Kansas City PM Characterization Study
Final Report

Appendix II
Quality Management Plan

Assessment and Standards Division
Office of Transportation and Air Quality
U.S. Environmental Protection Agency

Sponsors:

National Renewable Energy Laboratory, U.S. Department of Energy
Federal Highway Administration, U.S. Department of Transportation
STAPPA-ALAPCO Emission Inventory Improvement Program
Coordinating Research Council Inc. (Project No. E-69)

Prepared for EPA by
Eastern Research Group, Incorporated
Austin, TX

Bevilacqua-Knight Incorporated
Oakland, CA

NuStats LLC
Austin, TX

Desert Research Institute
Reno, NV

EPA Contract No. GS 10F-0036K

October 27,2006
Revised April 2008 by EPA staff

United States
Environmental Protection
Agency

EPA420-R-08-009
April 2008

Quality Management Plan

Eastern Research Group, Inc.
110 Hartwell Avenue
Lexington, MA 02421

April 2004

QMP REVISION HISTORY

Revision 1: April 15, 2004

QUALITY MANAGEMENT PLAN

SIGNATURES OF APPROVAL

Name: William S. Crews
Title: Project Manager
Org.: Bevilacqua Knight Inc.
Date. 8-1-06

Name: Rob Santos

Title: Quality Assurance Manager
Org.: NuStats
Date: 9 / 28 /06

Name: Eric Fujita
Title: Project Manager
Org.: Desert Research Institute
Date. 9/28/06

Name: Sandeep Kishan
Title: Vice President
Org.: Eastern Research Group
Date. 9/28/06

APPROVAL FOR THE AGENCY

Name: Greg Janssen
Title: Project Officer, US EPA
Org.: U.S. Environmental Protection Agency
Date: _____

Name: Carl Fulper
Title: Work Assignment Manager
Org.: U.S. Environmental Protection Agency
Date: _____

Name: Ruth Schnek
Title: OAR-NVFEL Quality Manager
Org.: U.S. Environmental Protection Agency
Date: _____

TABLE OF CONTENTS

Page

TABLE OF CONTENTS (Continued)

Page

TABLE OF CONTENTS (Continued)

Page

TABLE OF CONTENTS (Continued)

Page

TABLE OF CONTENTS (Continued)

Page

LIST OF FIGURES

LIST OF TABLES

EASTERN RESEARCH GROUP, INC.
QUALITY MANAGEMENT PLAN

INTRODUCTION

This Quality Management Plan (QMP) describes ERG's quality assurance/quality control (QA/QC) program in terms of the company's organizational structure, the functional responsibilities of management and staff, and the cooperative interaction among those staff planning, implementing, and assessing the activities conducted under a specific project. Quality management is the component within the overall corporate management structure that determines and implements the quality policy, which includes strategic planning, allocation of resources, and other systematic activities. ERG is committed to maintaining a corporate quality management program that is responsive to the requirements of the diverse work it performs, which ranges from field testing and laboratory analysis to education, training, and outreach. This company-wide commitment to provide services of consistent, high quality directs all QA activities.

The components of ERG's QA/QC program include:

- A statement of ERG's quality policy;
- A description of ERG's corporate and project organizational structures, and the relationship of the QA/QC function to these organizational structures;
- A description of the authority and responsibilities of the QA/QC function at both the corporate and project level; and
- A discussion of ERG's general approach for planning and implementing activities affecting quality in the Science and Engineering technical services areas.

The QMP includes the following sections:

1. Management and Organization;
2. Quality System Components;
3. Personnel Qualification and Training;
4. Procurement of Items and Services;
5. Documentation and Records;
6. Computer Hardware and Software;
7. Planning;
8. Implementation of Work Processes;
9. Assessment and Response; and
10. Quality Improvement.

SECTION 1

MANAGEMENT AND ORGANIZATION

ERG's quality system reflects the company's mission: **ERG provides quality technical services to meet the needs of our clients in a responsive and responsible manner**. The quality system provides the necessary elements to plan, implement, document, and assess the effectiveness of quality assurance and QC. QC is a system of routine technical activities implemented by the project personnel to measure and control the quality of data as they are collected and manipulated. QC activities include technical reviews, accuracy checks, and the use of standard procedures for data collection, analysis, and reporting. Quality assurance (QA) includes those activities that provide an independent assessment of a project or project tasks, including QC functions.

Responsibility for quality at ERG lies with management and depends on the cooperation of all employees. Specific responsibility for the quality of a given project lies with the Project management team (Project Manager and Task Leaders) who oversees the quality of all ERG services. All scientific and technical services provided by ERG must meet appropriate quality objectives that satisfy the client's needs and expectations, with the understanding that costs of QA/QC activities must be proportional to the needs of the program. In addition, ERG routinely incorporates technical and editorial reviews of documents to ensure that the client's needs and expectations are adequately met with documents that are technically correct and well-written and with data that are complete, accurate, precise, representative, and reproducible.

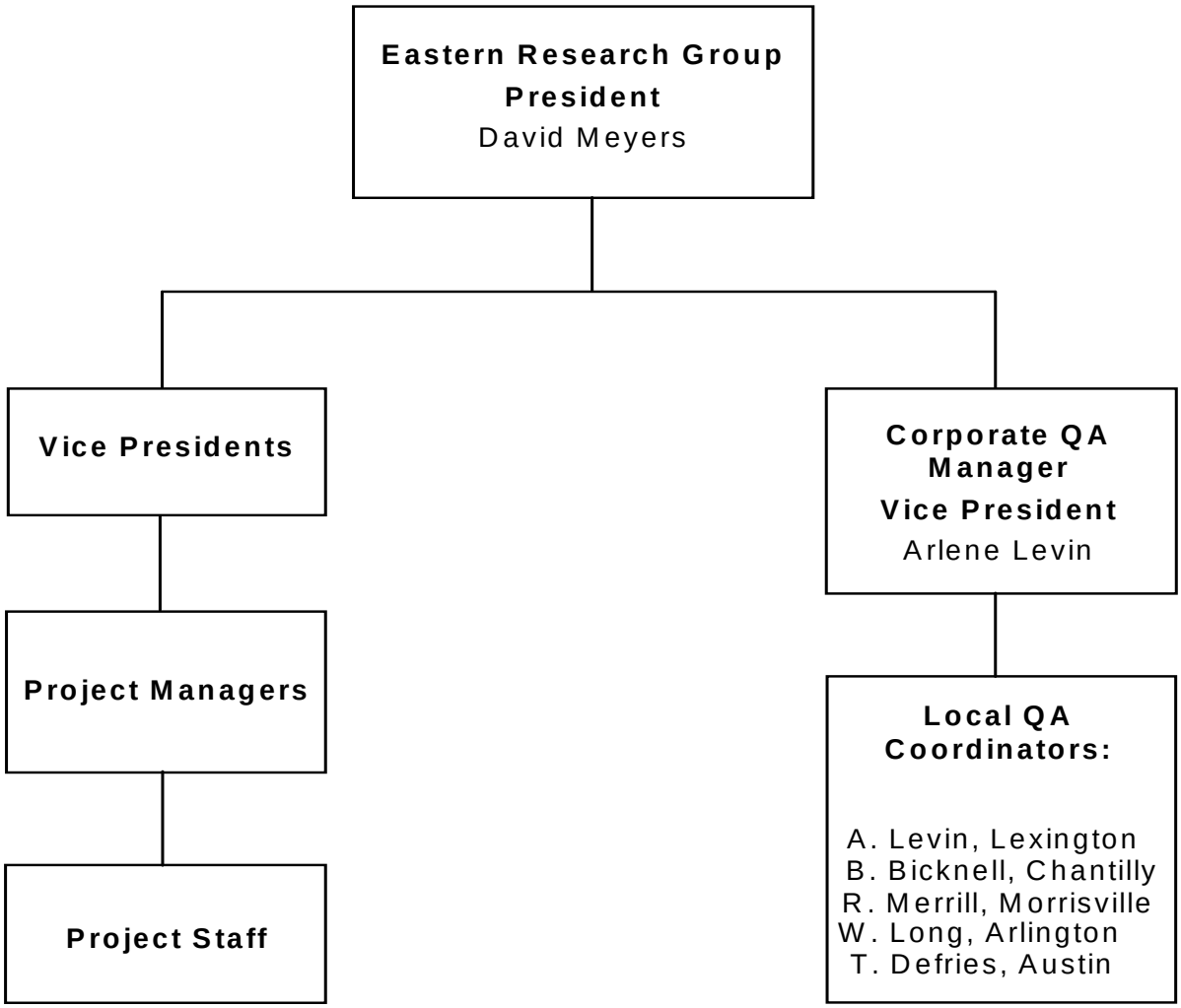
This Quality Management Plan (QMP) describes ERG's quality system, which is the structured and documented management system for the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation that ensure quality in work processes, products, and services. The quality system provides a framework for planning, implementing, and assessing work performed by the organization and for executing required QA/QC.

1.1 ERG QUALITY POLICY

ERG provides quality technical services to meet or exceed the needs of our clients in an effective and responsible manner. We measure our success as a company by our customers' satisfaction. It is our policy to maintain a corporate quality management program in order to be responsive to our clients' requirements for the diverse work we perform, which ranges from field testing and laboratory analysis to education, training, and outreach. ERG is committed to allocating the necessary resources for implementing, maintaining, and improving our quality management program, as well as preventing problems before they occur. Our company-wide pledge to provide services of consistently high quality drives all ERG quality assurance activities.

1.2 ORGANIZATION, RESPONSIBILITIES, AND AUTHORITY OF QUALITY ASSURANCE STAFF

The organization of the QA structure within ERG enables complete independence in program review. The Corporate QA Manager, ERG Vice President Arlene Levin, reports directly to ERG's President David Meyers, as indicated in the corporate organizational chart shown in Figure 1-1. She interacts with the Local QA Coordinators to assure that project-specific QA/QC programs are commensurate with project objectives and with ERG's quality system. The Local QA Coordinators, Mr. Andrew Burnette and Dr. Timothy DeFries (Austin, TX) report directly to Ms. Levin.



1-1. Corporate Organization

The independence of quality assurance is maintained at the project level (Figure 1-2). A project-specific QA coordinator is assigned to each project and given responsibility for coordinating the development and execution of QA/QC activities in all phases of the project. The Project QA Coordinator, directly responsible to the Local QA Coordinator, is responsible for ensuring the preparation of Quality Assurance Project Plans (QAPPs), which document project-specific policies, organization, objectives, functional activities, and specific QA/QC procedures; providing an independent review of the project approach, methods, experimental design, and QC activities; and conducting independent systems, performance, and data quality assessments through quality assurance audits. He/she verifies through continual evaluation that the overall quality management system is performing effectively and implements corrective measures, if necessary. Finally, he/she documents the results of all QA/QC activities in reports to ERG management. If the Project QA Coordinator is not the Local QA Coordinator, then he/she reports findings to the latter.

The independent authority of the QA staff is extremely important to ERG and to our clients. To this end, ERG confers sufficient authority on its QA staff to ensure that projects meet their defined data quality objectives and that data generated by ERG are of known quality. ERG has more than 23 years of experience supporting QA/QC activities on programs for EPA and other government clients. This experience gives us an understanding of the different levels of QA/QC activities necessary to cover the spectrum of quality objectives in ERG's scientific and technical programs, and it allows us to configure our QA staff and approach to best meet client needs. We are committed to meeting the QA/QC objectives of all our programs and our approach has proven effective for the broad range of our project work.

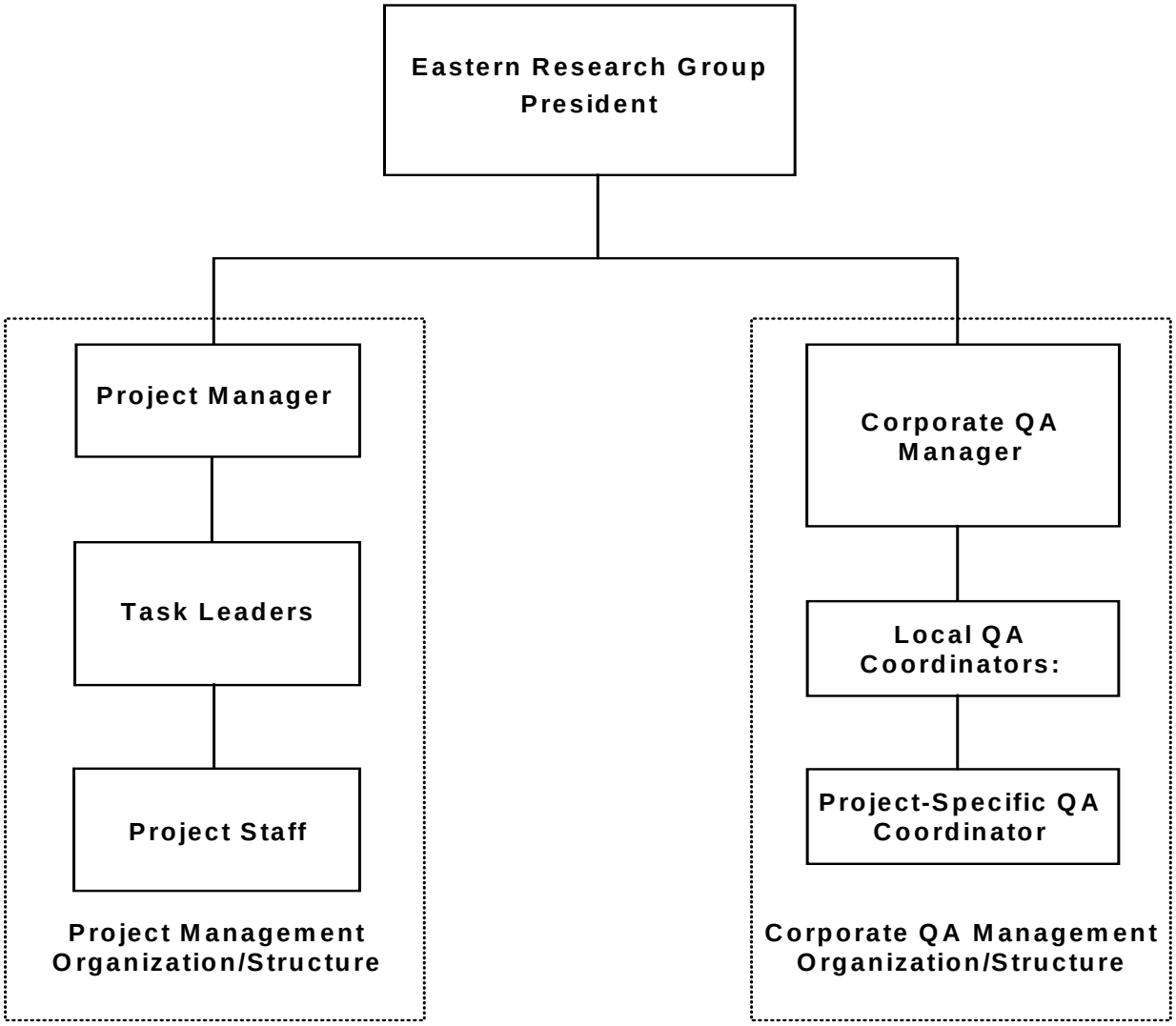


Figure 1-2. ERG's Corporate QA Structure Functions Independently of the Project Management Structure

The responsibilities, authority, and independence of ERG's corporate QA staff are outlined below.

