MANAGEMENT

#### 3.1 General

The initial phase of an EMSI project typically entails the acquisition, interpretation, and management of data. Data may be needed to characterize site conditions for planning purposes, for engineering design and construction, or to identify the nature and extent of chemicals of concern that require appropriate remedial action. Most of the data acquisition for the VB/I70 project will be Environmental Data or Environmental Technology.

**Environmental Data** is defined as any measurement of information that describes environmental processes, location, or condition; ecological or health effects and consequences, or the performance of environmental technology. Environmental data include any information collected directly from measurements or obtained from any other sources, i.e., existing /secondary data, such as those compiled from databases, data reports, literature, surveys, or produced from models.

**Environmental Technology** is an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies, and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment.

Any activity that involves the collection, generation, or use of environmental data or environmental technology will require development and approval of a QAPP, which is discussed later in this section. In all cases, EMSI follows specific procedures to establish DQOs in compliance with client, federal, and state requirements. This section of the QMP focuses on the general quality management procedures to be followed for data collection. These process activities should take place within the quality management systems described in Section 2.

#### 3.2 Planning and Scoping

As a general rule, all EMSI projects involving the generation, acquisition, and use of data must be planned prior to data collection. The foundation for the planning and scoping process is the development of project DQOs. DQOs are specific statements developed by the key data users and those responsible for activities affecting data quality (e.g., owners, federal, state, and local regulatory agencies) to specify the type, quantity, and quality of data needed to support site characterization conclusions and other project objectives. DQOs can be formally developed following the steps described below or informally addressed through a process by which project objectives are defined and data needs specified. The DQO process and any associated planning activities should be

documented to ensure that staff performing data acquisition activities are aware of and have agreed to the project data quality requirements.

The DQO process consists of the seven basic steps described below.

#### Step 1: State the Problem

The scope, objectives, requirements, and activities associated with a program or task are defined. A statement of the specific problem to be addressed or the question to be answered is typically required. Additional scope definition activities include identifying members of the scoping team and specifying resources available to address the problem.

#### Step 2: Identify the Decision

The key decisions to be made that require the collection of data are identified. The key decision for a particular phase or stage of a project is defined, as well as alternative actions that may be taken based on the results of the investigation. Any relationships between the key decision and other associated or subsequent decisions are identified.

#### Step 3: Identify the Inputs to the Decision

The data needed to make or support decisions are identified. The sources of all data are identified. Methods used to assess or manipulate collected data to arrive at project decisions are described.

#### Step 4: Define the Study Boundaries

The spatial and temporal boundaries of the data acquisition activity are defined. These boundaries ensure that the approach incorporates the time periods in which the data should be acquired, areas that should be sampled, and the time period to which the results should apply. This step includes defining the geographic areas for field investigations, the population of interest, the scale of decision-making, the time frame for the decision, the timing of sample collection, and any constraints on sampling or analysis.

#### Step 5: Develop a Decision Rule

A logical decision rule is formulated that defines conditions that would cause the decision-maker to choose among alternative actions. First, the statistical parameter that specifies the characteristic or attribute that the decision-maker needs to know about the population or problem is defined. Next, the action level for the decision is defined.

#### Step 6: Specify Tolerable Limits on Decision Errors

The decision-maker's acceptable limits on decision errors are specified in order to establish appropriate limits for uncertainty in the data. Activities include the following:

- Establishing a possible range for each parameter of interest by estimating its upper and lower bounds;
- Defining types of decision errors and identifying the potential consequences of each;
- Defining a range of possible parameter values where the consequences of decision errors are relatively minor; and
- Assigning probability values to points above and below an action level that define the acceptable probability for the occurrence of decision errors.

### Step 7: Optimize the Design

Evaluate information or data obtained from the previous steps and generate alternative data collection designs. Choose the most resource-effective design that meets all DQOs.

### 3.3 Data Collection Systems Design

Once project objectives or DQOs have been established, the project data collection system can be designed. The data collection system is designed to identify the most effective and efficient approach to sampling and analysis that will satisfy project DQOs. The data collection design process includes identification of the following:

- Personnel requirements and qualifications;
- Specifications for field sampling events;
- Health and safety considerations;
- Sample handling and custody;
- Selection of analytical methods;
- Analytical instrumentation requirements;
- Specification of calibration and performance evaluation samples for analytical methods;
- Data reduction, validation, and verification methods;
- Specification of methods for evaluating data and assessing limitations on data use;
- Specification of statistical methods;

- Data reporting requirements; and
- Required QC activities and oversight needs.

By following the data collection design process, data can be traced to sampling and analytical procedures, performance standards, and measuring equipment.

### 3.4 Planning Documents

The data collection system design and other project criteria and parameters are specified in project planning documents. These documents are reviewed and approved by the Project and, as appropriate, Task Managers, as well as designated QC Reviewers. The QC Reviewer shall be an appointed individual who was not involved in the design of the data collection system. Any design or procedure changes are subject to the same review and approval process as the original documents.

Different clients will have different requirements for planning documents. The general intent of the planning documents is to communicate the scope and procedures for intended activities so that these procedures can be reviewed and validated. The following sections describe planning documents generally required for environmental projects performed under U.S. EPA procedures (e.g., CERCLA, RCRA).

The type of data required for the VB/I70 project consists of environmental data and environmental technology, as defined above. A Work Plan, Field Sampling Plan, QAPP, and Health and Safety Plan that describe the objectives and acquisition protocol for collecting these data types will be required, as discussed below. In addition, information that originates from an external source, referred to as secondary data, will be required for the VB/I70 project. This information includes, but is not limited to criteria, codes, standards, manuals, and customer-furnished documents. The procedures described in PRO-QA-005 (Control of External documents) in Appendix A will be followed for secondary data.

#### 3.4.1 Work Plan

A Work Plan presents the structural design for a project and the strategy to be followed for completing the project. In a stepwise fashion, duties are identified and described, and milestones for their accomplishment are established. The resources to be used in the course of work are elaborated upon.

Project personnel, including the Project Manager and QC Reviewer, are identified, along with their respective responsibilities and anticipated levels of effort. Lines of interaction between the staff are outlined. In addition, the plan specifies material resources to be used, including laboratory and field equipment and computer software and hardware systems (e.g., programs, information databases, communication network).

### 3.4.2 Field Sampling Plan (FSP)

Under current U.S. EPA guidelines, data collection projects require a Sampling and Analysis Plan (SAP), which consists of an FSP and a QAPP. The FSP:

- Describes sampling objectives including the phase of the sampling and the ultimate use of the data;
- Identifies procedures for field activities and sampling protocols and procedures;
- Specifies the types, locations, and frequency of samples to be taken;
- Identifies procedures for sample analyses; and
- Identifies responsible individuals.

The FSP may also include pertinent instruction guides, SOPs, and operating manuals. SOPs will be prepared in accordance with EPA's Guidance for Preparing Standard Operating Procedures (EPA, 2007). For multi-year projects, the FSP and SAP will be reviewed annually for adequacy with the above-stated objectives, protocols, and procedures. Annual reviews will be documented using EPA Region 8 Crosswalk checklists.

### 3.4.3 Quality Assurance Project Plan

The QAPP is a written, comprehensive QA guidance document for a specific project. It presents, in specific terms, the policies, organization, objectives, functional activities, and QA/QC activities designed to achieve DQOs. Under EPA guidelines, the QAPP comprises 16 elements as follows:

1. Title page;
2. Table of Contents;
3. Project Description;
4. Project Organization and Responsibility;
5. Precision, Accuracy, Representativeness, Completeness, and Comparability (PARCC) Data Quality Objectives;
6. Sampling Procedures;

7. Sample Custody and Documentation;
8. Calibration Procedures and Frequency;
9. Analytical Procedures;
10. Data Reduction, Validation, and Reporting
11. Internal Quality Control Checks;
12. Performance and System Audits;
13. Preventive Maintenance;
14. Specific Routine Procedures to Assess Data Precision, Accuracy, and Completeness;
15. Corrective Actions; and
16. QA Reports to Management.

In addition, an analytical laboratory that is contracted by the project must maintain a current QA Plan and hold a current certification from the National Environmental Laboratory Accreditation Program (NELAP), or equivalent.

For multi-year projects, the QAPP will be reviewed annually for relevance and adequacy with the above-stated elements. Annual reviews will be documented using EPA Region 8 Crosswalk checklists.

The QAPP must be approved by the EPA Regional Quality Assurance Manager or designee prior to project initiation.

#### 3.4.4 Health and Safety Plan (HASP)

EMSI administers a health and safety program for its employees in compliance with Occupational Safety and Health Administration regulations in 29 CFR Part 1910. Site-specific HASPs are generated for each project and provide detailed health and safety information and guidelines for a project. A Site Safety Officer is assigned for each sampling operation and is responsible for implementing the HASP.

#### 3.5 Implementation of Data Acquisition Activities

Data acquisition activities are to be implemented according to project planning documents and procedures for sample custody, calibration, internal QC, document

control, preventive maintenance, and procurement control. Project planning documents may include procedures or standards for each of these controls. If planning documents do not contain such procedures, the following minimum quality requirements for these procedures should be met.

### 3.5.1 Sample Custody

Sample custody procedures are to be followed throughout sample collection, preservation, handling, packaging, shipping, storage, analysis, and ultimate disposal. The purpose of these procedures is to maintain sample integrity, to prevent damage, loss, deterioration, cross contamination and interferences, and to properly dispose of post-analysis sample materials. U.S. EPA approved chain-of-custody and documentation procedures should be used as a standard unless project criteria dictate otherwise.

### 3.5.2 Calibration Procedures

All tools, gauges, instruments, and other sampling, measuring, and test equipment used to gather, generate or measure environmental and engineering data shall be calibrated by subcontract laboratories or EMSI project personnel. These items should be calibrated at specific intervals to maintain accuracy and reproducibility within specified limits as defined by manufacturer specifications. Records of all calibration and maintenance activities should be maintained. Equipment should be calibrated using certified equipment and/or standards that are traceable to nationally recognized performance standards such as the National Institute of Standards and Technology, if such standards exist.

### 3.5.3 Internal Quality Control Procedures

Internal QC procedures and checks should be used throughout EMSI projects and should include inspections and acceptance testing. The QC checks should include:

- Collection and analysis of QC samples for field and laboratory operations;
- Active involvement by Project Managers and QA personnel; and
- Use of document control procedures.

#### 3.5.3.1 QC Samples

Field quality control samples consist of trip blanks, field blanks, equipment blanks, duplicate samples, and matrix spike/matrix spike duplicate samples. Laboratory QC samples include method blanks, reagent/preparation blanks, calibration standards,

internal standards, surrogate standards, lab duplicates/replicates, and laboratory control samples. The specific QC samples to be collected for each project and the frequency of collection are defined during project planning and specified in project planning documents.

#### 3.5.3.2 Project and Quality Assurance Management

Project and quality assurance management for data operations shall be consistent with general quality management procedures described in Section 2 of this QMP. QA responsibilities are delegated by the Project Manager through the QC Reviewer.

#### 3.5.3.3 Document Control

Document control for data acquisition activities shall be consistent with document control and records management procedures described in Section 2.8 of this QMP.

#### 3.5.4 Preventive Maintenance

A preventive maintenance program should be established for each data acquisition activity to ensure that field and laboratory equipment are maintained according to the specific procedures provided by the manufacturer so that the required sensitivity, accuracy, completeness, representativeness, comparability, and precision are achieved.

For projects involving field and/or laboratory work, preventive maintenance procedures and schedules for laboratory and/or field equipment should be described in the QAPP. If maintenance procedures are simply referenced in the QAPP, the complete procedure should be readily available to the field or laboratory staff using the equipment.

#### 3.5.5 Procurement Control

Control over the procurement of purchased items and services shall be consistent with the subcontractor procurement procedures described in Section 2.7, Subcontractor Management. Subcontractors are subject to the same procurement requirements as EMSI. Verification of subcontractor procurement procedures involves the performance of field QC checks, receiving inspections, field inspections, verification tests, subcontractor documentation reviews and onsite source audits.

#### 3.5.6 Geospatial Data

Geospatial data may be associated with chemical constituent and physical geological-related environmental data collected for the VB/I70 Globeville Landing Outfall Project.

Geospatial data collection and data management activities will be planned and implemented in accordance with the guidance policies and standards included in the following documents:

- EPA, 2008, National Geospatial Data Policy, CIO 2131.0, <http://www.epa.gov/irmpoli8/policies/21310.pdf>, August 24, 2008;
- EPA, 2003, Guidance for Geospatial Data Quality Assurance Project Plans (QA/G-5G), EPA/240/R-03/003, March 2003;
- Federal Geographic Data Committee (FGDC), 1998, FGDC-STD-001-1998, Content Standard for Digital Geospatial Metadata, June 1998; and
- FGDC, 1998, FGDC-STD-007.1-1998, Geospatial Positioning Accuracy Standards Part 1: Reporting Methodology, 1998.

### 3.6 Assessment of Data Usability

All acquired data shall be managed, distributed, and preserved in order to substantiate and document that the data are of known quality, are properly maintained, and meet the intended project usability and objectives. Technical data, including field data and the results of laboratory sample analyses, are tracked and validated. A project data storage and information system will be developed for each project, as applicable, to facilitate and manage data for tracking, data calculations, and data transfer to various forms, reports, and data storage systems.

#### 3.6.1 Data Reduction

Reduction of field measurement data and laboratory measurement data will be performed in accordance with project data validation procedures that specify the required documentation and technical criteria necessary to produce valid data. Laboratory data must be:

- Quantitative and statistically significant in relation to the standard analytical methods or procedures employed; and
- Satisfactory for custody and document control.

Field measurement data must meet criteria for:

- Complete documentation of sampling location, time, and personnel;
- Satisfactory documentation of field activities; and

- Correct sampling methods.

### 3.6.2 Data Validation

Field measurement data validation procedures include reviewing the raw data and supporting documentation generated during the field investigation. Data validation is performed to meet the project's intended data uses by checking the procedures used in the field and comparing the data to previous measurements.

Laboratory measurement data validation procedures are under the direction of the laboratory QA coordinator. The objective is to review the analytical data to ensure that the results for investigative and QC samples meet method-specified criteria prior to submittal to EMSI. The laboratory QA coordinator is responsible for assessing data quality and advising appropriate laboratory supervisors and EMSI's Project Manager of any data that are unacceptable or that may be unreliable for use.