1.2.1 Responsibilities, Authority, and Independence of the Corporate QA Manager

The Corporate QA Manager, Ms. Arlene Levin, plans, assesses, and improves ERG's quality system. She is organizationally independent, reporting directly to the ERG president. She is also responsible for:

- Developing QA policy for ERG in accordance with EPA and other client QA policies and direction from ERG management;
- Developing the corporate QMP, reviewing it annually, and revising it as necessary;
- Reviewing quality-related documents that are part of an ERG procurement, to determine if they are adequate to meet ERG's client's needs;
- Ensuring that all ERG project personnel understand the ERG quality system, through training and access to QA policy and procedure documents;
- Interacting with the Local QA Coordinators to assure that project-specific QA/QC programs are commensurate with project objectives and with ERG's quality system;
- Ensuring that independent audits are conducted to determine the effectiveness of the ERG QA/QC program;
- Working with Local QA Coordinators in conducting management systems reviews, described in Section 9.2.1 of this QMP;
- Implementing corrective actions for quality problems raised by Local and Project QA Coordinators;

- Recommending required management level corrective actions; and
- Stopping work of inadequate quality until identified deficiencies are resolved.

1.2.2 Responsibilities, Authority, and Independence of the Local QA Coordinators

Local QA Coordinators are designated for all ERG offices. They are organizationally independent, reporting to the Corporate QA Manager, Arlene Levin, who reports directly to the ERG president. (Ms. Levin also functions as the Local QA Coordinator for the Lexington office.) Local QA Coordinators are responsible for:

- Assisting the Corporate QA Manager in developing QA policies and procedures;
- Working with the Project Management Team to assure that project-specific QA/QC programs are commensurate with project objectives and with ERG's quality system;
- Assisting the Project Manager, and ERG Task Leaders in identifying and assigning appropriate project-specific QA coordinators and peer reviewers;
- Reviewing and approving QAPPs prepared by project staff;
- Reviewing reports from Project QA Coordinators of QA/QC procedures developed and executed for each project;
- Conducting independent audits to determine the effectiveness of the ERG QA/QC program, conducting management systems reviews, and independent technical assessments;
- Maintaining records of internal QA audits;
- Designating an appropriate individual to create needed standard operating procedures (SOPs), reviewing the draft procedure or designating an appropriate technical reviewer, and circulating the approved SOP to technical staff members;

- Maintaining copies of SOPs pertaining to the ERG location in a central filing system;
- Ensuring that all ERG personnel performing work covered by the QMP are notified of any changes and are informed of current requirements; and
- Submitting a summary of all unresolved or in-progress Requests for Corrective Action to ERG senior management (described in Section 10.2 of this QMP).

1.2.3 Authority to Stop Work for Quality Considerations

As discussed in Section 9 of ERG's Corporate QMP, the Project QA Coordinator audits the QA/QC performance of the project team. If the Project QA Coordinator finds deficiencies in project team performance, he/she notifies the ERG Task Leader, the Project Manager and Local QA Coordinator. If the deficiencies are not resolved, the Project QA Coordinator recommends that the ERG Task Leader stop work, replace personnel, or make other necessary changes so that the deficiencies are resolved. If deficiencies are still not resolved, the Project QA Coordinator notifies the Local QA Coordinator and Corporate QA Manager who ensure that the quality system outlined in this QMP is implemented and maintained. If the ERG Task Leader is unavailable, the Project Manager serves in his place.

1.2.4 Access of QA Staff to Management

ERG's QA/QC program is implemented at three staff levels, the Corporate QA Manager and Local QA Coordinators, described above, and the Project QA Coordinators, described in Section 1.3, below. The Project QA Coordinators serve as internal consultants to the Project Manager, and Task Leaders in developing project-specific QC systems. The Local QA Coordinators report to the Corporate QA Manager, Arlene Levin, who reports directly to the ERG president. This structure ensures that QA personnel have access to the appropriate levels of management in order to plan, assess, and improve ERG's QA/QC program.

"If you don't get a reasonable response to an issue or problem in a reasonable amount of time, contact me directly. Please don't feel that you're bothering me, or that I'm too busy. If something is of concern to you, I'd like to know about it and get a chance to do something about it."

ERG President, David Meyers
From President's Message on ERG Intranet

In addition, QA staff, like all ERG staff, can contact the ERG president directly about concerns they feel have not been resolved at a lower management level.

1.3 PROJECT ORGANIZATION AND STAFF RESPONSIBILITIES

This section describes the organizational structure ERG uses to manage projects including the integration of QA/QC activities. For all work assignments, staff responsibilities, authority, and lines of communication are delineated in project-specific work plans and in the QAPPs. These plans are reviewed and approved by participants before work begins. The plans are disseminated using document control procedures to ensure that any changes made to the original plans are implemented by all project staff. Figure 1-3 presents a typical project-level QA organization.

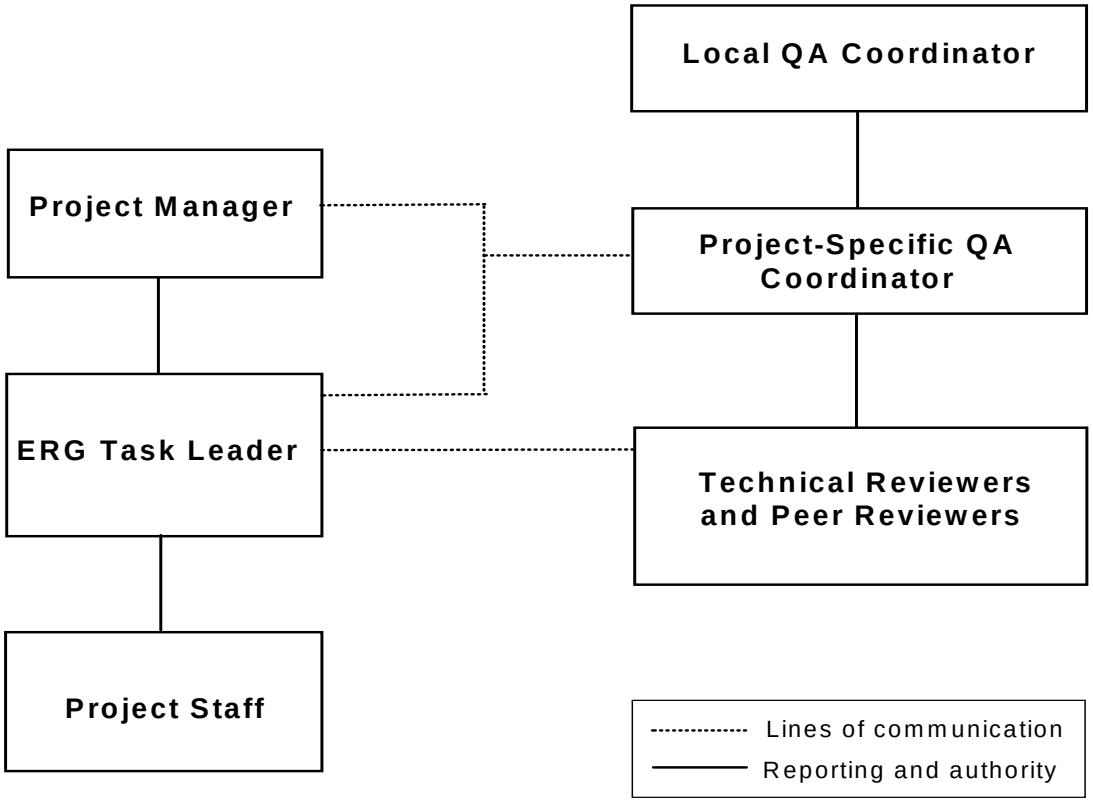


Figure 1-3. Typical Project-Level QA Organization

1.3.1 Project Manager

Project Managers (sometimes called Principal Investigators) at ERG have overall responsibility for individual work assignments. They organize and direct the technical activities and functions as the primary liaison between the client, management, and the project team. The duties of an ERG Project Manager include:

- Responding quickly to client requests and inquiries;
- Communicating with the client on technical matters and the and ERG Contract Manager on contractual matters;
- Informing project staff of contract requirements and ensuring the staff follow the requirements;
- Reviewing contract modifications;
- Reviewing all work assignments, work plans, and cost estimates;
- Ensuring that the project receives the appropriate staffing levels and technical expertise;
- Initiating and reviewing subcontractor work assignments;
- Managing and reviewing technical and financial progress reports and invoices;
- Implementing ERG's Security Plan for Handling Confidential Business Information;
- Implementing ERG's QMP;
- Assuring ERG remains free of conflict-of-interest;
- Working with the Project QA Coordinator and the ERG Task Leader to resolve any quality problems that arise; and

- Serving as the point-of-contact with ERG management on all matters relating to the contract.

- Coordinating the technical components (including personnel, facilities, and equipment) required under the contract;

- Assisting with the selection of project personnel;

- Monitoring the technical activities on each work assignment to ensure the technical objectives, budget, and schedule are met;

- Managing preparation and implementation of work plans, test plans, quality assurance project plans and cost estimates in accordance with EPA directions and format; and

- Reviewing performance of ERG Task Leaders; and

- Maintaining an awareness of new client policies and technical issues and communicating these to all work assignment staff.

1.3.2 ERG Task Leaders

ERG Task Leaders (sometimes called ERG Work Assignment Managers) coordinate the activities of the individual tasks required for completion of a given work assignment. In executing these duties, ERG Task Leaders:

- Are available to the client for action on any problem related to specific work assignments;

- Prepare and implement work plans, test plans, health and safety plans, and quality assurance project plans and associated project instructions in response to work assignments;

- Provide the client with periodic status briefings or reports;

- Implement ERG's cost and performance tracking and control system;
- Complete project on-time, within-budget, and in accordance with work order or assignment technical and regulatory objectives;
- Maintain and document all work assignment-related records, files, calculations, assumptions, and professional engineering judgments;
- Follow ERG's QMP and ensure the technical quality of reports, memoranda, and other communications from inception to delivery;
- Monitor the technical activities of each ERG project staff member to ensure that they are meeting the highest technical standards and adhering to the budget and schedule;
- Review the performance of ERG staff;
- Keep the ERG Project Manager informed on all aspects of each task, including expenditures, technical progress, problems, and recommended solutions;
- Monitor subcontractor performance and provide performance data to the ERG Project Manager;
- Ensure compliance with all QC acceptance criteria as specified in any QAPP or other project-specific supplement to the QMP; and
- Keep the Project QA Coordinator and the Project Manager advised of any quality problems that arise.

1.3.3 Project QA Coordinators

Project QA Coordinators are responsible for the development and execution of QA activities throughout the course of a project, including work plan, test plan, health and safety plan, and quality assurance project plan development and execution, data analysis, and reporting. ERG identifies a Project QA Coordinator for each work assignment or group of related work assignments on this contract. In this capacity, the Project QA Coordinators:

- As required by the work order or assignment, ensure preparation of a QAPP that documents the project-specific policies, organization, objectives, functional activities, and specific QA/QC procedures designed to achieve quality goals or requirements. (e.g., QAPPs prepared for EPA projects will comply with *EPA Requirements for Quality Assurance Project Plans*, EPA/240/B-01/003 March 2001 (QA/R-5), and/or NRMRL QMP Appendix C: *Quality Assurance Planning Requirements*, as specified by the client).

- Verify that the requirements of the approved QAPP and other ERG QA/QC procedures are communicated to the project team;

- Serve as internal consultants to the Project Manager, and ERG Task Leaders in defining quality goals or requirements and in developing a project-specific QC system that is responsive to them;

- In consultation with the Local QA Coordinator, verify that subcontractors' quality related procedures are adequate and executed;

- Provide an independent review of the project approach, methods, and sampling design;

- Provide the mechanism for bringing quality problems to the immediate attention of the Project Manager or, if warranted, to the attention of the Local QA Coordinator or Corporate QA Manager for implementation of corrective action;

- Provide an independent assessment of performance through QA audits;

- Oversee any external QA audit activities requested by the client if required by work assignment; and

- Document the results of all QA/QC activities in reports to ERG management and, if required by the work assignment, to the client(s).

1.3.4 Project Staff

Project staff are responsible for executing the project QA/QC requirements specified in the QAPP and other project plans. They are responsible for documenting the results of their

QA/QC activities and communicating with the Project QA Coordinator, who is responsible for reporting to the ERG Local QA Coordinator.

1.4 ERG TECHNICAL ACTIVITIES AND PROGRAMS SUPPORTED BY THE QA/QC PROGRAM

ERG's QA/QC program, described in this QMP, is designed to ensure the quality of services provided to clients in a wide variety of scientific, technical, and informational areas, including Environmental Data Operations (EDOs) involving the collection, evaluation, and use of environmental data. The QMP applies to all basic research, applied research, engineering, modeling, design construct and/or operation of technology, method development, sampling and analysis, secondary data use, database and software development, data review and validation, scientific assessment, and training activities conducted by ERG. ERG's QA/QC program does not, however, address quality-related activities for administrative areas of the company (e.g., human resources, facilities, accounting).

Not all elements of the QMP may be applicable to every project conducted by ERG. For example, QC procedures applicable to environmental sampling are not be appropriate for a project involving development of a training course or video. For work assignments involving measurement activities, environmental data generation (e.g., surveys, field sampling) or environmental data use, ERG develops a QAPP that meets requirements as defined by the client in the applicable work orders or assignments.

1.4.1 Oversight of Subcontractor Activities

Subcontract agreements are issued to firms, and occasionally individuals, who perform sections of ERG's prime contract scope of work at any dollar level. ERG demands the same

high level of quality and performance from subcontractors and consultants as it does from its own employees, and subcontractors are bound by the same requirements and restrictions as ERG under the Prime Contract. These agreements contain all required flowdowns of the prime contract plus many flowdowns that pertain to the type of work to be performed, including any requirements for QAPPs included in a specific work assignment.

The ERG Corporate QA Manager is responsible for verifying that subcontractor's quality related procedures are adequate and executed. The Project Manager reviews the performance of ERG subcontractors and consultants and does not approve the payment of invoices unless subcontractor performance meets contract requirements.

1.4.2 Coordination of QA and QC Activities

The Corporate QA Manager is responsible for internal coordination of QA and QC activities among the local offices, represented by the Local QA Coordinators. She also serves as the Local QA Coordinator for the Lexington, MA, location. This coordination assures that project-specific QA/QC programs are commensurate with project objectives and with ERG's QA policy. The Local QA Coordinators, Mr. Andrew Burnette and Dr. Timothy DeFries (Austin, TX), work directly with the Project Manager to ensure that each project has, as appropriate, a Project QA Coordinator. Local QA Coordinators may serve as Project QA Coordinators, facilitating this coordination.

1.4.3 Management's Assurance that ERG's QA/QC System is Understood and Implemented

ERG Management assures that applicable elements of ERG's QA/QC program are understood and implemented in all programs that generate or use environmental data. Section 3, below, discusses training conducted to ensure that staff understand ERG's QA/QC program. See Section 9 for a discussion of the tools used to assess the implementation of ERG's QA/QC program.

SECTION 2

QUALITY SYSTEM COMPONENTS

2.1 INTRODUCTION

ERG is dedicated to providing quality services to our clients. Our success and growth depend on our record of providing high-quality work, which encompasses delivering on time and within budget what we promise and what our clients expect. This insistence on quality and integrity is the foundation for establishing quality objectives for every project.

This section of the QMP describes the principal components of ERG's quality system and defines who is responsible for managing and implementing each component of the system. This section also identifies the tools used to implement each component of ERG's quality system. The services ERG provides to our clients are organized as projects. Thus, ERG's quality system consists of components that are applied to ERG as a whole and components applied to each project. A project may comprise one or more related tasks or work assignments.

Components of ERG's *corporate quality system* include:

- Quality System Documentation;
- Quality System Annual Reviews and Planning;
- Quality System Management Assessments; and
- Training.

Section 2.2 contains a description of each of these components, management roles and responsibilities in their implementation, and the tools used in their implementation.

Components of ERG's *project quality system* include:

- Project Quality Planning;
- Project Quality Documentation;
- Project Data Quality Assessment; and
- Project Quality Assessment.

Section 2.3 contains a description of each of these components, management roles and responsibilities in their implementation, and the tools used in their implementation.

2.2 ERG CORPORATE QUALITY SYSTEM COMPONENTS

This section describes the *corporate quality system*, specifically, management roles and responsibilities in implementing the system and the tools used in its implementation.

2.2.1 ERG Corporate Quality System Documentation

Description: Documentation of the ERG corporate quality system is the written record of the management systems and technical activities ERG uses to ensure the quality of the work processes, products, and services we provide to our clients.

Roles and implementation responsibility: ERG's Corporate QA Manager, Arlene Levin, is responsible for developing and documenting ERG's quality system in accordance with EPA and other client QA policies and direction from ERG management. She is also responsible for developing, reviewing, and revising the corporate QMP, the major tool used to document ERG's quality system. The Local QA Coordinators are responsible for preparing new or revised Standard Operating Procedures (see below). The cognizant ERG Confidential Business

Information (CBI) Document Control Officer is responsible for developing, reviewing, and revising the statute-specific CBI plans ERG uses to manage CBI in our possession.

Tools for Implementing Corporate Quality System Documentation:

Quality Management Plan. The major tool for documenting ERG's corporate quality system is the QMP. The QMP describes how ERG structures its quality system and describes the general roles and responsibilities for staff and management. A QMP tailored to specific contract requirements is prepared at the direction of our clients (see Section 2.4, below).

ERG's QMP is based on guidelines from *American National Standard: QA Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (ANSI/ASQC-E4)* [dated 01/03/95], and *EPA Requirements for Quality Management Plans (EPA QA/R-2)* [dated 03/20/01]. The ERG Corporate QA Manager reviews this QMP at least annually and revises it as necessary. Revisions are made in order to clarify roles and responsibilities, address problem areas, and to institutionalize improvements. The QMP is also revised when existing functions that affect programs covered by the QMP are reorganized, or if audits of the QA program determine that corrective actions are necessary.

When the QMP is revised, it is re-distributed to all Local QA Coordinators. The Local QA Coordinators are responsible for ensuring that all ERG personnel performing work covered by the QMP are notified of any changes and are informed of current requirements.

Standard Operating Procedures (SOPs). SOPs are written instructions that document a routine or repeated activity. SOPs detail work processes in order to facilitate consistent

conformance to technical and quality system requirements. Use of SOPs helps to ensure data quality.

ERG's SOPs follow the guidelines and requirements stated in EPA Methods for Analysis of Water and Waste, Standard Methods, SW-846, NIOSH, ASTM, and *Guidance for the Preparation of Standard Operating Procedures (QA/G-6)* [dated March 2001]. SOPs are developed for each analytical method (e.g., U. S. EPA Method 1613), engineering activity (e.g., calculations, spreadsheet data manipulation), or laboratory function (e.g., sample preparation, maintaining a laboratory notebook). When the need for a new SOP is determined, the Local QA Coordinator designates an appropriate individual to create needed SOPs, and reviews the draft procedure or designates an appropriate technical reviewer. The Local QA Coordinator approves the SOP after all peer reviewer comments are resolved, then circulates the approved SOP to technical staff members, as discussed in Section 5.2.3 of the QMP.

Appropriate SOPs are identified in each QAPP. An index of ERG SOPs (which include measurement and non-measurement related procedures) is included in Appendix A.

CBI Plans. ERG's procedures for handing CBI are documented in plans designed and prepared by ERG based on requirements established by EPA. CBI Plans are approved by the cognizant client CBI Document Control Officer. The plans are developed to meet the statutory requirements under which EPA collected the CBI from the public. ERG has approved plans for handling CBI in the Chantilly, VA; Morrisville, NC; and Lexington, MA offices.

2.2.2 ERG Corporate Quality System Annual Reviews and Planning

Description: An annual, internal review of the corporate quality system to determine if the quality system is implemented and is operating as prescribed in the QMP. Annually, plans (including schedules and resource needs) are developed for implementing corrective actions and quality system improvements identified during the quality system annual review.

Roles and implementation responsibility: The Corporate QA Manager is responsible for ensuring that independent audits are conducted to determine the effectiveness of the ERG quality system. Local QA Coordinators are responsible for reporting to the Corporate QA Manager results of independent audits they have performed to determine the effectiveness of the ERG quality system, management systems reviews, and independent project quality technical assessments.

Tools for implementing Corporate Quality System Annual Review:

Quality System Compliance Checklist. This checklist details the required elements of the management systems and technical activities specified in the QMP**.**

2.2.3 ERG Corporate Quality System Management Assessments

Description: Assessments of the ERG quality system to determine if the system (management structure, policies, practices, and procedures) is adequate for ensuring the quality of data operations conducted for our clients.

Roles and implementation responsibility: Senior management, with input from QA staff and project management, are responsible for conducting corporate quality system management assessments.

Tools for implementing Corporate Quality System Management Assessments:

Client Satisfaction Survey. ERG asks our clients directly if they are satisfied with the quality of our work. ERG President David Meyers or his designee calls Clients responsible for our prime contracts every year to obtain their feedback on our services. Additionally, each year an ERG senior manager calls each Client, Contract Officer, and Delivery Order/Work Assignment Manager. The manager who makes the call is not involved with the contract, so the clients may feel freer to assess ERG's performance from a broader perspective. We call our clients to ask for their assessment of:

- The technical quality of our work;
- Whether ERG staff have been easy to work with;
- ERG's responsiveness to the client's concerns;
- Our adherence to schedules and budgets;
- What the client might like to see us do differently (how can we improve?); and
- Any other issues that need to be addressed.

In addition, we ask our clients if our overall performance has been excellent, good, fair, or poor.

2.2.4 Training

Description: A centrally administered program of courses of broad or general applicability, supplemented by additional job- and task-specific training coordinated at the local level.

Roles and implementation responsibility: An employee's supervisor is responsible for defining the training requirements for specific jobs in each technical area. The Corporate QA Manager and Local QA Coordinator are responsible for ensuring that all ERG project personnel understand the ERG quality system, through training and access to QA policy and procedure documents. Local QA Coordinators are responsible for training staff in QA/QC procedures.

Tools for implementing Corporate Quality System Training:

See Section 3.0 for a discussion of training conducted to ensure that staff understand ERG's QA/QC program. Training tools include:

- Training in specific SOPs;
- On-the-job training;
- In-house training courses (e.g., Project Management Training and QA Training);
- Workshops;
- Classroom training programs; and
- Professional certification.

2.3 ERG PROJECT QUALITY SYSTEM COMPONENTS

Components of ERG's *project quality system* include planning, documentation, data quality assessment, and project quality assessment. This section contains a description of each of these components, management roles and responsibilities in their implementation, and the tools used in their implementation.

2.3.1 Project Quality Planning

Description: Project quality planning is the process of identifying the quality requirements of the project work, and identifying the management structures and technical activities used to ensure that products meet our clients needs and expectations.

Roles and implementation responsibilities: The Project Manager is responsible for the quality of the work performed on each project, and he/she works with the client and with the Local QA Coordinator to establish an appropriate QA/QC program for each project or work assignment. The type of QA/QC program depends on the requirements specified by the client and the intended use of the data or final report. The Project Manager and Local QA Coordinator also decide if a Project QA Coordinator is needed.

Tools for implementing Project Quality Planning:

Work Plan. The work plan translates the client's needs into specifications for producing the desired result. The work plan considers cost and schedule constraints and describes acceptance criteria for the results or measures of performance. Frequently, the Work Plan is

accompanied by a QA narrative that specifies QA/QC parameters for the proposed project. For projects that involve environmental data generation or use, ERG develops a QAPP.

QA Project Plan (QAPP). A QAPP, usually prepared in conjunction with a Sampling and Analysis Plan or Laboratory Test Plan, details the QA/QC and other technical activities necessary to ensure that the results of the work will satisfy the stated performance criteria. QAPPs are always prepared for projects that involve original data gathering, generation, or measurement, such as environmental sample collection and analysis. Projects that support litigation, regulatory enforcement, human health studies and regulatory development contain the standard elements listed in the EPA guidelines (*EPA Requirements for QA Project Plans (QA/R-5)*) and address all quality issues associated with sample collection, analysis, data validation, and reporting. Many procedures are standardized, such as sample collection and analysis, instrument calibration, chain-of-custody procedures, and data validation procedures and calculations. Research and Development projects follow applicable guidelines defined by the client, ERG QA staff and scientific common sense. Project-specific QA objectives are developed, and any constraints or adaptations to standard procedures are incorporated and reviewed prior to conducting any field activities.

The Local QA Coordinator, independent of the project team, reviews and approves QAPPs. The Project QA Coordinator is responsible for ensuring that a QAPP is prepared, and that it meets the client's specifications. The Project QA Coordinator may prepare the QAPP themselves, or it may be prepared by the project team (Program Manager, ERG Task Leader, or a team member). If the project team prepares the QAPP, the Project QA Coordinator reviews it and verifies that it meets the clients needs. The Local QA Coordinator approves the plan after all peer reviewer and Project QA Coordinator reviewer comments are resolved. The Project QA

Coordinator verifies that the requirements of the approved QAPP are communicated to the project team.

Data Quality Objectives. Data Quality Objectives are statements that clarify the technical and quality objectives of a project, define the appropriate type of data, and specify tolerable levels of decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions. The Data Quality Objectives Process is a systematic strategic planning tool, based on scientific method, that identifies and defines the type, quality, and quantity of data needed to satisfy a specified use. The key elements of the Data Quality Objectives Process are:

- Concisely defining the project objective;
- Defining the boundaries of the study;
- Identifying the decision to be made;
- Identifying the key inputs to that decision;
- Developing the decision rule;
- Specifying tolerable limits on potential decision errors; and
- Selecting the most resource-efficient data collection design

This Data Quality Objectives Process uses a graded approach, developing managerial controls that are commensurate with the importance of the work and consequences of potential decision errors (see *Guidance for the Data Quality Objectives Process,* EPA QA/G-4, EPA/600/R-96/055). Applying this process results in data quality objectives as qualitative and/or quantitative outputs. These parameters are derived in consultation with the client and are defined for the client in a Work and/or Sampling and Analysis Plan and in the QAPP. The parameters are defined internally for ERG staff through project instructions prepared for each project to communicate requirements of a technical nature and in the areas of QA/QC.

2.3.2 Project Quality Documentation

Description: An auditable trail that documents project quality planning, implementation, and assessment. Includes plans, check-lists, sign-off sheets, review memoranda, and other project-specified documentation.

Roles and implementation responsibility: The Program Manager is responsible for ensuring that project quality documentation is produced and maintained.

Tools for implementing Project Quality Documentation:

Document Review Sign-Off Sheet. Document review sign-off sheets are used to manage internal review of work assignment deliverables (memoranda, Sampling and Analysis Plans, Sampling Episode Reports, technical and engineering assessments, etc.). They provide an auditable trail of the sequence and nature of review performed for every deliverable. The Project Manager, in conjunction with the ERG Task Leader, determines the level of review a document receives based on its nature and scope. Reviewers sign off on the sheet only after they are satisfied that their comments have been addressed. If errors are discovered during the review process, corrections are made by the principal author and noted on the sign-off review sheet. An error discovered after delivery is brought to the attention of the Project Manager. He/she determines the severity of the error and its resolution, contacts the client to discuss the error and resolution, and determines the level of review necessary to check the corrected deliverable.

2.3.3 Project Data Quality Assessment

Description: Data quality assessment is used to assess the type, quantity, and quality of data in order to verify that the planning objectives, QAPP components, and sample collection

procedures were satisfied and that the data are suitable for their intended purpose. Data quality assessment is a five-step procedure for determining statistically whether or not a data set is suitable for its intended purpose. This assessment is a scientific and statistical evaluation of data to determine if they are of the type, quantity, and quality needed and may be performed either during a project to check the process of data collection or at the end of a project to check if objectives were met.

Roles and implementation responsibility: A Data Quality Assessment may be performed by a project team member, by the Local QA Coordinator, or his/her designee at any point in a project in which data have been generated.

Tools for implementing Project Data Quality Assessment:

Graphical and statistical tools are used for project data quality assessment. Graphical tools include, but are not limited to:

- Histogram/frequency plots;
- Box and whisker plots;
- Ranked data plots;
- Scatter plots;
- Time series plots, including correlograms; and
- Spacial plots.

Statistical tools used for project data quality assessment include, but are not limited to:

- Hypothesis tests for a single population;
- Hypothesis tests for comparing two populations; and
- Regression analysis.

2.3.4 Project Quality Assessment

Description: A project quality assessment determines if:

1) project work meets our clients' needs and expectations and the quality requirements specified in the work plan; and

2) the management structures and technical activities specified in the work plan have been implemented.

Roles and implementation responsibility: The Project Manager has primary responsibility for assessing the quality of project work. Second assessments are made by a project's technical reviewer(s). Assessments may also be performed by the Local QA Coordinator or his/her designee.

Tools for implementing Project Quality Assessment

Technical Assessments. Technical assessments include initial (conceptual) review of project plans, ongoing (developmental) review, and review of the final product. Initial review evaluates the objectives, concepts, methods, logic, and form(s) of intermediate and final products. Ongoing developmental reviews look at the intermediate products as they evolve from draft stages into final form. ERG performs reviews in-house and also solicits intermediate or developmental review from clients.

The use of technical reviewers is an essential part of ensuring scientific and technical QC. A technical reviewer is a qualified senior staff member who is not directly involved in the work assignment. He/she typically reviews the work assignment:

- At the *work plan stage*, addressing whether the conceptual approaches are fundamentally sound to meet the project objectives;
- At *key interim milestones* to determine if the project team is still on target; and
- *Prior to submission of draft and final products* to determine if the objectives have been fulfilled in a technically sound manner.

Each work assignment product or task is assigned a technical reviewer in the work plan and his or her participation is budgeted as a line item cost. The responsibilities of a technical reviewer include an initial review of the project plan, to ensure that:

- Project goals are well-defined, realistic, and appropriate to meet the needs of the client;
- The approach proposed to meet the goals is reasonable and likely to result in a successful project; and
- The necessary resources in terms of time, dollars, and staff are dedicated to the project.

A thorough technical review is performed on all work products prior to submission of draft and final products.

In addition to on-going technical review, periodic quality reviews are conducted by senior management to assess the work being directed by their staff members. These reviews focus on continuous improvement efforts; whether a current, detailed project plan is in place; whether recent deliverables have been peer-reviewed and submitted on time and within budget; and whether the Project Management Team is soliciting and responding to client feedback. See Section 9.2.3 for additional discussion of senior technical management's formal project review.