EMSI should perform independent data validation of data generated. The level of effort and level of detail to which data will be validated will be in conformance with client requirements and project objectives. The procedure for performing validation includes at a minimum the following:

- Compiling a list of investigative samples;
- Compiling a list of QC samples;
- Reviewing the laboratory analytical procedures and instrument performance criteria;
- Evaluating the completeness and integrity of the data;
- Preparing a data summary; and
- Reviewing the data summary for potential data quality problems.

EMSI data validation should be performed by identified personnel qualified and experienced in laboratory data validation.

Field and laboratory measurement data will be validated where appropriate according to EPA functional guidelines or using other appropriate criteria such as method-specific statements of work or protocols.

Data are qualified according to the intended use of the data based on the performance criteria originally established during the DQO process. The data qualifiers should be consistent with method- or project-specific statements of work. Data qualifiers should be

attached to the data whenever they appear in hard copy or computerized form to ensure that data users are aware of the limitations and quality of the data.

### 3.6.3 Data Reporting

Documents are prepared and distributed which summarize the field activities and the results of all data collected. These reports include the following:

- Presentation of results;
- Summaries of field data from field measurements;
- Field location of sampling points;
- Field measurement data logbooks;
- Laboratory deliverables; and
- Data validation reports summarizing the validation process used and the specific results and comments pertaining to a sample or group of samples.

### 3.6.4 Data Assessment

After the laboratory and field data have been reduced, validated, and reported, the project staff should assess the data with respect to the project DQOs. Field and laboratory data are assessed in terms of precision, accuracy, representativeness, completeness, and comparability (PARCC). Precision, accuracy, and completeness are evaluated quantitatively, while representativeness and comparability are evaluated qualitatively. The goals of this assessment are:

- To establish site-specific PARCC parameters;
- To use these parameters to develop a database with known limitations of data usability; and
- To evaluate these limitations relative to the intended uses of the data.

Should the results of these assessments reveal that DQOs are not being met, the Project Manager should assess the situation and initiate corrective action as appropriate.

## 3.7 Performance and System Audits

Activities performed during data acquisition that may affect data quality may be assessed through audits to verify that the requirements of the QAPP and other planning documents are implemented as prescribed. Audits include performance evaluation audits and technical systems audits. Both self-assessments and independent assessments should be performed. The assessment results should be documented, reported to, and reviewed by management. The purpose of these assessments is to provide management and clients with an ongoing evaluation of the quality of the results produced by EMSI's data collection activities and to indicate how well the objectives for a given project are being met.

The QAPP will describe the procedures to be followed in conducting audits, and should include an auditing plan and/or checklist. Designated QA audit personnel must be experienced and knowledgeable about the activities which they are auditing and completely independent of these specific activities audited. Several different types of audits can be conducted: management audits, laboratory audits, field audits, and performance evaluation audits.

- **Management audits** are designed to evaluate whether quality management functions and responsibilities related to data acquisition and assessment are being performed in accordance with the QAPP and company QA policy.
- **Laboratory audits** are performed to verify continuity of personnel, instrumentation, and quality control requirements. A laboratory audit typically consists of random data audits and review of laboratory quality control data. The laboratory documentation normally examined during an audit includes sample receiving, sample log-in, sample storage, chain-of-custody, sample preparation and analysis records, instrument operating records, and any other documentation related to the generation of analytical data by the laboratory.
- **Field audits** are performed to evaluate procedures for sample identification, sample control, chain-of-custody, field documentation, sampling operations, sample preservation, packaging, and shipping.
- **Performance evaluation** audits are performed periodically to determine the bias of a total measurement system. These audits typically consist of a performance evaluation sample that is submitted to and analyzed by the audited laboratory. In some cases, the laboratory is made aware of the submittal of samples. At other times, the samples are submitted to the laboratory in such a way that the laboratory is necessarily unaware it is being audited.

The frequency of these audits and performance evaluations are project-dependent, and are specified in project-specific QAPPs.

### 3.8 Corrective Actions

A "closed-loop" corrective action system for data acquisition and assessment work should be maintained for each project consistent with procedures described in Section 2. Any issue requiring corrective action also requires verification that the corrective action has successfully corrected the deficiency. Project mechanisms to suspend or stop deficient activities and, if necessary, to issue restricted usage letters and labeling for materials impacted by a corrective action requirement should be clearly specified in the QAPP.

The general approach for defining corrective action requirements should involve:

- Identifying corrective action needs and causes;
- Establishing appropriate corrective action responses; and
- Verifying the timely implementation and effectiveness of the corrective action taken.

Corrective action may require additional data collection activities. In the field, corrective action is initiated by the Project Manager and/or Task Manager. All problems should be identified and reported. Although corrective action for deviations from standardized field procedures may not always be required, all deviations from project planning documents should be noted in the field logbooks along with the field team leader's justification and rationale for the changes. Corrective actions should be always implemented when SOPs are not met, when non-representative conditions are indicated, and/or when specific tasks have not been performed.

## **4 DESIGN, CONSTRUCTION, OPERATION OF ENGINEERED SYSTEMS**

This section describes QA Program elements that apply to the design, construction, and operation of engineered systems. These elements should be applied in conjunction with the quality management system described in Section 2. Engineered systems include those facilities, structures, processes, mechanical and electrical devices designed by EMSI to protect the environment from pollution or contamination, protect human health and safety, and improve public infrastructure. QA Program elements include:

- Project planning and scoping;
- Project organization;
- Design phase quality control reviews;
- Construction phase quality control reviews;
- Operations and maintenance procedures;
- Construction inspection and acceptance testing; and
- Corrective actions.

It is the Project Manager's responsibility to see that the necessary QA documents are provided to appropriate project staff and that the acceptability of design documents is verified in a timely manner.

### **4.1 Project Planning and Scoping**

Project activities for the design and construction of engineered systems must be planned to define their implementation sequence and to identify the parties responsible for the overall quality of the various system elements. A Project Procedures Memorandum (PPM) should be prepared that establishes basic management criteria and applicable project QA measures. The PPM should include:

- Description of the engineered system to be designed and constructed;
- Design objectives, design criteria, regulatory requirements, and performance and quality standards;
- Scope of work and task breakdown structure;

- Work schedule
- Project and task budgets;
- Expected rates of expenditure;
- Project team organization;
- Project requirements for equipment, travel and subsistence, and subcontractors;
- Project review requirements; and
- Quality Assurance Project Plan or Construction Quality Assurance Plan.

The EMSI Project Manager is responsible for preparing and distributing the PPM to the appropriate members of the project team.

Project construction phase activities should be planned during the preconstruction stage with regard for quality and safety and to avoid project implementation problems while the project is still in design. A project Construction Quality Assurance Plan (CQAP) serves to establish project quality objectives and procedures for loss prevention, quality control, and general coordination between EMSI and the construction contractor. The CQAP includes the specific QC requirements of the contract documents, applicable regulatory codes and requirements, EMSI corporate and professional standards, and loss prevention considerations.

#### 4.2 Project Organization

Adherence to project quality control procedures is the responsibility of the Project Manager. The Project Manager may delegate responsibility for the quality of a design to a QC Reviewer. The Project Manager may delegate responsibility for construction to a Construction Services Manager.