2.4 QUALITY MANAGEMENT PLAN DEVELOPMENT

ERG's QMP is based on guidelines from *American National Standard: Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (ANSI/ASQC-E4)* [dated 01/03/95], and *EPA Requirements for Quality Management Plans (QA/R-2)* [dated 03/20/01). The ERG Corporate QA Manager reviews this QMP at least annually and revises it as necessary.

SECTION 3

PERSONNEL QUALIFICATION AND TRAINING

This section documents ERG's procedures for assuring that all our employees have the necessary skills to accomplish their work effectively. The procedures described in this section include ERG's approach to hiring and training of staff, conducting performance reviews and evaluations, and performing routine health examinations of employees who work with hazardous materials.

3.1 ERG TRAINING POLICY

It is ERG's policy to identify QA and QC training needs for all levels of management and staff, and to provide resources for this training. The goal of this training is to assure that QA and QC responsibilities and requirements are understood at every stage of project implementation. The ultimate responsibility for ensuring that training needs are identified and appropriately addressed rests with ERG senior management, specifically ERG President David Meyers and the Corporate QA Manager, Arlene Levin.

3.2 DETERMINATION OF INITIAL CAPABILITY

Technical staff managers at ERG must recruit top-quality people, know the capabilities of their staff, and match the skills of their staff to the specific needs of their projects. Senior technical staff managers work together to define future project needs in terms of both the numbers and the capabilities of people required to perform the work. Staff are selected for their qualifications for specific technical areas, as well as for their ability to function effectively as members of a project team.

ERG has well-established procedures to ensure that all newly hired employees have excellent technical skills and can function effectively as members of a project team. Procedures used to identify potential scientific and technical staff include:

- Screening potential candidates during an on-campus interview or by phone to assess their interests, background, personal characteristics, and technical and communication skills. Before ERG invites a candidate for an interview, the manager responsible for the hiring process reviews academic transcripts.

- During the interview on site, eight to ten ERG staff members at a variety of technical levels in the organization speak with the candidate. The candidate also makes a formal presentation focusing on a specific example of past technical work and provides a writing sample related to the work to allow technical managers within ERG to evaluate whether the candidate has the necessary communication skills and technical judgment to be effective in the company's project-oriented environment.

- After the interview and presentation, the technical manager in charge of hiring consults with the candidate's references about any concerns identified in the interview. No candidate receives a job offer from ERG unless the majority of the people participating in the interview feel that he/she would be a valuable member of the staff.

3.3 TRAINING

ERG ensures that personnel have the knowledge and skill necessary to complete our client's projects. Employment at ERG entails a career-long educational process, beginning with new employee training and continuing through training in project management and specific technical activities. Employees receive additional training as their job descriptions and responsibilities change and evolve and as new technology is introduced.

3.3.1 Training of New Employees

All new employees attend a general orientation and receive on-the-job training specific to their areas of responsibility. General orientation addresses the motivating principles and concepts underlying the company's approach to quality as well as technical and managerial precepts fundamental to conducting business at ERG. All employees engaged in field sampling activities receive an initial 40 hours of training in hazard identification and safe work practices, with an annual 8-hour refresher course.

3.3.2 Training Needs Identification

An employee's supervisor is responsible for defining the training requirements for specific jobs in each technical area. These requirements are communicated through technical managers, who monitor attendance at training sessions and who ensure that their staff are adequately informed about the codes and standards necessary to perform the work. Orientation activities are scheduled as required for specific programs, either as a continuing series of training seminars or under the supervision of a senior technical staff member. Training commonly provided at ERG, with the employees required to participate is listed in the table below.

Employee Responsibilities	**Related Training**
Work with CBI	Required training supported by annual refresher courses
Work managing projects	ERG Project Manager Course
Work at hazardous waste sites	OSHA-mandated 40-hour HAZWOPER instructional courses, followed by annual refresher sessions
Holding security clearances	Initial briefing followed by periodic security education and awareness programs

3.3.3 Training Courses and Programs

At ERG, our objective is to ensure that the quality of technical services is consistent regardless of who does the work or which office performs the task. This degree of standardization requires a training program that is flexible enough to meet the diverse needs of a number of different technical service areas, while ensuring that all employees receive the necessary training appropriate for their specific work area. ERG's corporate training program includes a centrally-administered program of courses of broad or general applicability, supplemented by additional job- and task-specific training coordinated at the local level.

At the corporate level, ERG offers a diversity of training courses open to all employees. Individual courses range in duration from single classes (e.g., hazard communication training, CPR training, confidential business information training) to those which meet weekly for several months (e.g., Project Management, Application of Statistics). Through these courses, ERG ensures that managers and technical personnel develop not only the technical skills to do their jobs, but also the management and communication skills required to perform their jobs with excellence.

A coordinator is assigned for each course and given responsibility for securing meeting space, for making the necessary arrangements for audio-visual aids or other special equipment, and for enlisting instructors. Announcements of upcoming classes are included as a regular agenda item in managers' meetings. While employee participation in many of the offered courses is voluntary, specific training may be required of an employee before he/she is permitted to perform certain tasks.

In addition to centrally-administered corporate training courses, each technical group defines supplemental training requirements commensurate with its specific technical activities. The Project Managers are responsible for developing and implementing training programs to meet these requirements. These training efforts typically include some combination of the following:

- Training in specific SOPs;
- On-the-job training;
- In-house training courses;
- Workshops;
- Classroom training programs; and
- Professional certification.

In addition to a formal management training program, ERG has an active technical seminar program. Topics are selected based on their relevance to ongoing project work conducted by ERG for EPA and other clients. In our Morrisville Laboratory, technical seminars focus on improving measurements performance on the Environmental Laboratory Accreditation Program (NELAP).

A second aspect of the technical seminar program is designed to give employees in various groups an opportunity to make presentations to their co-workers on the objectives, approach, and results of their work. Scheduled on a frequent basis, these seminars cover an array of topics and often incorporate briefings from employees on recent off site training that aid staff in completion of project objectives. This program enables ERG's technical staff members to refine their presentation skills in front of a group and affords managers another mechanism for reviewing work results and for promoting cross-training of staff.

3.3.4 Documentation of Training

Records of attendance and compliance with educational activities are maintained in the personnel office along with other personnel records.

3.3.5 Retraining

ERG's training program is intended to ensure that all personnel have the necessary level of experience or training to enable them to competently perform designated tasks. A new job description, the introduction of new technology, or a change in responsibilities may result in a lack of knowledge, skills, or abilities needed to perform a job successfully . When this situation arises, staff are trained in the new requirements.

3.4 FORMAL QUALIFICATIONS AND CERTIFICATIONS FOR SPECIALIZED ACTIVITIES

ERG ensures that personnel have and maintain the appropriate statutory and regulatory qualifications necessary to execute project work for our clients. Listed below is a summary of regulations pertinent to specific work areas:

- *OSHA Safety and Health Standards (29 CFR 1910).* OSHA regulations specify the general industry safety standards applicable to all workplaces. In addition, the OSHA standards contain Subpart Z, "Toxic and Hazardous Substances," which includes standards for handling specific chemicals classified as occupational carcinogens. A generic form of these standards has been developed by ERG and is the basis for all procedures for handling toxic chemicals. Recently included in Subpart Z (1900.1200) is a set of standards on communicating information involving hazards to employees. The system in place at ERG exceeds those requirements.

- *Resource Conservation and Recovery Act (RCRA).* The regulations promulgated under RCRA define the requirements for management, storage, transportation, and disposal of hazardous wastes.

- *International Air Transport Association (IATA).* The IATA regulations govern shipments of hazardous materials in international airspace. Shipments with both national and international routes must comply with U.S. Department of Transportation (DOT) and IATA regulations.

- *Nuclear Regulatory Commission (NRC).* NRC regulations are applicable to the operation and monitoring of equipment containing radioactive sources. Radioactively labeled chemicals are also regulated by NRC, DOT, and by the states.

- *Other Regulatory Requirements.* Several federal agencies have developed specific guidelines and protocols for laboratory operations involving carcinogens and other hazardous materials. These guidelines and protocols comprise a significant portion of ERG's hazardous materials safety and health program. ERG complies with or exceeds all the following:

  – National Cancer Institute (NCI), "Safety Standards for Research Involving Chemical Carcinogens," NIH 76-900,

  – National Institutes of Health (NIH), "Guidelines for the Laboratory Use of Chemical Carcinogens," NIH 81-2385,

  – Department of Health and Human Services, "Guidelines for the Laboratory Use of Chemical Substances Posing a Potential Occupational Carcinogenic Risk",

  – National Toxicology Program (NTP), "Health and Safety Minimum Requirements for Bioassay Laboratories," updated to the current "Health and Safety Minimum Requirements for Support Contractors",

  – National Institute for Occupational Safety and Health (NIOSH), "Working with Carcinogens",

  – NIOSH, "A Management Guide to Carcinogens," NIOSH 77-205,

– NIOSH, "Safety and Health Manual", and

– "Lab Safety at the Centers for Disease Control (CDC)," CDC76-8118.

3.5 EVIDENCE OF PERSONNEL JOB PROFICIENCY

The annual performance evaluation for all employees is another important component of ERG's quality system. Through this process, ERG recognizes the good work of employees and identifies areas that need improvement. In private discussions, staff members and their direct supervisors establish training needs and identify personal performance goals for the coming year. They also hold performance and goal-achievement evaluations throughout the year.

Objective evidence of personnel job proficiency is obtained in a variety of ways, depending on the employee's assignment. For example, initial determination of an employee's ability to perform specific technical procedures, such as physical or chemical measurements, typically involves repeated measurements of a reference material according to a Standard Operating Procedure. The employee must demonstrate acceptable performance, usually in terms of pre-established limits for measurement accuracy and reproducibility, in order to be certified by the technical manager to perform the test routinely. Results of these demonstrations are maintained by the technical manager.

3.6 PHYSICAL REQUIREMENTS AND EXAMINATIONS

ERG provides annual medical examinations for employees working with hazardous materials. Medical examinations are provided every three years for other employees engaged in field sampling. Medical doctors who specialize in occupational medicine perform a baseline evaluation of new employees, which includes extensive blood and urine chemistry plus cardiovascular, pulmonary, hearing, and vision tests. The initial examination provides a written

assessment of the employee's physical ability to perform certain assigned tasks and identifies any limitations. Periodic follow-up examinations allow monitoring of potential physiological effects caused by exposure to workplace hazards and provide continuing assurance that an employee's physical condition is adequate to deal with the physical requirements associated with certain types of work. ERG's personnel office maintains employee medical records for a minimum of 30 years.

SECTION 4

PROCUREMENT OF ITEMS AND SERVICES

This section describes ERG's processes for reviewing and approving procurement documents for purchased items and subcontracted services, and also describes ERG's processes for reviewing and approving responses to solicitations and for ensuring that procured items and services are of acceptable quality.

4.1 INTRODUCTION: ERG's PROCUREMENT PROCEDURES

ERG has developed internal procurement procedures to standardize operations, meet government requirements, and provide day-to-day guidance in five areas:

- General procedures;
- Contracts/subcontracts;
- Purchasing;
- Receiving; and
- Government property control.

These procedures also ensure that purchased items and services are of acceptable quality. ERG's Purchasing System, detailed in the *ERG Procurement Manual*, was reviewed by Defense Contract Management Command in April 1999 during ERG's first Contractor Purchasing System Review (CPSR). ERG received U.S. governmental approval for its purchasing system in a letter dated July 9, 1999, from Cassandra B. Bain, EPA, to David Meyers, ERG.

Procurement activities at ERG are led by the corporate Procurement Officer, Craig Pilon, who oversees contract managers and contract specialists, as well as all purchasing and related operations. ERG's contract managers assist project staff in defining procurement requirements

and choosing an appropriate procurement document. The ERG contract managers also generate and approve Subcontracts, Consulting Agreements, and other related agreements that may be required, such as licenses, confidentiality agreements, etc., and verify that these documents clearly describe quality requirements.

The objectives of ERG's procurement organization are to acquire supplies and services responsibly and to meet federal requirements for competitive bidding, record maintenance and justification, and small/minority business contracting.

As a government contractor, ERG is responsible for spending taxpayers' dollars wisely, promoting small, disadvantaged, woman-owned and HUBZone businesses, and maintaining records justifying its actions. These records are subject to review by three agencies: the Defense Contract Management Command, the Small Business Administration, and the Defense Contract Administration Agency, and a cognizant agency, the U.S. EPA.

4.2 PROCUREMENT PLANNING AND CONTROL

ERG's procedures for planning and controlling the procurement of items and services are addressed in detail in *The ERG Procurement Manual*. The contents of the manual are listed in Table 4-1.

Table 4-1

Contents of ERG Procurement Manual

Title
• Quick Start • Purpose • Applicability • Standards of Conduct • The Procurement Process • Flow Chart • Structure of The Procurement Organization • Defining Your Requirement • Direct v. Indirect Purchasing • Purchasing for Overhead, G&A, and Service Center Accounts • Deciding Whether to Rent, Lease, or Purchase • Blanket Purchase Agreements • Obtaining Labor Services (Temporary Agencies, Independent Contractors, Subcontractors and Consultants) • Selecting an Agreement Type • U.S. Government Sources of Supply and Rates • Selecting a Vendor, Subcontractor, or Consultant • Determining if Prices are Reasonable • Clauses for Subcontracts, Consulting Agreements, and Purchase Orders • Obtaining Travel Services • Achieving and Reporting Subcontracting Goals • Government Property • Inspection and Acceptance • Subcontract and Purchase Order Administration • Vendor Data Base • Paying Vendors • Definitions • Forms

The general steps of the procurement process are:

1. Project staff identify the need. After reviewing the client's statement of work, project staff identify what products and/or services will be required to accomplish it. They also identify long-lead items and services in order to establish a timetable for procurements.

2. The Project Manager, and Contract Manager decide whether the need can be filled by in-house resources, team subcontractors, or should be acquired from outside sources. For services, they identify the technical qualifications and expertise required. They also identify any specific quality standards that are required.

3. The Project Manager, and Contract Manager decide what method should be used to fill the need -- use of an existing vendor relationship such as a Blanket Purchase Agreement (BPA) or initiation of a new solicitation.

4. Project staff draft the solicitation. The degree of complexity of the procurement method should be directly related to the complexity, quality requirements, and dollar value of the requirement.

5. The Contract Manager reviews, approves, and issues the solicitation. With the Contract Manager's approval, project staff may solicit bids from suppliers (e.g., obtain phone quotations).

6. The Project Manager evaluates the offers. A combination of technical quality, schedule, location, price and other variables will be combined to determine which proposal will best meet ERG's needs. Negotiate, where applicable, treating offerors equally and fairly.

7. The Project Manager documents the procurement process and award decision.

8. The Contract Manager obtains necessary ERG and client authorizations, and issue the appropriate procurement document (Subcontract, Consulting Agreement, or Purchase Order).

9. The subcontractor begins work and completes performance. The ERG Project Manager manages changes to the work in the same businesslike, cost-effective, and fair manner as the initial procurement process.

10. The Project Manager closes out the procurement by inspection/acceptance of the work product, payment of final invoices, and preparation of required administrative paperwork.

4.3 PROCUREMENT TECHNICAL AND QUALITY REQUIREMENTS

This section presents procedures for ensuring that procurement documents adequately specify quality requirements.

4.3.1 Types of Procurement Documents Used By ERG

The Federal Acquisition Regulation (FAR) considers any contracts or contractual actions entered into by ERG to furnish supplies or services for performance of a prime contract a "subcontract". ERG uses three basic types of procurement documents, all of which are "subcontracts" according to the above definition:

Purchase Orders (POs): POs are used to initiate purchases of standard commercial items (and occasionally services). POs contain standard ERG terms and conditions and minimal flowdown requirements from the FAR. To initiate a PO, the ERG Requestor completes a Purchase Request, has it signed by the cognizant ERG Manager, attaches the necessary addenda, and submits it to the Contract Manager in his/her division.

Consulting Agreements: Consulting Agreements are used for individuals, and occasionally firms, who are providing advisory or review services relating to ERG's statement of work at any dollar level. Consulting Agreements contain all required prime contract flowdown clauses and the basic clauses necessary to protect ERG's and the Government's/Client's interests. Consulting Agreements are designed for work that is limited in scope or length, usually takes place at the Consultant's location, has minimal reporting required, and involves

minimal risk to ERG or the Consultant. The ERG Contract Manager for each division issues or authorizes Consulting Agreements.

Subcontracts: Subcontract Agreements are issued to firms, and occasionally individuals, who perform sections of ERG's prime contract scope of work at any dollar level. Because of the need for the Subcontractor to be bound by the same requirements and restrictions as ERG under the Prime Contract, and because of the increased risk associated with extended or on-site work, these agreements contain all required flowdowns of the prime contract plus many flowdowns that pertain to the type of work to be performed. In addition, the roles and responsibilities of ERG and the Subcontractor are more carefully defined, to avoid potential misunderstanding or disputes. The ERG Contract Manager for each division issues subcontracts.

ERG has developed efficient and cost-effective procedures for placing and administering subcontracts and hiring consultants. ERG demands the same high level of quality and performance from subcontractors and consultants as it does from its own employees. Whenever a particular task requires a specialty that must be obtained (or that can be more cost-effectively obtained) from outside the company, the Project Manager selects, retains, and supervises a subcontractor or consultant. ERG's Contracts Department oversees the subcontracting process to ensure that all standards of the federal government are met.

ERG is dedicated to delivering high quality work products that may be used without fear of challenges related to Conflict of Interest (COI). Thus, like ERG, our subcontractors and consultants have no relationships with companies, individuals, or trade associations in the areas covered under a particular work assignment that would impair their objectivity or prevent them from providing impartial assistance or that would constitute an apparent COI. In general, if we discover any real or apparent COI, we do not allow the firm or the individual to participate in the work assignment unless otherwise instructed by the government.

To monitor the compliance of our subcontractors and consultants with the COI clauses contained in our prime contract (and which are passed on to the subcontractors through flow-down clauses in their subcontract agreements), ERG requires that each subcontractor sign a work assignment COI certification, and that this certification be returned to ERG before commencing work on the work assignment. This COI certification process provides ERG with an ongoing mechanism for monitoring adherence to COI provisions. In addition, ERG requests that the subcontractor certify that it has informed its personnel of their obligation to report personal and organizational COI.

To initiate a Consulting Agreement or Subcontract Agreement, the ERG Requestor completes a Purchase Request form, attaches the necessary addenda, has it signed by the cognizant Manager, and submits it to the ERG Contract Manager for his/her division.

4.3.2 Procedures for Review, Approval, and Ensuring Adequacy of Procurement Documents

To ensure that procurement documents are accurate, complete, and clearly describe the item or service needed and the associated technical and quality requirements, ERG has developed written procurement procedures, specified in *The ERG Procurement Manual*. Authority to sign procurement documents is limited to a few specified individuals. These individuals are responsible for ensuring that all the procedures specified in *The ERG Procurement Manual* have been followed.

Procurement documents clearly describe the item or service needed. ERG's procurement procedures require the employee requesting the purchase of an item or service to establish a clear statement of work (SOW), special technical requirements, necessary reporting, quality requirements, transportation, packing and packaging requirements, and schedule. When

applicable, the SOW includes a quality system consistent with EPA requirements. When required by the work assignment, the SOW includes preparation of a QAPP according to *EPA Requirements for QA Project Plans (QA/R-5)* [dated 03/20/01].

The Purchase Order or Subcontract SOW describes how ERG verifies that suppliers have conformed to ERG's requirements, with provisions for ERG to inspect and accept, within a reasonable period of time, the item or service prior to payment.

The ERG Procurement Manual includes a pre-purchase checklist to help procurement requestors clearly define their purchase requirements.

4.3.3 Review and Approval of Responses to Solicitations

The Project Managers review quotations or proposals for the procurement, and identify responses that satisfy all technical and quality requirements and select a supplier. The project staff document this selection in a written source selection analysis, using a standard format, that is signed by the Project Manager and remains in the procurement file.

4.3.4 Requirement for Suppliers to Demonstrate Capability

ERG uses the following steps to evaluate suppliers' capabilities.

Where a prime contract has been awarded to ERG, the first priority for awarding work under that prime contract goes to the team subcontractors whose qualifications and staff have been established in the initial procurement process. Team subcontractors whose proposals have led to an award under a competitive procurement are considered to have been competitively-procured, provided their rates and fee are consistent with the proposal that led to the award. If

team subcontractors are able to perform the requirement and provide a reasonable cost estimate (within the constraints of their prime contract bid and team subcontract with ERG), no further competition or solicitation is necessary.

If team subcontractors are not qualified to perform the work, ERG identifies other subcontractors using our internal supplier list, then outside sources such as the SBA's Pro-Net database or referrals from the Office of Small and Disadvantaged Business Utilization at the Contracting Agency. The ERG Project Manager establishes subcontractor capabilities by reviewing ERG's Supplier Procurement History file; obtaining resumes of professional personnel; researching the technical and business reputation of a company; and, where appropriate, checking the past performance references.

Prior to award of a Subcontract or Consulting Agreement, the Contract Manager making the award checks the List of Parties Excluded from Federal Procurement and Non-Procurement Programs (**www.arnet.gov**) to ensure that the vendor that has been selected is not suspended or debarred from Government contracting.

4.4 PROCUREMENT DOCUMENT SPECIFICATION, REVIEW, AND CHANGES

As discussed in Sections 4.2 and 4.3 above, *The ERG Procurement Manual* documents the procedures that ERG uses to prepare and review procurement documents, and to ensure that they are accurate, complete, and conform to EPA's requirements. The technical requirements of a procurement document are defined by the requestor and reviewed and approved by the technical Project Manager. The Contract Manager identifies the corporate and flowdown clause requirements of the procurement and works closely with the technical Project Manager to assure that it meets the technical and administrative goals as established at the onset. Only Contract Managers, the ERG Purchasing Officer, and ERG Officers have authority to approve

Subcontracts and Consulting Agreements. Prior to approval, these individuals ensure that all the authorizations and backup required in *The ERG Procurement Manual* and by the client Prime Contract have been obtained or completed.

4.4.1 Review of Changed Procurement Documents

All ERG Subcontracts and Consulting Agreements contain general terms and conditions of sale that include, among other things, provisions for changing or stopping work. When formalized, a change is incorporated in a modification to the subcontract.

Where the scope of work changes during performance, or where factors outside the subcontractor's or ERG's control intervene, careful documentation is made as to the nature of the change, the vendor's/subcontractor's proposed price to implement the change, and the negotiation process that transpired prior to Subcontract modification. Only the Contract Manager is authorized to modify, or approve modification of, a Subcontract or Consulting Agreement.

4.5 ENSURING THAT PROCURED ITEMS AND SOURCES ARE OF ACCEPTABLE QUALITY

Procured items and services are reviewed by the requestor to ensure compliance with requirements and specifications. Approval by the ERG Project Manager or his/her designee is required before invoices are paid.

4.5.1 Inspection and Acceptance

Purchase Orders and Subcontracts for items or services to be delivered to ERG contain the quality requirements to which the items or service is to conform and provisions for ERG to inspect and accept, within a reasonable period of time, the item or service prior to payment.

Prime contracts with EPA specify quality requirements and inspection/acceptance points. Purchase Orders and Subcontracts are tailored to reflect the quality requirements and inspection/acceptance criteria of the prime contract.

In defining requirements, ERG Requestors carefully review what types of quality specifications are appropriate to a Purchase Order or Subcontract and indicate the QA requirement in the Purchase Request. ERG Requestors ensure that all products and services ordered have been inspected and accepted prior to payment of vendor invoices.

ERG requests warranties, when they are appropriate to the supply/service required; however, the cost of warranties, if priced separately, is evaluated in light of the anticipated period of use, repair costs, complexity, and other variables.

4.6 EVALUATION OF SUBCONTRACTOR AND CONSULTANT PERFORMANCE

Subcontractors and consultants are under the direct supervision of the Project Manager, who ensures that project goals are met. The Project Manager evaluates all subcontractor and consultant deliverables. ERG may also audit facilities of subcontractors or consultants that collect environmental data or measurements. The subcontractor or consultant may be subject to a performance evaluation audit by ERG project staff or by the QA Coordinator. A subcontractor or consultant producing data for ERG may be subject to a data quality audit.

4.6.1 Paying Suppliers of Items and Services

ERG pays most suppliers within the latter of: 1) 30 days from receipt of a correct invoice, or 2) 30 days from product/service acceptance. The payment terms and invoicing address appear in all ERG Purchase Orders, Subcontracts, and Consulting Agreements. For supplies/services ordered via a Purchase Order, the requestor (or designee):

- Marks invoice receipt date on invoice;
- Assures that supplies/services have been received/performed and are accepted by ERG;
- Verifies that the amount invoiced matches the amount ordered;
- Prepares an ERG Voucher, and attaches the original invoice; and
- Has the Voucher signed by the ERG manager with budgetary responsibility.

For supplies/services ordered via Subcontracts and Consulting Agreements, the Division Contracts staff (based on the location of the Project Manager, the order of these steps may vary):

- Log the invoice receipt date on Subcontractor/Consultant invoice;
- Send the invoice to the ERG Project Manager for approval that the work has been performed, hours delivered, products received, etc.;
- Check the invoice against the Subcontract/Consulting Agreement Terms using the Invoice Checklist;
- Prepare/review a Voucher form with invoice information;
- Log the invoice in the Subcontract File, and document payment in the Subcontract records (applicable only to files not maintained in Lexington office); and

- Approve the invoice by signing on the Voucher, and forward invoice plus supporting documentation to Accounts Payable for payment.

All Vouchers have the signature of the ERG manager with budgetary responsibility to authorize payment. Vouchers for Subcontracts and Consulting Agreements are also approved by ERG Contracts staff prior to payment.

SECTION 5

DOCUMENTS AND RECORDS

This section of the QMP describes ERG's controls for quality-related documents and records related to the ERG corporate quality system and describes ERG's controls for documents and records related to ERG projects.

5.1 IDENTIFICATION AND CLASSIFICATION OF RECORDS

As described below, ERG's quality-related documents are associated with the corporate quality system or individual projects.

5.1.1 Corporate Quality System Documents and Records

Documents and records related to the ERG quality system include the documentation described in Section 2.2.1, and the output of quality system assessments described in Section 9. The Corporate QA Manager is responsible for identifying quality system documents that require control. These documents include, but are not limited to:

- Quality Management Plan;
- Standard Operating Procedures;
- Confidential Business Information Plans; and
- Assessments of ERG's Quality Assessment, including related checklists.

5.1.2 Project Documents and Records

Technical activities generate reports, supporting documentation, and analytical data. This information is organized in project files to facilitate retrieval and to maintain security and confidentiality. The Project Manager is responsible for identifying project documents that require control. Project files are organized into the following categories:

- Work Plan;
- Sampling Plan, if applicable;
- QA Project Plan;
- Project Instructions;
- Original data and calculations;
- Technical reports;
- Project quality assessments;
- Correspondence; and
- Progress, draft, and final reports.

Project documentation can be 1) paper (hard) copies, for example, correspondence and field notes; 2) computer files, for example, databases and web applications; or 3) records that can be maintained in both forms, for example, the word processing file and the hard copy document printed from it.

5.2 GENERATION OF RECORDS

Quality-related records generated at ERG include project records and corporate quality system records (e.g., SOPs and QMPs).

5.2.1 Project Records

The Project Manager is responsible for reviewing project documents and records to verify their conformance to technical requirements and quality system requirements. This review is conducted using selected project quality assessment tools described in Section 9. The project work plan (and QAPP if required) designates the work processes and assessment tools used on the project. The Project Manager is also responsible for ensuring that records and documents accurately reflect completed work.

Project QA planning documents designating responsibilities and specifications for quality are reviewed and signed by all accountable project employees.

Records of engineering calculations document each step with supporting references, key assumptions, professional engineering judgments, equations, or engineering fundamentals. The calculations are signed or initialed by the engineer who completed them, then checked, and after discrepancies are resolved, are signed by a qualified project team member.

All records generated by measurement activities are signed or initialed by the person performing the work and are reviewed by an appropriate supervisor. Measurement results become part of a project report which is reviewed by an ERG technical reviewer. All laboratory notebook records are kept in black ink, dated and signed by the person making the entries, and routinely reviewed and approved by the appropriate supervisor, as evidenced by his/her initials and date of inspection. Laboratory notebook maintenance procedures are regulated by a SOP, which is followed by all laboratory staff.

If corrections to laboratory records are necessary, the individual making the correction must provide a reason, which is maintained with the original data. He/she signs and dates the correction in black ink and transmits it to the appropriate project staff. Corrected laboratory reports identify the original data along with the corrected data report.

5.2.2 Corporate Quality System Records (SOPs and QMP)

As discussed in Section 1.2.1, the Corporate QA Manager is responsible for developing and revising the corporate QMP. The QMP is reviewed and approved by ERG President David Meyers and the Local QA Coordinators. The Corporate QA Manager is responsible for issuing the revised document to staff and ensuring that obsolete documentation is removed from the ERG Intranet.

As discussed in Sections 1.2.2 and 2.2.1, the Local QA Coordinators are responsible for designating an appropriate individual to create SOPs, needed at their location, reviewing the draft procedure or designating an appropriate technical reviewer, circulating the approved SOP to technical staff members; and maintaining copies of SOPs pertaining to the ERG location in a central filing system.

5.2.3 Quality System Document Control

ERG has developed and instituted document control mechanisms for the review, revision, and distribution of the QMP and QAPPs. Annually, the Corporate QA Manager reviews the QMP, and the document is revised as necessary. Two versions of the QMP are then circulated, a "Distribution Copy" and an "Information Copy." Distribution copies feature a unique serial number on the cover corresponding to a distribution list maintained by the QA staff. Whenever revisions are made, everyone on the distribution list receives the latest revision with their

assigned serial number. Information copies have no specific designations, and their status is not tracked or updated.

Each QAPP has a signed approval form, title page, table of contents, and EPA-approved document control format (shown below) that appears in the upper right-hand corner of each page:

Section No. Revision No. Date Page No. – of –___

QAPPs also contain a distribution list, including subcontractors and consultants as applicable. During the course of the project, any revision to the QAPP is circulated to everyone on the distribution list.