#### 4.3 Design Phase Quality Control Reviews

Design phase QC reviews are independent assessments of how engineered designs meet project planning and scoping requirements. The Project Manager should select QC Reviewers for their general knowledge of the technology chosen for the project and for their objectivity in assessing liability issues. QC reviews should be scheduled at strategic stages of the project design, such as after the concept design stage, after preliminary design, and at scheduled points during the final design phase. The types of QC and technical reviews required on a design project are described below.

#### 4.3.1 Design Document QC Checking

QC checking of design documents provides reasonable assurance that calculations, data summaries or tabulations, design diagrams, process flow charts, drawings, cost estimates, specifications, and material and equipment lists are accurate and consistent with technical standards, criteria, and tolerances. Checking should be performed systematically by project team members in accordance with the General Checking and Review Procedure SOP included in Appendix A.

#### 4.3.2 Quality Control Reviews

Quality control reviews are performed by the designated QC Reviewer in tandem with ongoing QC checking of design documents by project staff. QC reviews of interim designs are formal, systematic, and critical reviews conducted after various phases of design development have been completed. The objectives of QC reviews are to identify design irregularities and anticipate potential design implementation problems, and to initiate appropriate corrective actions to ensure the final design meets client requirements. A comprehensive approach to QC reviews should be taken so that all items pertaining to meeting the needs of our clients are addressed. Typical components of a QC review for design and/or construction projects should include review of:

- Clarity of project scope and objectives;
- Client needs expressed in the design criteria compared with the technical specifications;
- Validation of the design data collection rationale and methods;
- Factual basis for design, conclusions, and findings;
- Relevance of technical opinions and recommendations to project scope;
- Professional registration verification;
- Conformance with local standards of practice;
- Items pertaining to process specifications and operations service requirements; and
- Presentation of data conclusions and findings and construction contract requirements.

QC reviews are normally conducted at the conclusion of project development stages, i.e.,

- 10 percent for conceptual design;
- 30 and 60 percent for design development, and
- 90 percent for final design.

#### 4.3.3 Value Engineering Reviews

Value engineering evaluations are performed on EMSI projects at the request of, or with the agreement of the client. These evaluations involve reviewing alternative design options of relatively equal quality, with the result being a final design that serves the client's required function at the lowest possible life cycle cost. These reviews are conducted jointly with the client in a structured format that involves several distinct phases:

- Information phase;
- Creative phase;
- Evaluation phase;
- Investigative phase; and
- Recommendation phase.

The degree of formality of a value engineering review varies with the type, size, and complexity of the project, funding constraints, and operations and maintenance strategy. Teams of three to five independent reviewers, who may include qualified personnel from peer engineering firms, should become involved in the project at no later than the 30 percent stage. Recommendations from the value engineering review team are communicated orally and in written form to the design team, which then makes the final decision on implementation.

#### 4.3.4 Constructibility/Biddability Reviews

Constructibility/biddability reviews are primarily intended to protect owners of constructed facilities from damages due to defects in documents and to minimize unnecessary changes to the design documents during construction. These reviews are performed by qualified personnel experienced in construction management or engineering at two design stages between the 30 and 60 percent stage and by the 95 percent stage. Typical items addressed include:

- Construction sequencing and scheduling;
- Attention to existing site constraints;
- Temporary facilities needs;
- Practicality of construction; and
- Clarity of contract bid documents and drawings.

#### 4.4 Construction Phase Quality Control Reviews

Construction phase QC consists of preparatory and follow-up actions that involve review of construction specifications. Specifications must clearly describe to bidders the scope of construction work and define the standards for technical performance and quality acceptance. These standards become the basis for onsite construction QC activities such as construction observation, inspection, and acceptance testing. Depending on contract agreements, construction QC is performed by EMSI either as the owner's representative or as the construction manager. Verification of the design intent and communication of the contractor's understanding of the contract requirements and response by the engineer are made through the submittal review and field clarification order process.

If EMSI is the site remediation contractor, the prime construction contractor on a design/build contract, a qualified construction manager should be given the authority, through the contract documents, to exercise control over the means and methods of construction. These activities would include: prequalification of subcontractors to perform the construction work, training, and certification of EMSI and subcontractor personnel for hazardous waste work and for OSHA 1920.01 industrial hygiene and safety compliance. Standardized subcontractor procurement procedures described in Section 2 of this QMP should be followed for hiring qualified subcontractors and equipment vendors for construction. Construction materials purchasing, transport, storage, and inspection are subjected to more direct QC when EMSI is the prime contractor. These requirements are documented in various project-specific QC or site management plans.

At construction completion, the design engineer/construction manager should document the completed work through preparation of contract record drawings. Results of inspections and tests are documented in a final construction report to the owner and interested agencies.

#### 4.5 Operations and Maintenance Procedures

Operations and maintenance (O&M) procedures are prepared by EMSI for specific elements of designed engineered systems for environmental remediation. These

procedures are the responsibility of the Project Manager and are normally prepared in three stages:

- Outline at the 50 percent design development stage;
- Final draft at 95 percent final design stage; and
- Final O&M manual at the 50 percent construction completion stage.

The O&M procedures address personnel qualifications and organizational responsibilities, including operator certification requirements. Procedures are established to assure that only qualified and accepted materials, equipment items, or services are used in the operation of the engineered systems. Preventive maintenance schedules should be included in accordance with the design and the manufacturers' specifications to ensure that warranty provisions are met within established operating parameters.

A typical O&M procedures plan addresses the following items:

- Schematic operating diagrams;
- Pre-startup equipment settings;
- Startup procedures;
- Operating modes;
- Shutdown procedures;
- Post-shutdown procedures;
- Emergency operating procedures/contingency plan;
- Preventive maintenance; and
- Spare parts lists.

The O&M procedures should address system performance when inoperability of the associated engineered systems could result in loss of monitoring data, decreased treatment capacity or remediation efficiency, or safety hazards due to the release of contaminants in excess of established limits.

## 4.6 Construction Inspection and Acceptance Testing

### 4.6.1 Procedures/Responsibilities for Inspection and Acceptance Testing

Construction inspection and acceptance testing procedures should be described in the project specific CQAP. As a minimum, a project CQAP should address procedures and responsibilities for:

- Inspections and acceptance testing of installed systems and subsystem components in accordance with approved design specifications;
- Verification under field conditions that the installed systems and subsystem components meet operational performance requirements;
- Tracking of deviations from acceptance criteria and corrective actions and deficiencies
- Documentation and reporting of inspections and acceptance testing;
- Calibration and control of measuring and test equipment against acceptable and documented baseline standards.

### 4.6.2 Procedures for Tracking Inspection and Acceptance Test Results

The CQAP should describe procedures for tracking the work flow through the various phases, including inspections and acceptance testing. The QC Reviewer for construction should maintain records of all quality control operations, activities, and tests performed for all project activities, including any of these for suppliers and subcontractors. These records are maintained as part of the project history file. Records should include the completed quality control inspection/test procedures to show evidence that required activities or tests have been satisfactorily performed. Records of quality control activities include:

- Procedures used for quality control inspection/tests;
- Procedures for quality control of any field engineering analyses activities;
- The results of inspections or tests or quality control reviews with authorized signatures;
- Nature and extent of defects and causes of rejection, including corrective actions taken; and

- Results of quality control audits.