Another document control mechanism addresses SOPs, CBI, contracts, correspondence, and reports. SOPs are company-confidential, prepared and filed by individual laboratories or groups and maintained in a central filing system controlled by the Local QA Coordinator. Each SOP has a signed title page and document control format, as depicted in Figure 5-1.

Internal QA audit reports are maintained by the Local QA Coordinator at the site where the audit occurs and are indexed according to date and area of the audit. QA audit reports from external agencies are indexed according to a year-based sequential numbering system that is also cross-referenced by areas audited and by auditing agency. These files are maintained by ERG's Contracts Office.

ERG
EASTERN RESEARCH GROUP, INC.

CONFIDENTIAL

STANDARD OPERATING PROCEDURES

ENGINEERING AND SCIENCE DIVISION

	Procedure No: ERG-MOR-006	5-6
GROUP: Morrisville Measurements Group		
TITLE Standard Operating Procedure for the Analysis of Tenax® Tubes According to EPA Method TO-1/TO-17	REVISION NO.: 0	EFFECTIVE DATE:
	SUPERSEDES: N/A	
REFERENCES: ERG-MOR-005, ERG-MOR-010, ERG-MOR-023		
SATELLITE FILES: Chromatography Laboratory, Mass Spectrometry Laboratory		
REASON FOR REVISION: Original		

1.0 PURPOSE

Volatile organic compounds (VOCs) are emitted into the atmosphere from a variety of sources including industrial and commercial facilities, hazardous waste storage facilities, and vehicular traffic. Many of these organic compounds are toxic. Knowledge of the levels of such toxic VOCs in the atmosphere is required in order to determine human health impacts.

Conventional air monitoring methods such as those used for workspace monitoring have relied on carbon adsorption approaches with subsequent solvent desorption. Solvent desorption techniques allow injection of only a small portion (tidally 5-7%) of the sample into the analytical system. This dilution factor is prohibitive for performing successful analysis of...

WRITER: NAME/DATE 2/23/00		
ACTIVITY MANAGER: NAME/DATE Judith McCartney 2/23/00	QUALITY ASSURANCE COORDINATOR: NAME/DATE Theresa Kemmer Woody 2/23/00	MANAGER: NAME/DATE Joan V. Bursey 2/23/00

Figure 5-1. SOP Title Page

5.3 PROJECT RECORD MAINTENANCE

This section describes ERG's procedures for managing records for active and inactive projects. Records include paper files, electronic files, and documentation of project quality assessment. Paper files (hard copies) include: letters, memoranda, reports, notes, telecons, calculation sheets, spreadsheet printouts, database printouts, and e-mail printouts. Electronic files include spreadsheets, databases, software programs, models, electronic messages, and electronic copies of text and figures.

Laboratory data are logged by date according to project. Laboratory data include analytical results and all supporting information, including calibrations, QC data for analysis of samples, and raw data. Every project conducted in the laboratory has individual files. These files contain chain-of-custody documentation (if appropriate), project instructions, project notes about the data, and copies of any final data reports.

5.3.1 Organization

A unique project charge number is assigned upon receipt of the work assignment or technical directive and is used to track all labor and material costs associated with the project. This number is also used on all project files. If laboratory analysis is required, a laboratory subtask is created using the same number, and all resulting data and analyses are indexed according to the project and task number. QC records are maintained by the Project Manager according to project number.

Central Project Files. The Project Manager is responsible for designating an appropriate individual to develop a filing system, including an outline for the file, document labeling system,

file sign-out system, and filing procedures. The Project Manager is also responsible for designating a person or persons (typically a project secretary or project assistant) to use the project file system to establish and maintain the project file and to communicate the file system requirements to all project team members. The central project files may be stored in a clearly labeled area in an individual office accessible to all project team members, or in a dedicated file room.

Electronic Files. Electronic copies of project data and calculations, programs, models, databases, text, and figures are stored on identified project areas on ERG network servers that are accessible to all project team members. The Project Manager is responsible for designating an appropriate individual to develop a plan to organize the electronic files, including removal of obsolete documentation.

5.3.2 Transmittal and Distribution

Distribution lists are established at the beginning of each project to ensure timely dissemination of information to appropriate technical and administrative staff. At the end of the project, copies of all reports and other records designated by the Project Manager are maintained in ERG's project archives.

5.3.3 Control of Record Access (Confidential Business Information)

All documents released to ERG by clients under a confidentiality agreement are handled in accordance with the terms of a client-approved security plan. For our EPA clients, EPA Acquisition Regulation 1509.505-4 requires contractors to comply with the requirements of 40 CFR Part 2 and the provisions of their contracts relating to the treatment of CBI. Under 40 CFR

Part 2, Subpart B, ERG is required to protect CBI from unauthorized disclosure. This CBI may have been collected by EPA under the authority of the Toxic Substance Control Act (TSCA), Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Resource Conservation and Recovery Act (RCRA), the Clean Water Act (CWA), or the Clean Air Act (CAA). Any CBI in ERG's possession is handled in accordance with a set of written procedures designed and prepared by ERG and approved by the cognizant EPA CBI Document Control Officer. ERG has approved plans for handling CBI in the Morrisville, NC; Chantilly, VA; and Lexington, MA offices. Among many other requirements, access to CBI documents is limited to authorized users through a specified sign-out procedure.

Contractually established confidentiality requirements are communicated to project staff in the project instructions. A corporate SOP is available for the handling of confidential business material (*Eastern Research Group Manual for the Handling of Confidential Business Information*). A project-specific CBI plan is developed as required by the client. ERG staff who are required to handle CBI receive special training in the appropriate procedures, along with a mandatory refresher course each year.

5.3.4 Retrieval and Preservation (Protection)

Storage and Retrieval. Active project files consist of paper records and electronic files stored on ERG's computer network. Management of inactive files varies by ERG locations. At Chantilly, paper records of inactive projects are warehoused in storage rooms. Inactive electronic files (including spreadsheets and databases) are moved to tape or compact disk for long-term storage. Archive procedures for computer files are discussed in Section 6.2.4.

At ERG's Morrisville, NC, laboratory, at the completion of a project, record material that has been stored on the computer network is archived on compact disc (typically one disc per

contract). These compact discs, filed by contract number, are stored in ERG's laboratory. Paper files for inactive projects are archived in clearly labeled cartons in limited access facilities at 900 Perimeter Park, Morrisville. The contents of each carton are listed on multi-carbon inventory forms that identify:

- Project identification information;
- Originator's name;
- Name of the person receiving the carton for storage;
- Date of receipt;
- Category of contents (e.g., project files, equipment); and
- Description of the contents (e.g., test reports, work plan, reference reports).

This indexing system facilitates retrieval of any carton or document on request.

Preservation. Stored records are protected from damage, loss, and deterioration. Records stored on site are located in locked climate-controlled file rooms, in a limited-access building. The buildings are equipped with smoke alarms and sprinkler systems in case of fire. Facilities are protected by perimeter alarms, automatic dry pipe sprinklers for fire protection, and an interior alarm system monitored by a manned central station. Access to the facility storage are is limited to authorized personnel.

In the event that fire or other disaster strikes leaving records damaged and unsecured, ERG will transfer the records under close supervision to another secure location (the client's location or off-site storage facility).

5.3.5 Retention and Disposition

Project files and laboratory data are maintained for a designated period of time. If there are no additional contractual requirements, project files along with laboratory and field data are maintained for 10 years. Project Managers are notified of impending disposition of information and must approve the decision.

Documents obtained from clients or other entities or created by ERG that fall under statutory (CWA, CAA, TSCA, or RCRA) CBI requirements are destroyed or returned to the appropriate person(s) in accordance to the entities' written instructions. Other classified or confidential records are destroyed by shredding or incineration.

5.4 EVIDENTIARY RECORDS (CHAIN-OF-CUSTODY AND CONFIDENTIALITY)

ERG's procedures for chain-of-custody and confidentiality procedures for evidentiary records are described in this section.

5.4.1 Chain-of-Custody Procedures

Chain-of-custody procedures provide legally defensible documentation of sample custody from collection through disposition. Chain-of-custody procedures apply to field monitoring, sample collection, and analyses of environmental media and are tailored for specific project needs specified in the QAPPs. These procedures include standard requirements for sample labeling, chain-of-custody forms, field data sheets, field and laboratory notebooks, sample control procedures, and sample handling and shipment procedures.

QA steps taken to implement chain-of-custody procedures include presenting all documentation requirements in the QAPP, training field personnel in all procedures prior to beginning field work, and having project management and staff regularly review field and laboratory notebooks and sample custody documentation during field activities. Technical systems audits may also be conducted for field activities, and these audits provide an additional level of QA checks for chain-of-custody procedures.

Chain-of-custody procedures are initiated at the time of sample collection. Information about sample location, identification, field conditions, field meter measurements (e.g., pH, conductivity), and other pertinent information is recorded in black ink on preformatted field data sheets and/or field notebooks. Notebooks and data sheets are initialed by the personnel recording the information.

Changes in recorded entries are made by crossing out the information with a single line so the original information is not obscured, dating the change, and initialing it.

Preprinted labels are placed on sample containers at the time of collection and must be completed in waterproof ink. Sample labels must contain legible information about the sample, such as date and time of collection, initials of the person collecting the sample, and preservatives used (if any). Sample control numbers, consisting of simple sequential numbers or alphanumeric codes, are commonly used to identify samples. For air sampling, an alphanumeric sequence that identifies the sampling train, component of the sampling train, sampling run, date, and initials of the person recovering the sampling train may be used. Use of alphanumeric codes allows submission of blind samples such as field blanks or audit samples for QC purposes. Use of sample identification numbers minimizes the potential for transcription errors between the field and the laboratory.

ERG's Morrisville, NC, laboratory maintains logs of samples received for preparation or analysis. The master log, kept in a secure location and completed daily, contains the sample control number or identification, sample location, date, analytical methods required, sample volume/containers, field personnel, and sample tracking information. Entering samples into the master log is the responsibility of the Project Manager, Field Task Leader, or his/her designee. All sample documentation, including data sheets, notebooks, and the master log, are subject to review by the Project QA Coordinator.

Chain-of-custody forms are completed and an original copy is kept with the samples at all times. Each time possession of the samples changes, the chain-of-custody form is initialed and dated to indicate release and acceptance of the sample. The completed forms provide sufficient information to document sample possession through all stages of the sampling and analysis process. Standard forms are used to indicate the sample identification, analyses required, project name, responsible individual(s), and comments relating to special handling precautions required or special requests.

Sample handling and shipping procedures are established for each individual project. If samples are shipped rather than hand-delivered to the laboratory, Department of Transportation procedures for labeling and packaging are followed. An airbill number or other shipment identification number is recorded on the chain-of-custody form, and the laboratory is notified of the date and time of shipment. Sample security during transport is maintained by ensuring containers (e.g., boxes, coolers) are still sealed upon arrival at the laboratory.

5.4.2 Confidentiality Procedures for Evidentiary Records

ERG develops procedures for ensuring the confidentiality of evidentiary records at the direction of our clients. For example, at the direction of our client's attorneys, correspondence with these attorneys may be marked:

- *Attorney Work Product*;
- *Privileged and Confidential*; and
- *Attorney-Client Communication*.

SECTION 6

COMPUTER HARDWARE AND SOFTWARE

Computer hardware and software are necessary to support environmental programs. ERG uses computers to manage operations, communicate with clients, research technical information, generate scientific and technical reports, organize and analyze environmental data, and store information for easy retrieval. Computers allow our staff to perform data calculations and analyses efficiently and accurately, and allow us to present the results in an easy-to-understand format using figures, tables, color, and graphics. Computer systems used to generate or analyze data must be thoroughly evaluated to ensure that they perform the required function and that the results are accurate. ERG's computer hardware and software use is consistent with the requirements outlined in *EPA Directive 2100 (EPA 1998)*. Work done by ERG on the EPA contracts adheres to all EPA Information Technology Requirements, as necessary. This section of the QMP describes ERG's QC procedures for computer hardware and software.

6.1 ENSURING QUALITY SOFTWARE

ERG ensures the quality of our computer software meets our client's requirements by implementing processes for software development, installation, testing, use, maintenance, control, and documentation. ERG's processes for addressing each of these processes are described in detail below.

6.1.1 Software Development

Software development is an integral component of ERG's expertise. Software development is the process by which user needs are translated into software requirements, software requirements are translated into design, the design is implemented into code, and the code is certified for operational use. When a project requires new software, the ERG Project Manager or an ERG Task Leader prepares a Software Development Plan. This document integrates management activities, software development tasks, and QA procedures to guide and coordinate the actions of the software development team. The Software Development Plan details the software-specific management organization, resources, schedules, and procedures that will be used during preparation of the software and describes the work effort by task, including program milestones and periodic quality checkpoints. ERG updates the Software Development Plan as necessary to reflect any technical or management changes.

The Software Development Plan specifies:

- *Functional requirements* which are specific functions or operations that a system or system component must be capable of performing;
- *Performance parameters* which are requirements specifying system component performance characteristics such as speed, accuracy, frequency, etc;
- *System interfaces* which are hardware, software, or database elements with which a system or a system component must interface, or that establishes constraints on formats, timing, or other factors caused by such an interface; and
- *Reliability goals* which are the ability of a software system to perform its expected functions for a stated period of time and set of conditions without failure.

ERG's Software Development Plan also identifies acceptance criteria which the completed software system must satisfy before it is certified for operation and specifies the basis for these requirements. ERG consults both ANSI/IEEE Standard 730.1-1995 and ERG's Software Development SOPs when preparing the Software Development Plan.

6.1.2 Software Installation

ERG establishes software installation instructions for each piece of software that we develop. The software installation instructions are reviewed by the Project Manager or ERG Task Leader. ERG distributes copies of the instructions with the software usually in the form of a ReadMe.txt file or posted on a project website on the Internet.

6.1.3 Software Testing

After the initial version of a software tool is developed, ERG initiates a verification and validation testing phase. Verification testing is defined as "finding errors through the execution of a program in a test or simulated environment" (Glenford Myers, *The Art of Software Testing*, 1979) or "the process of evaluating software to determine whether or not an object in a given phase of the software development process satisfies the requirements of the previous phases" (IEEE Standard 1012-1998). The test environment that ERG chooses is based on the specific functionality of the application. The Software Development Plan identifies the project criteria for operation of the software before verification testing is performed. ERG thoroughly documents the results of all verification tests.

Validation testing is defined as "finding errors by executing a program in a real environment" (Myers, 1979) or "the process of evaluating software at the end of the software development process to ensure compliance with requirements" (IEEE Standard 1012-1988).

Validation testing may take the form of client-directed acceptance tests, or it may be identified as deliverable acceptance criteria in the Software Development Plan. Validation testing establishes that the final product meets all the system requirements detailed in the Software Development Plan.

6.1.4 Software Use, Maintenance, and Control

ERG maintains a master copy of all software that ERG develops. Depending upon project requirements, many versions of software may be created through ERG's iterative development cycle. ERG maintains version control during the software development life cycle by organizing development files on the file server with directory structures that correspond to version number or release data.

If the software developed includes a web application, ERG will often times host and maintain the web application on ERG servers. ERG's hardware configuration is presented in Section 6.2.2.

6.1.5 Software Documentation

Documentation is the foundation of successful software development and provides guidance for software support. ERG maintains two levels of documentation for software development projects, 1) programmer's notes and software life cycle documents, and 2) user's manuals. The Project Manager or ERG Task Leader ensures that documentation is accurate and up-to-date.

Software Development Documentation. ERG's programmers' notes and software development life cycle documents provide accurate records of the development process. This documentation is consistent with the requirements outlined in *EPA Directive 2100 (EPA 1998)*. Software development life cycle documents include:

- *Software Requirements Specification* which establishes a detailed functional description, a representation of system behavior, an indication of performance requirements and design constraints, appropriate validation criteria, and other information pertinent to requirements.
- *Design Specification* which outlines the design model, data design, architectural design, and the design of required internal and external program interfaces. The Design Specification contains a requirements cross reference. The purpose of this cross reference is to establish that all requirements are satisfied by the software design and to indicate which components are critical to the implementation of specific requirements.
- *Test Specification* which includes the overall plan for testing the software.
- *User's Manuals*. Depending upon the software development project, ERG may also develop user's manuals to assist in use of the software. ERG generates User's Manuals in a variety of forms, including hard copy manuals, electronic help files integrated with the software, or on-line help.

6.1.6 Commercial Software

ERG maintains a standard set of commercial software that is accessible to each workstation. As specified by particular project requirements, ERG may install additional software. Software installation is coordinated with the local area network (LAN) administrator.

As additional software requirements arise, ERG evaluates the needs on a case-by-case basis. Our evaluation considers the impact of any implemented changes, performance issues,

and costs prior to purchase. All commercial software used on the EPA projects are compatible with the EPA computer system designated in the work assignment.

6.2 ENSURING QUALITY HARDWARE

ERG ensures that the quality of computer hardware meets ERG's requirements by implementing processes that ensure a stable computer network, an optimized hardware configuration, and properly maintained hardware. Each of these processes is described in detail below.

6.2.1 ERG's Computer Network

ERG uses a network of personal computers functioning with the Windows Operating System. The computers in each of ERG's offices are joined in Local Area Networks (LANs) consisting of file servers, user computers, printers, specialty servers, and cables that connect them together. The offices and satellite locations are joined by telephone link in a Wide Area Network (WAN). At each ERG location, all areas that house computers are secure and temperature-controlled, and heating and air conditioning units maintain an acceptable humidity range. Power to computer units is conditioned to prevent spiking and surging in the power supply. ERG ensures that the automated data collection system has sufficient facility and storage to retain raw data, including archives of computer-resident data.

ERG's Management Information Systems (MIS) department oversees the network communications system hardware and software and personal computers for all of our offices and satellite locations. ERG's MIS department consists of the director, Wendy Rodriguez, a senior systems/network engineer, Joe Savastano (located in our Lexington office), and LAN administrators, one of whom is located in each office. The MIS department meets weekly via

conference calls, and the director receives weekly activity reports from each office's LAN administrator.

6.2.2 Hardware Configuration

ERG's hardware configuration is shown in Figure 6-1.

System security and virus protection are an ever-increasing concern in the business world today. As illustrated in Figure 6-1, ERG ensures information protection by operating up-to-date security systems and virus protection programs. ERG's WAN is secured by a firewall, eliminating unauthorized access and maintaining system security. ERG's MIS director, Wendy Rodriguez, and ERG's Vice President of Internet Technologies, Hui Zhou, subscribe to several list servers to be notified of security patches for all operating systems. At a minimum of once a month, a member of the ERG computer staff accesses the web site of every application provider that ERG uses to ensure that all patches and updates are applied. For many web development projects, ERG has implemented 128-bit encryption via secure socket layer (SSL) and has created password-protected sites that only ERG employees and clients with proper authorization can access.

To protect data and systems from virus infection, ERG's systems are fully automated to launch virus protection software and receive daily or more frequent virus protection updates. ERG's MIS staff subscribe to e-mail list groups to receive notification of virus updates. When a new virus surfaces, the MIS director immediately notifies all MIS staff, who load the latest virus pattern updates to the servers. The updated virus patterns are copied to staff personal computers,

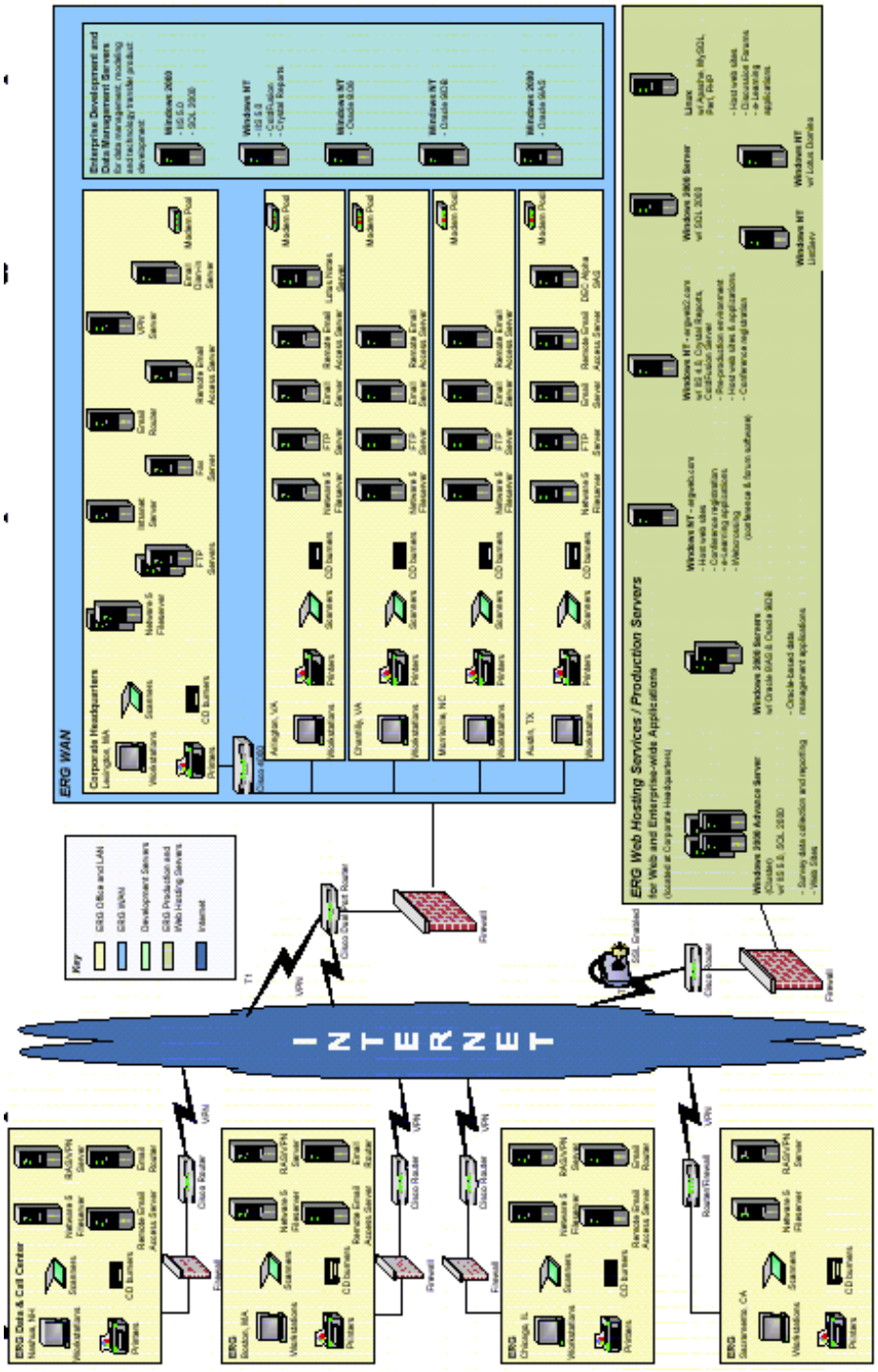


Figure 6-1. ERG Hardware and Software Infrastructure

automatically, when employees log in to the LAN. If a virus alert occurs during the course of the work day, all ERG staff are alerted via company-wide e-mail to log out of their computers and log back in to activate the virus pattern update.

ERG's MIS director is responsible for evaluating the purchase of new hardware. Due to rapid advances in technology, ERG purchases only top-of-the-line technology. ERG evaluates the need for newer technology, performance issues, and conducts a cost/benefit analysis prior to purchasing new hardware.

When new hardware is purchased, ERG implements a "trickledown system" that facilitates the introduction of new technology and the removal of obsolete technology. For example, when ERG receives a new workstation, the current workstation of the user receiving the new workstation is trickled (handed) down to another user who has an older workstation. This process allows for the oldest machines to be removed from inventory on a regular basis.

6.2.3 Hardware Testing

ERG's MIS department checks ERG's systems, network communications, and servers each morning before the normal business day begins to ensure proper operation and that no downtime is experienced by ERG's technical staff. The MIS department also checks ERG's backup systems daily to ensure that the previous evening's file systems backup was executed successfully.

When new hardware is introduced, ERG's MIS staff are responsible for ensuring a smooth transition to the new hardware. This transition includes testing in a simulated work environment during non-business hours to minimize interruptions of business operations.

Contingency plans are established, which include making a full backup tape of data potentially affected by the change in hardware.

6.2.4 Hardware Use, Maintenance, and Control

ERG LAN Administrators perform hardware maintenance and control. Our LAN Administrators perform the following to ensure the stability of ERG's hardware:

- *Tape backup*. The information on all file servers in the company is copied to magnetic tape to provide a backup for the server. Full backups are scheduled for Friday nights, and every file on the server is copied to tape. Once a month, a copy of the full backup is removed to a fire-proof safe for storage. The backup tape is stored for one year, then reused (e.g., the June 2002 backup is made over the June 2001 tape). Incremental backups are scheduled for weekday nights, and copy only files that have changed since the last backup to tape. These types of backups save wear and tear on the backup tape drives by reducing the amount of information that must be copied. Once a week, the MIS department moves a full set of the week's backup tapes off site to ensure their safety.

- *Tape archive***.** When files are no longer needed on the server, they are moved to tape for indefinite long-term storage. The space made available on the server by archiving can be used for currently active projects. ERG's archive procedures involve two identical backups of the files requested for archiving. The first backup is to an on-site tape. The second backup is to an off-site tape. After both backups are complete, ERG generates detail reports on both runs and compare the number of files backed up and their sizes. Once ERG verifies the backups, ERG removes the files from the server. The tapes are retained indefinitely.

- *Y2K compliance and other issues***.** The LAN administrators are also responsible for personal computer, file server, e-mail, user, and technical support for each of their local offices. All of ERG's systems and software applications have been tested and validated for Y2K compliance.

6.2.5 Hardware Documentation

ERG maintains records of ERG's hardware inventory on the file server. These inventory files are backed up according to the procedures outlined above. ERG's LAN administrators are responsible for maintaining and updating inventory records with the introduction of new hardware and the removal of obsolete hardware. All technical manuals for ERG hardware are maintained in the network server rooms.

6.2.6 Laboratory Automated Data Collection Systems

State-of-the-art computer software, especially in the areas of chromatography and spectroscopy, is available only from third parties. Generally, these vendors are unwilling to share the software source code or to comply with the regulatory requirements imposed by Good Laboratory Practice (GLP) Standards. Therefore, most hardware and software validation of third-party computer systems depends on evaluation of performance parameters.

Testing

Automated data collection systems are regularly tested, inspected, and maintained by ERG's MIS department with technical support from project staff. Written SOPs are available for routine maintenance operations, and the procedures identify the individual responsible for the performance of each operation. Written records are kept of all maintenance and include the date of the operation and a description of whether the operation was routine and followed the written procedure. Records of nonroutine maintenance are also kept in the system maintenance log, including whether this maintenance was the result of failure and/or malfunction. The maintenance log documents the problem, how and when the problem occurred, the remedial action taken, and acceptance criteria to ensure normal functioning of the repaired system. Each laboratory with an automated data collection system is responsible for backup and recovery

procedures to guarantee that the software for the system can be recovered after a system failure. When an automated data collection system contains data that must be secured, physical and functional access to the system is limited to authorized personnel only, and the introduction of unauthorized external data and software is prohibited.

Each set of data manipulated via computer contains QC samples that indicate whether the analytical method is working properly. Routine acceptable recoveries on QC samples also indicate that the computer system is acquiring data and performing calculations correctly. For chromatography, for instance, a set of standards prepared at a minimum of five levels is injected with each set of samples. Review of the results for the standard curve (y-intercept, slope, and correlation coefficient) indicate that the instrument is calibrated and the analytical method is working properly. Area counts for the standards are monitored to determine that they are within QC limits. These indicators give the project staff a guide for performing a miniature validation on each set of data generated and analyzed.

All data generated from computer runs are evaluated by laboratory personnel and are reviewed in detail by the senior technical reviewer for any unusual occurrences that could indicate a potential problem. When the raw data are verified, the technical reviewer checks random sections of the data manually to confirm that the computer system was operating properly on that day. If data are transferred from raw form to a spreadsheet for calculations, the senior technical reviewer will verify that the data transfer was performed correctly.

Technical Management

Project Managers:

- Designate an individual with primary responsibility for the automated data collection system(s) used on their project;
- Ensure that there is a QA/QC program in place to oversee the automated data collection system(s);
- Ensure that the personnel, resources, facilities, computer, and other equipment, materials, and methodologies are available, as scheduled;
- Receive reports of QA inspections or audits of computers and/or computer-resident data and promptly take corrective actions in response to any deficiencies;
- Ensure that personnel clearly understand the functions they are to perform using automated data collection system(s); and
- Ensure that deviations from these guidelines for automated data collection system(s) are documented and reported to the designated responsible person and that corrective actions are taken and documented.

Responsible Person

ERG's MIS staff in cooperation with the local Project Managers and the local Quality Assurance Coordinator ensures that:

- There are sufficient personnel with adequate training and experience to supervise and/or conduct, design, and operate the automated data collection system, and that they maintain their skills and competence;
- There are procedures to guarantee that data are accurately recorded in the automated data collection system;

- A data security risk assessment has been made, points of vulnerability determined, and all necessary security measures implemented;
- The automated data system has written SOPs and appropriate software documentation that is complete, current, and available to staff;
- All significant changes to operating procedures and/or software are approved and signed by management;
- There are adequate acceptance procedures for software and software changes;
- Problems with automated collection systems that could affect data quality are documented when they occur and are subject to properly documented action; and
- All applicable Good Automated Laboratory Practices are followed.

Standard Operating Procedures

The local QA Coordinator for ERG's laboratory ensures that SOPs are written for:

- The security of the system, including physical security, securing access to the system and its functions, and restricting installation of external programs and software;
- Verification of manually or electronically entered data;
- Data analysis, processing, storage, and retrieval;
- Proper methods for executing data changes to include the original data element, the changed data, the date of the change, the individual responsible for the change, and the reason for the change;
- Backup and recovery of data; and
- Electronic reporting, when applicable.

ERG maintains the SOPs and other manuals that document automated data collection procedures as part of its SOP program for each office location. Published literature or vendor documentation used as a supplement to SOPs is referenced within the SOP. ERG also maintains historical file of SOPs, which includes documentation of all revisions and their dates. Through the historical record, it is possible to ascertain the software version used for the collection, analysis, processing, or maintenance of all data sets on automated data collection systems.