#### 4.6.3 Tracking Deficiencies

Tracking construction non-conformances and corrective actions, including documenting root cause analysis and measures taken to prevent reoccurrence, is the responsibility of the EMSI Construction Manager. Once corrective actions have been completed, project records should reflect actions taken to verify that the resulting work meets project and client requirements.

#### 4.6.4 Field Reporting System

A field reporting system should be developed to provide feedback of pertinent information on performance deficiencies for all onsite work activities. The EMSI Construction Manager is responsible for ensuring that daily quality control reports are prepared. Standard EMSI test and inspection forms, together with the daily report, should be used where appropriate for all reporting of daily activities. The reporting system should reflect specific scope of work requirements and applicable project regulations and be consistent with the project document control and records management procedures described in Section 2.

#### 4.6.5 Testing Procedures

Field testing procedures in the CQAP should specify that only approved laboratories should be used for operational and/or acceptance testing. Project-specific lists of tests to be performed for specific items of work should be described including:

- Test name;
- Approved test standard;
- Frequency and estimated number of required tests;
- Responsible personnel;
- Laboratory certification, if required;
- Test standard or protocol;
- Reference specification.

Data collection procedures should be consistent with Section 3.

#### 4.6.6 Calibration and Control of Measuring and Testing Equipment

CQAP procedures should be established to maintain sufficient control over all measuring and testing equipment used for operational process monitoring and acceptance. Control should be exercised over instruments, field gauges, sensors, and special test equipment to ensure that the equipment is of the proper type, range and accuracy and is properly calibrated according to the design specifications and nationally recognized performance standards.

The control of measuring equipment and test equipment and test methods should take into account the following factors, as appropriate:

- Correct specification, including range, precision, and serviceability under specified environmental conditions;
- Initial calibration;
- Periodic recalibration, adjustment, and repair to maintain the required accuracy in use;
- Documentary evidence covering identification of instruments, frequency of recalibration, calibration status, and procedures for use, handling and storage; and
- Traceability to reference standards of known accuracy and stability.

Provisions should be made to recalibrate equipment found unsatisfactory for acceptance testing and recertify the equipment to specified tolerances before using for acceptance testing.

#### 4.7 Corrective Actions

A "closed-loop" corrective action system for design and construction work shall be maintained for each project consistent with the procedures described in Section 2. Any issue requiring corrective action also requires verification that the corrective action has successfully corrected the deficiency. Project mechanisms to suspend or stop deficient activities and, if necessary, to issue restricted usage letters and labeling for materials impacted by a corrective action requirement should be clearly specified in the PPM and CQAP.

The general approach for defining corrective action requirements should involve:

- Identifying corrective action needs and causes;
- Establishing appropriate corrective action responses; and
- Verifying the timely implementation and effectiveness of the corrective action taken.

In the field, corrective action is initiated by the Project Manager and/or Construction Manager. All problems should be identified and reported. Although corrective action for deviations from standardized field procedures may not always be required, all deviations from project planning documents should be noted in the field logbooks along with the field team leader's justification and rationale for the changes. Corrective actions should be always implemented when SOPs are not met, when non-representative conditions are indicated, and/or when specific tasks have not been performed.

## 5 REFERENCES

American Society for Quality/American National Standards Institute (ASQ/ANSI) E4:2014, Quality Management Systems for Environmental Information and Technology Programs, 2014.

Federal Geographic Data Committee (FGDC), 1998, FGDC-STD-001-1998, Content Standard for Digital Geospatial Metadata, June.

FGDC, 1998, FGDC-STD-007.1-1998, Geospatial Positioning Accuracy Standards Part 1: Reporting Methodology.

U.S. Environmental Protection Agency (EPA), 1984, EPA Order 2160, Records Management Manual, U.S. Environmental Protection Agency, Washington, DC., July.

EPA, 1998, EPA Order 1900, Contracts Management Manual, U.S. Environmental Protection Agency, Washington. DC., February.

EPA, 1999, EPA Directive 2100 (1999), Information Resources Management Policy Manual, U.S. Environmental Protection Agency, Washington. DC.

EPA, 2000, EPA Order 5360 A1, EPA Quality Manual for Environmental Programs, U.S. Environmental Protection Agency, Washington, DC., May.

EPA, 2000, EPA Order 5360.1 A2, Policy and Program Requirements for the Mandatory Quality Assurance Program, U.S. Environmental Protection Agency, Washington. DC., May.

EPA, 2000, Guidance for the Data Quality Objectives Process (QA/G-4), EPA/600/R-96/055, Office of Environmental Information, August.

EPA, 2001, EPA Requirements for Quality Management Plans (QA/R-2), EPA/240/B-01/002, Office of Environmental Information, March.

EPA, 2001, EPA Requirements for Quality Assurance Project Plans (EPA QA/R-5), EPA/240/B-01/003, Office of Environmental Information, March.

EPA, 2002, Guidance for Quality Assurance Project Plans (EPA QA/G-5), EPA/240/R-02/009, Office of Environmental Information, December.

EPA, 2003, Guidance for Geospatial Data Quality Assurance Project Plans (QA/G-5G), EPA/240/R-03/003, March.

EPA, 2007, Guidance for Preparing Standard Operating Procedures (SOPs), EPA QA/G-6, EPA/600/B-07/001, April.

EPA, 2008, National Geospatial Data Policy, CIO 2131.0, <http://www.epa.gov/irmpoli8/policies/21310.pdf>, supercedes 2100 Information Resources Management (IRM) Policy Manual Chapter 13: EPA National Locational Data Policy 1991, August 24.

## Tables

**Table 1 – Relationship of EMSI QMP to EPA Requirements**

<b>Required Element from QA/R-2</b>	<b>EMSI QMP Location</b>
<b>MANAGEMENT AND ORGANIZATION</b>	
1. Signed and dated by senior manager?	Cover
2. Signed and dated by senior line management?	Cover
3. Signed and dated QA manager?	Cover
4. Includes signature lines for Quality Staff approval?	Cover
5. Includes signature lines for OEI approval?	Cover (EPA)
6. Includes statement of the organization's QA policy?	Section 1
6a. QA policy statement includes general objectives/goals?	Section 1
6b. QA policy statement includes allocation of intramural, extramural, and travel funds and personnel?	Section 1
7. Includes organizational chart?	Subsection 2.3
7a. Organizational chart identifies all components of organization?	Subsection 2.3
7b. Organizational Chart identifies position of QA manager?	Subsection 2.3
7c. Organizational Chart identifies lines of reporting of the QA manager?	Subsection 2.3
7d. Organization Chart identifies any other QA staff?	Subsection 2.3
8. Includes discussion of authorities of the QA manager and staff?	Subsection 2.3
9. Documents the independence of QA manager?	Subsection 2.3
10. Describes procedures to ensure QA staff have access to appropriate levels of management?	Subsection 2.3
11. Discusses technical activities or programs that require quality management?	Subsections 2.5-2.8
12. Discusses where oversight of delegated or extramural programs is needed?	Subsection 2.9
13. Identifies where internal coordination of QA and QC activities among organizations is needed?	Subsection 2.10
14. Discusses how management assures understanding and implementation in all programs?	Subsection 2.10
15. Describes process for resolving disputes?	Subsection 2.10

<b>Required Element from QA/R-2</b>	<b>EMSI QMP Location</b>
<b>QUALITY SYSTEM COMPONENTS</b>	
16. Includes description of quality system?	Subsection 2.10
17. Describes principal quality system components (e.g., quality system documentation, annual reviews and planning, project specific quality documentation)?	Subsection 2.10
18. Description of components includes how they are implemented?	Subsection 2.10
19. Description of components includes responsibilities of management and staff?	Subsection 2.10
20. Lists tools for implementing each component (e.g., QMPs, Quality Systems Audits, Training Plans, QA Project Plans)?	Subsection 2.10
21. Identifies internal organizations that develop QMPs?	Subsection 2.10
22. Identifies review and approval procedures for these internal QMPs?	Subsection 2.10
23. Includes assurance that QA responsibility is incorporated into performance standards (consistent with Agency personnel policy)?	Subsection 2.10
<b>QUALIFICATIONS AND TRAINING</b>	
24. States policy regarding QA training for management and staff?	Subsection 2.4
25. Describes process for identifying, ensuring, and documenting that personnel have necessary quality-related qualifications?	Subsection 2.4
26. Describes process for ensuring personnel maintain quality-related qualifications?	Subsection 2.4
27. Describes process for identifying the need for quality-related retraining based on changing requirements?	Subsection 2.4
28. Includes roles, responsibilities, and authorities in description of above processes?	Subsections 2.2, 2.3, 2.4
<b>PROCUREMENT OF ITEMS AND SERVICES</b>	
29. Describes process for reviewing and approving all extramural agreements (grants, cooperative agreements and contracts)?	Subsections 3.5.5, 4.3
29a. Review process ensures documents are complete and accurate?	Subsections 3.5.5, 4.3
29b. Review process ensures agreement clearly describes the item or service needed?	Subsections 3.5.5, 4.3
29c. Review process ensures agreement describes the associated technical and quality requirements?	Subsections 3.5.5, 4.3
29d. Review process ensures agreement describes the quality system elements for which the supplier is responsible?	Subsections 3.5.5, 4.3

<b>Required Element from QA/R-2</b>	<b>EMSI QMP Location</b>
29e. Review process ensures that the supplier's conformance to the customer's requirements will be verified?	Subsections 3.5.5, 4.3
30. Describes process for reviewing and approving applicable responses to solicitations to ensure that they satisfy all technical and quality requirements?	Subsections 3.5.5, 4.3
30a. Review process ensures the review of evidence of the supplier's capability to satisfy EPA quality requirements?	Subsections 3.5.5, 4.3
30b. Review process ensures procured items and services are acceptable?	Subsections 3.5.5, 4.3
31. Describes process for review and approval of suppliers' quality-related documentation (e.g., QA Project Plans and QMPs)?	Subsections 3.5.5, 4.3
32. Includes discussion of any policy and criteria for delegations of review of QA Project Plans and QMPs?	Subsections 3.5.5, 4.3
33. Describes process to ensure EPA extramural agreement policies satisfied?	Subsections 3.5.5, 4.3
34. Includes roles, responsibilities, and authorities in description of above processes?	Subsections 3.5.5, 4.3
<b>DOCUMENTS AND RECORDS</b>	
35. Describes process for identifying quality-related documents and records (including electronic) requiring control?	Subsection 2.9
36. Describes process for preparing, reviewing, approving, issuing, using, authenticating, and revising documents and records?	Subsection 2.9
37. Describes process for ensuring that records and documents accurately reflect completed work?	Subsection 2.9
38. Describes process for maintaining documents and records including transmittal, distribution, retention, access, preservation, traceability, retrieval, removal of obsolete documentation, and disposition?	Subsection 2.7
39. Describes process for establishing and implementing appropriate chain of custody and confidentiality procedures for evidentiary records?	Subsection 3.2
40. Above processes comply with EPA Order 2160 and EPA Directive 2100, Chapter 10?	Subsections 2.7, 2.9, 2.10, 2.11
41. Includes roles, responsibilities, and authorities in description of above processes?	Subsections 2.7, 2.9, 2.10

<b>Required Element from QA/R-2</b>	<b>EMSI QMP Location</b>
<b>COMPUTER HARDWARE AND SOFTWARE</b>	
42. Describes process for developing, installing, testing, using, maintaining, controlling, and documenting computer hardware and software?	Subsection 2.8
43. Describes process for assessing and documenting the impact of changes to user requirements and/or the hardware and software on performance?	Subsection 2.8
44. Describes process for evaluating purchased hardware and software?	Subsection 2.8
45. Describes process for ensuring that data and information produced from or collected by computers meet applicable requirements and standards?	Subsection 2.8
46. Includes roles, responsibilities, and authorities in description of above processes?	Subsections 2.9, 2.10
47. Are the requirements of EPA Directive 2100 are addressed in the above processes?	Subsections 2.8, 2.9, 2.10
<b>PLANNING</b>	
48. Includes a description of the systematic planning process for environmental data operations?	Section 3
48a. Does process include identification and involvement of all customers and suppliers?	Subsection 3.2
48b. Does process include description of the project goal, objectives, and questions and issues to be addressed?	Subsections 3.2, 3.3, 3.4
48c. Does process include identification of project schedule, resources, milestones, and any applicable requirements?	Subsections 3.2, 3.3, 3.4
48d. Does process include identification of the type and quantity of data needed and how the data will be used to support the project's objectives?	Subsections 3.3, 3.4, 3.5
48e. Does process include specification of performance criteria for measuring quality?	Subsections 3.5, 3.6
48f. Does process include specification of needed QA and QC activities to assess the quality performance criteria?	Subsection 3.6
48g. Does process include description of how, when, and where the data will be obtained (including existing data) and identification of any constraints on data collection?	Subsections 3.3, 3.4, 3.5
48h. Does process include description of how the acquired data will be analyzed, evaluated, and assessed against its intended use and the quality performance criteria?	Subsections 3.3, 3.6
49. Describes process for developing, reviewing, approving, implementing, and revising QA Project Plans?	Subsections 2.10, 2.11, 3.7, 3.8, 4.7

<b>Required Element from QA/R-2</b>	<b>EMSI QMP Location</b>
50. Describes process for evaluating and qualifying data collected for other purposes or from other sources?	Subsections 3.5, 3.6
51. Includes roles, responsibilities, and authorities in description of above processes?	Subsections 3.2, 3.3, 4.1, 4.2
<b>IMPLEMENTATION OF WORK PROCESSES</b>	
52. Describes process for ensuring that work is performed according to planning and technical documents?	Subsections 3.5, 4.4, 4.6
53. Describes process for identifying operations needing procedures?	Subsection 4.5
54. Describes process for preparation, review, approval, revision, and withdrawal of these procedures?	Subsection 4.5, 4.6, 4.7
55. Describes policy for use of these procedures?	Subsections 1.2, 1.4
56. Describes process for controlling and documenting the release, change, and use of planned procedures?	Subsections 2.9, 2.10, 3.7, 3.8, 4.6, 4.7
56a. Process includes description of necessary approvals?	Subsections 2.9, 2.10
56b. Process includes removal of obsolete documentation from work areas?	Subsection 2.10
56c. Process includes verification that the changes are made as prescribed?	Subsections 2.10, 2.11, 3.7, 3.8, 4.6, 4.7
57. Includes roles, responsibilities, and authorities in description of above process?	Subsections 2.3, 3.4, 4.2
<b>ASSESSMENT AND RESPONSE</b>	
58. Describes the process for assessing the adequacy of the quality system at least annually?	Subsection 2.11
59. Describes the process for planning, implementing and documenting assessments and reporting results to management?	Subsection 2.11
59a. Process includes selecting an assessment tool, the expected frequency, and the roles and responsibilities of assessors?	Subsection 2.11
59b. Process includes determining the level of competence, experience and training needed for assessment personnel?	Subsection 2.11
59c. Process includes ensuring that personnel have no real or perceived conflict of interest, and have no direct involvement or responsibility for the work being assessed?	Subsection 2.11
59d. Process includes ensuring that personnel conducting assessments have sufficient authority, access to programs and managers, access to documents and records, and organizational freedom?	Subsection 2.11

Required Element from QA/R-2	EMSI QMP
60. Describes process for management’s review of, and response to, findings?	Subsection 2.11
61. Describes process for identifying how and when corrective actions are to be taken in response to the findings of the assessment?	Subsection 2.11
61a. Process includes ensuring corrective actions are made promptly?	Subsection 2.11
61b. Process includes confirming the implementation and effectiveness of any corrective action?	Subsection 2.11
61c. Process includes documenting actions?	Subsection 2.11
62. Describes process for addressing disputes encountered as a result of assessments?	Subsection 2.11
63. Includes roles, responsibilities, and authorities in description of above processes?	Subsection 2.11
<b>QUALITY IMPROVEMENT</b>	
64. Describes process for ensuring that conditions adverse to quality are prevented, identified promptly, corrected promptly and that actions are taken toward prevention, documented and actions tracked to closure?	Subsection 1.2
65. Describes process for encouraging staff to establish communications between customers and suppliers, identify process improvement opportunities, and identify and propose solutions for problems?	Subsection 1.2
66. Includes roles, responsibilities, and authorities in description of above processes?	Subsection 1.2
<b>OTHER REVIEW CRITERIA</b>	
67. Are regulatory or other citations accurate?	
68. Are there any inconsistencies in the text?	
69. Is the writing clear?	
70. Are organizational units identified consistent with the most recent reorganization?	
71. Are past QS management assessment findings resolved?	
72. Are activities described in the QMP consistent with QA Annual Report and Work Plans?	
73. Are tasks proposed for other organizations not covered solely by this QMP documented elsewhere (e.g., in another organization’s QMP)?	

## Figures

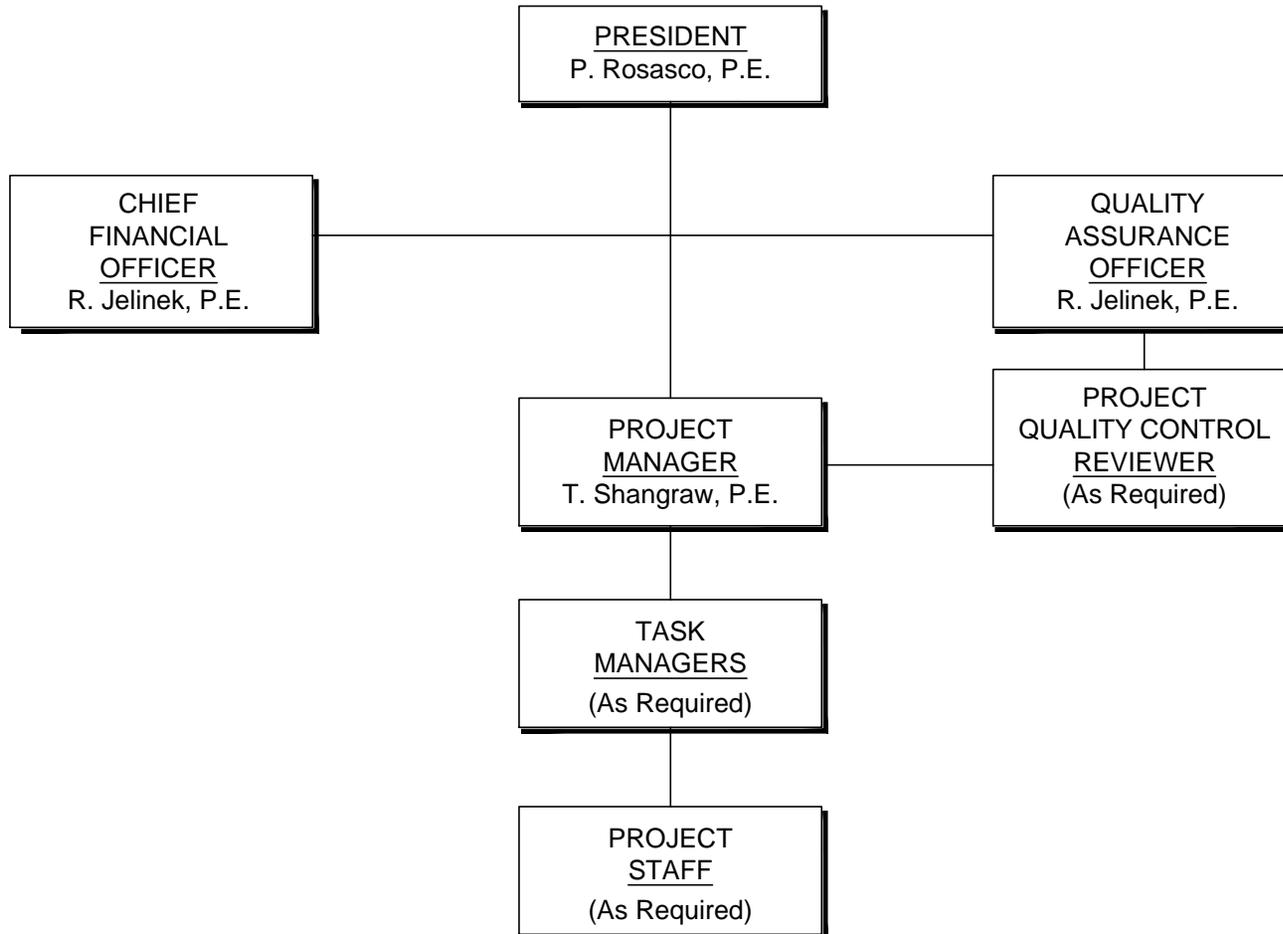


Figure 1  
Functional Organizational Structure  
(February 2016)

Quality Assurance Management Plan

## Appendix A

## Appendix B

**Form B-1**

**Project Planning and Scoping Checklist**

Project Name:						Project Number:					
Project Manager:						Date:					
Reviewer:						Status (circle)					
<b>1. Objectives and Scope</b>											
a. Is there a signed contract?						Yes	No	Not Reviewed	Not Applicable		
b. Are the objectives of the project clearly defined?						Yes	No	Not Reviewed	Not Applicable		
c. Is the overall technical approach commensurate with the objectives?						Yes	No	Not Reviewed	Not Applicable		
d. Are the limitations of the proposed scope of work well understood and conveyed to the client?						Yes	No	Not Reviewed	Not Applicable		
e. Is there conformance to the contracted scope of work?						Yes	No	Not Reviewed	Not Applicable		
f. Are the project members appropriately assigned and briefed?						Yes	No	Not Reviewed	Not Applicable		
<b>2. Methods and Procedures</b>											
a. Are the proposed methods and procedures technically sound and adequately defined?						Yes	No	Not Reviewed	Not Applicable		
b. Have competent subcontractors been identified?						Yes	No	Not Reviewed	Not Applicable		
c. Have the permit issues been adequately considered?						Yes	No	Not Reviewed	Not Applicable		
d. Are the QC requirements adequately identified?						Yes	No	Not Reviewed	Not Applicable		
e. Is there a change order procedure documented?						Yes	No	Not Reviewed	Not Applicable		
<b>3. Deliverables</b>											
a. Have the client and the project manager agreed on the number and scope of deliverables?						Yes	No	Not Reviewed	Not Applicable		
<b>4. Budget and Schedule</b>											
a. Have detailed cost estimates been prepared?						Yes	No	Not Reviewed	Not Applicable		
b. Are cost estimates correct?						Yes	No	Not Reviewed	Not Applicable		
c. Has detailed project schedule been prepared and discussed with the client?						Yes	No	Not Reviewed	Not Applicable		
d. Is the schedule reasonable?						Yes	No	Not Reviewed	Not Applicable		

**Form B-2**  
**Quality Control Review Checklist**

Project Name:		Project Number:			
Project Manager:		Date:			
Reviewer:					
		Status (circle)			
<b>1. Objectives and Scope</b>					
a. Are the objectives of the project clearly defined?		Yes	No	Not Reviewed	Not Applicable
b. Is the overall technical approach commensurate with the objectives?		Yes	No	Not Reviewed	Not Applicable
c. Are the limitations of the proposed scope of work adequately described?		Yes	No	Not Reviewed	Not Applicable
d. Is there conformance to the contracted scope of work?		Yes	No	Not Reviewed	Not Applicable
<b>2. Data Collection Rationale</b>					
a. Is the rationale for data collection adequately described?		Yes	No	Not Reviewed	Not Applicable
b. Is a QAPP needed?		Yes	No	Not reviewed	Not Applicable
<b>3. Methods and Procedures</b>					
a. Are the methods and procedures used technically sound and adequately explained?		Yes	No	Not Reviewed	Not Applicable
b. Were data collection procedures followed?		Yes	No	Not Reviewed	Not Applicable
<b>4. Conclusions</b>					
a. Is the data interpretation process logical, and can it be followed?		Yes	No	Not Reviewed	Not Applicable
b. Are conclusions clearly stated?		Yes	No	Not Reviewed	Not Applicable
c. Are conclusions adequately supported by facts?		Yes	No	Not Reviewed	Not Applicable
<b>5. Opinions and Recommendations</b>					
a. Are opinions supported by data and conclusions?		Yes	No	Not Reviewed	Not Applicable
b. Do recommendations and opinions reflect reasonable professional judgment?		Yes	No	Not Reviewed	Not Applicable
c. Are recommendations clearly separated from conclusions?		Yes	No	Not Reviewed	Not Applicable
<b>6. Professional Registrations</b>					
a. Have documents been reviewed and signed by registered professionals where appropriate?		Yes	No	Not Reviewed	Not Applicable

**Form B-3**

**Quality Assurance Audit Checklist**

Project Name:		Project Number:			
Project Manager:		Date:			
Reviewer:					
		Status (circle)			
<b>1. Scope</b>					
a. Did proposal define work performed?		Yes	No	Not Reviewed	Not Applicable
b. Did work plan define work performed?		Yes	No	Not Reviewed	Not Applicable
c. Did project meet objectives?		Yes	No	Not Reviewed	Not Applicable
<b>2. Budget and Schedule</b>					
a. Were all scope items budgeted?		Yes	No	Not Reviewed	Not Applicable
b. Were all equipment and support labor budgeted?		Yes	No	Not Reviewed	Not Applicable
c. Were cost estimates correct?		Yes	No	Not Reviewed	Not Applicable
d. Was the project completed within budget?		Yes	No	Not Reviewed	Not Applicable
e. Was the project completed on schedule?		Yes	No	Not Reviewed	Not Applicable
<b>3. Field Investigation</b>					
a. Were field procedures audited?		Yes	No	Not Reviewed	Not Applicable
b. Were field notes reviewed?		Yes	No	Not Reviewed	Not Applicable
c. Were boring logs edited?		Yes	No	Not Reviewed	Not Applicable
<b>4. Chemical Analysis</b>					
a. Were data quality objectives established?		Yes	No	Not Reviewed	Not Applicable
b. Were QC samples collected?		Yes	No	Not Reviewed	Not Applicable
c. Were QC data reviewed?		Yes	No	Not Reviewed	Not Applicable

**Form B-3 (continued)**  
**Quality Assurance Audit Checklist**

Status (circle)					
<b>5. Calculations</b>					
a. Was methodology correct?	Yes	No	Not Reviewed	Not Applicable	
b. Was math correct?	Yes	No	Not Reviewed	Not Applicable	
<b>6. Design</b>					
a. Was design in conformance with Project Procedures Memorandum?	Yes	No	Not Reviewed	Not Applicable	
b. Was design review completed?	Yes	No	Not Reviewed	Not Applicable	
<b>7. QA/QC Plan</b>					
a. Were separate QA/QC plans required?	Yes	No	Not Reviewed	Not Applicable	
b. Did QC procedures conform to company policy?	Yes	No	Not Reviewed	Not Applicable	
<b>8. Report</b>					
a. Was a technical edit performed?	Yes	No	Not Reviewed	Not Applicable	
b. Were graphics correct?	Yes	No	Not Reviewed	Not Applicable	
c. Was draft report reviewed?	Yes	No	Not Reviewed	Not Applicable	
d. Were signatures correct?	Yes	No	Not Reviewed	Not Applicable	
<b>9. Contractual Procedures</b>					
a. Was there a signed contract?	Yes	No			
b. Did scope of work, budget, and schedule comply with contractual obligations?	Yes	No			
c. Are change orders properly documented for scope, budget, and schedule changes?	Yes	No			
d. Are subcontracts in accordance with company policy?	Yes	No			

**Form B-4**  
**Quality Assurance Audit Form**

Project Name: \_\_\_\_\_ Project Number: \_\_\_\_\_

Project Manager: \_\_\_\_\_ Date: \_\_\_\_\_

Audited by: \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed with President: \_\_\_\_\_ Date: \_\_\_\_\_

Project Objective/Brief Scope Description:

\_\_\_\_\_

1. Was a project management plan or PM procedures memo prepared? Yes      No

2. Who is the professional in responsible charge of the work?  
(This is the scientist or engineer of record, not necessarily the Project Manager) \_\_\_\_\_

3. List QC reviewer(s) names and their specialty areas.  
\_\_\_\_\_  
\_\_\_\_\_

4. What is the estimated physical project completion stage? \_\_\_\_\_ %

5. Have QC reviews been completed and documented? Yes      No

6. Are there any significant quality assurance issues that need follow-up by management? If so, please identify them below:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

cc: Project Manager  
    President