6.3 INFORMATION MANAGEMENT

ERG ensures the quality of the information we produce, maintain, and disseminate by adhering to specific QA/QC procedures. These procedures are consistent with the requirements outlined in *EPA Directive 2100 (EPA 1998).*

On work assignments issued by EPA or one of its prime contractors, ERG develops and maintains information management systems that are compatible with existing or developing databases from the EPA Office issuing the work assignment. Data sets and analysis software and documentation are accessible to the EPA WAM and will be provided to EPA when the contract expires.

Prior to developing environmental information databases, ERG uses existing databases, information systems, models, and websites to the maximum extent possible. If existing products are found to be usable for fulfilling requirements for deliverables, ERG notifies the EPA WAM to facilitate coordinating use of such products.

ERG adheres to clause EPAAR 1552.211-79 “Compliance with EPA Policies for Information Resources Management (IRM),” when performing IRM-related. Table 6-1 lists EPA websites where the guidance documents articulating EPA policies may be found.

6.3.1 Data Entry

ERG ensures the integrity of the computer-resident data collected, analyzed, processed, or maintained on the system by:

- Identifying the individual responsible for direct data input at the time of its collection;
- Requiring that any change in automated data entries be made in a manner that does not obscure the original entry and that includes the reason for the change, the date, and the identity of the individual making the change; and
- Using SOPs to verify the accuracy of manually entered data and electronically transferred data collected.

Table 6-1

EPA Information Technology Requirements

Website	Name	Comments
http://www.epa.gov/irmpoli8	IRM Policies, Standards, Guidance and Planning Documents	The 2100 Series (2100-2199) of the Agency's Directive System contains the majority of the Agency's IRM policies, standards, and procedures.
http://www.epa.gov/edr	Data Standards and Environmental Data Registry	ERG adheres to Trading Partner Agreement (TPA) Data Exchange Templates (DETs) and data standards detailed in EPA Environmental Data Registry (EDR). This includes any development/enhancement of information resources (information resources for this process include systems, databases, and models/web applications that utilize information in OW systems and databases) as well as any data products flowing to or from EPA information resources.
http://basin.rtpnc.epa.gov/ntsd/ITARoadMap.nsf	Information Technology Architecture Road Map (ITARM)	ERG adheres to all technical specifications listed in the ITARM for development/enhancement of information resources.
http://www.epa.gov/eims	Environmental Information Management System (EIMS)	When developing or enhancing an information resource ERG first conducts a thorough search of existing information resources, through means such as EIMS, to ensure development or enhancement of information resources does not duplicate existing information resources. If duplication is determined, ERG consults with the client to ensure that existing information resources are optimally utilized in conjunction with information resource being developed or enhanced. For any development or enhancement of information resources, ERG works with EPA on inserting and updating resource description information in EIMS.
http://www.epa.gov/storet	Monitoring information in STORET	Any water quality, biological, sediment, and ecological monitoring data collected as part of contract activities are entered into STORET or made available to EPA in a STORET compatible format.

6.3.2 Assuring Database Quality

ERG assures the quality of the databases ERG develops and maintains by:

- Review of database design by a team member knowledgeable in relational databases as outlined in ERG's SOPs for Database Development;
- Review of the design and output of queries by one other team member as outlined in ERG's SOPs for Database Queries;

- Review of programming code utilized in data manipulation or report generation by one other team member;
- Establishing QA/QC procedures for data entry before data entry begins by the Project Manager, or ERG Task Leader;
- Performing manual QA/QC of the results generated by programming code by a knowledgeable team member;
- Performing manual QA/QC of information presented on reports by a knowledgeable team member;
- Maintaining version control of interim databases by a responsible team member;
- Documenting database structures and maintaining documentation in project files by a responsible team member; and
- Performing integrity checks on the database prior to release by the Project Manager or Task Leader.

6.3.3 Assuring Spreadsheet Quality

ERG ensures the quality of the spreadsheets ERG develops and maintains by:

- Reviewing spreadsheet design by a knowledgeable team member;
- Reviewing the design and output of equations and formulas by one other team member as outlined in ERG's SOPs for Spreadsheet Development;
- Establishing QA/QC procedures for data entry before data entry begins;
- Maintaining version control of interim spreadsheets by the ERG Task Leader;
- Maintaining documentation in project files by a responsible team member; and
- Performing integrity checks on spreadsheets prior to release by the Project Manager, or ERG Task Leader.

6.3.4 Modeling

Computer software is routinely used to model physical processes. Common types of modeling activities include characterization of pollutant release, environmental dispersion and resulting health risks, simulation of physical processes (e.g., combustion kinetics, response of structural materials to stress, etc.), and prediction of economic impacts associated with proposed activities or regulations. Modeling activities involve determining the appropriateness of the model to the application, converting physical information to model inputs, configuring the model inputs to match the physical process, running the model, and relating the model results back to the physical process.

The objective of a modeling activity is usually to assess the impact of a proposed change in the configuration or operation of a physical process. The impact can affect the physical process itself (e.g., modeling to determine the rupture strength of a tank) or the environment surrounding the process. Typically, specific information requirements dictate the need for modeling and define the activity objective. However, the ERG Task Leader and Project QA Coordinator evaluate the modeling objectives to ensure that modeling is required to supply the needed information; in some situations, the same or better information can be generated more efficiently using physical scale models, calculations, or another approach.

Documentation within or accompanying each model should guide the user in setting up and operating the model. The ERG Task Leader and Project QA Coordinator ensure that the procedures include concise guidance for determining the appropriateness of the specific model to supply the needed information, for evaluating and selecting the proper hardware to run the model, and for establishing model parameters and inputs.

When a model or other software program is used to calculate emissions, manual verification (by hand) of each type of calculation is performed. If calculations are complex and cannot be easily reconstructed, an alternative approach ERG uses is to duplicate the results using another calculation method.

EPA modeling guidance such as *Guidance for Quality Assurance Project Plans for Modeling (QA/G-5M) Peer Review Draft* [dated 04/30/02] is consulted when developing QA/QC procedures for modeling activities.

SECTION 7

PLANNING

This section documents how ERG uses systematic planning processes, including the Data Quality Objectives Process, to ensure that data or information collected for each contract or project are of the needed and expected quality for their intended use.

7.1 SYSTEMATIC PLANNING PROCESS: WORK ASSIGNMENT REVIEW

ERG uses a systematic process to plan projects involving environmental data operations. The process of articulating the project goals, objectives, and questions and issues to be addressed begins upon receipt of a work assignment. After reviewing the work assignment, the Project Manager, identifies the staff members who will serve as the ERG Task Leader(s) and Project QA Coordinator. The Project Manager and Task Leaders(s) comprise ERG's Project Management Team, and they confer with the client, to review the work assignment requirements. Direct communication between the client and ERG's Project Management Team ensures a clear understanding by all participants of EPA's needs and expectations and of the results and products that will be provided by ERG. This initial conference between ERG and the client achieves the two objectives described below.

7.1.1 Identification of Key Information Users ('Customers') and the Organization(s) That Will Supply the Information to the Users

During the initial discussion between the client and the ERG Project Management Team, the key users of the project output are identified. ERG works with the client to ensure the these "customers" are involved in planning the project. In addition to identifying the project's

"customers," ERG works with the client to understand what organization(s) are the "suppliers" responsible for meeting these customers' needs.

7.1.2 Project Goals and Objectives

During the initial work assignment discussion, the ERG Project Management Team and the client work to define the client's needs and expectations in terms of technical and quality goals by discussing the questions and issues to be addressed by ERG during the execution of the work assignment.

7.2 SYSTEMATIC PLANNING PROCESS: WORK PLAN DEVELOPMENT

After the initial conference, the ERG Task Leader prepares a Work Plan to translate the client's needs into specifications for producing the desired result.

7.2.1 Schedule, Milestones, and Budget

The ERG Task Leader develops a work breakdown structure, which identifies staff members, assigns responsibilities, and defines scopes, schedules, budgets, and performance measurement baselines or time-phased budgets. The work breakdown structure breaks the job down into the smallest, practical manageable pieces. The ERG Task Leader uses the work breakdown structure to prepare a work plan and cost estimate responding to the work assignment. The Project Manager reviews and approves the work plan before it is delivered to the client. The work plan includes:

- The person responsible for the work effort (ensuring that the proper experience level and technical discipline are represented);

- A description of the scope of work;
- The measurable milestones associated with the work effort;
- The scheduled start and completion dates; and
- A budget estimate (including labor hours, labor costs, and all necessary other direct costs, including travel, photocopying, materials, subcontracts, and shipping).

In accordance with the specifications designated in the applicable work assignment, the Work Plan is accompanied by a project-specific supplement to this QMP. This narrative may be a complete QA Project Plan following EPA requirement in QA/R-5 or it may be a subset of QA/R-5 requirements specified by the client. The narrative specifies QA/QC parameters for the proposed project and describes acceptance criteria for the results or measures of performance. ERG's design of project quality assessment is described in Section 7.3.

7.2.2 Regulatory and Contractual Requirements

The Work Plan identifies regulatory and contract requirements, such as managing CBI in accordance with ERG's approved plan, obtaining client approval of non-local travel, and use of a QAPP for each work assignment that involves measurement activities or gathering or generation of original data.

Requirements of the Paperwork Reduction Act that affect collection of data are identified. For Federal Government programs, the ERG Task Leader works with the client to identify that all data collection activities requiring Information Collection Requests are approved by the Office of Management and Budget.

7.2.3 Definition of Data Needs and Use

The Work Plan presents the general outline of the program and identifies the type and quantity of data needed and how the data will be used to support the project's objectives. For projects that require field sampling and/or field monitoring, a combined site-specific Field Test Plan and QAPP is prepared to provide a detailed description of the site(s) to be sampled, sampling and analytical methods to be applied, the project management structure for field sampling, and the schedule for sampling and analytical activities. As discussed in Section 7.4, ERG prepares a QAPP for each work assignment that involves measurement activities or gathering or generation of original data. The Project QA Coordinator ensures that a QAPP is prepared as required by the work assignment.

7.2.4 How, When, and Where the Data Will Be Obtained

The Work Plan identifies how, when, and where data required for completion of the project will be obtained. The data may be collected by ERG or obtained from a secondary source. See Section 7.5 for a discussion of the procedures used for evaluating and qualifying secondary data.

7.2.5 Data Analysis, Evaluation, and Assessment (Refer to 7.3)

Data quality assessment design is discussed in detail in Section 7.3. The QAPP describes how acquired *measurements* data will be:

- Analyzed in the field and/or in the laboratory;
- Evaluated (QA review, verification and validation);
- Assessed against the quality performance criteria; and
- Assessed against their intended use.

The Work Plan or a project-specific QA/QC plan prepared in response to a work assignment, describes how other acquired data (e.g., survey data) will be:

- Analyzed statistically;
- Evaluated (QA review, verification and validation);
- Assessed against the quality performance criteria; and
- Assessed against their intended use.

7.3 DESIGN OF QUALITY ASSESSMENT

For each work assignment, ERG develops a plan for assessing if the data or information collected are of the needed and expected quality for their intended use. ERG's plan includes procedures for documenting this assessment of data quality. These plans are prepared in accordance with the specifications designated in the applicable work assignments. This quality assessment plan is a QAPP (see 7.4) or a project-specific QA/QC plan.

All data quality assessments specify:

- The quality measurements used;
- The quality *performance criteria* for those quality measurements; and
- The QC and QA activities needed to assess the quality performance criteria.

Quality *performance criteria* are based on the ultimate use of the data to be collected and QA/QC practices required to support that use. In the decision making process, these criteria allow a user to limit decision errors to a fixed level for determining whether or not an Action Level (regulatory or risk-based) has been exceeded.

The Data Quality Objectives (DQOs) Process (described in Section 7.6) is used to develop acceptance or performance criteria based on the ultimate use of the data to be collected. The DQOs Process is also used to define the quality required for the decision in terms of acceptance limits on the probabilities of committing a decision error. Each step of the Data Quality Objectives Process defines criteria that will be used to establish the final data collection design.

7.4 QAPP

ERG prepares a QAPP for each work assignment that involves field and laboratory measurement activities or gathering or generation of original data. Standard laboratory analysis methods are performed under our NELAC - approved Laboratory Quality Systems Manual. ERG prepares QAPPs in accordance with requirements designated in the applicable work assignment. ERG follows *EPA Requirements for QA Project Plans (QA/R-5)* for work that generates enforcement or regulatory data. Quality Assurance narratives that include the appropriate subset of EPA QA/R-5 requirements are prepared for research programs not directly related to regulatory or enforcement actions. ERG does not begin work involving environmental data generation or use until the client has approved the required quality documentation.

As described in Section 2.3.1, Project staff or the Project QA Coordinator prepare the QAPP, and the Project QA Coordinator ensures that this QAPP meets the appropriate requirements. The Local QA Coordinator reviews and approves QAPPs prepared by project staff before they are submitted to the client. The ERG Task Leader ensures that the procedures specified in the QAPP are implemented and that collected data comply with all acceptance criteria specified in the QAPP.

The QAPP addresses all quality issues associated with sample collection, analysis, data validation, and reporting. Many procedures, such as sample collection and analysis, instrument calibration, chain-of-custody procedures, and data validation procedures and calculations are standardized. Project-specific QA objectives are developed, and any constraints or adaptations to SOPs are incorporated and reviewed prior to conducting any field.

7.5 SECONDARY DATA

The term "secondary data" is defined as data that were collected for a different purpose than that for which they are now being used. In addition to a different purpose than the original data collection, the level of QA/QC provided at the time of data collection may be unknown. Secondary data may be used to support decision-making or to guide research. Secondary data sources include existing databases, such as EPA's PCS and TRI databases and databases from other government agencies, such as Department of Energy and Department of Agriculture; and self-sampling data submitted by industrial facilities. Evaluation of the quality of secondary data reduces the likelihood of a decision error.

7.5.1 Assuring the Quality of Secondary Data from Existing Databases

ERG's procedures for ensuring the quality of secondary data from existing databases include the following steps:

1. Identify the data and how they will be used (e.g., preliminary assessment of pollutant loadings from an industrial category, development of BAT-based limitations, demonstration of facility compliance with regulatory requirements). Develop appropriate data acceptance criteria.

2. Develop a QAPP or project-specific supplement to the QMP, detailing planned QC for acquiring, managing, and using the secondary data. This plan details:

a) How the data will be obtained.

b) File tracking procedures. If the work assignment includes receipt of data submitted from multiple entities, a central tracking system for incoming electronic and/or hardcopy data is developed.

c) The system used for storing and archiving the data.

d) The system used to check the quality of the incoming data. If data are received in multiple, small data deliveries, the checks may be done using a check list. For large existing databases, the checks will be made using automated (query) procedures. The data are checked to identify:
   – Corrupted files;
   – Data out of acceptable range; and
   – Missing data (e.g., missing values, missing units, missing identifying information).

e) Procedures used to develop surrogate data for missing or erroneous data.

f) Quality checks made after the transfer of data between database systems (e.g., checks for number of records, file completeness).

3. Ensure that the QA/QC plan is implemented.

7.5.2 Assuring the Quality of Existing Measurements Data

ERG procedures for validating existing measurements data include the following steps:

1. Use experienced reviewers for validating the data submissions.

2. Verify that the documentation provided is sufficient to assess the quality, usability, and comparability of the data to the protocol that would be used to collect new data (e.g., an EPA Sampling and Analysis Plan).

3. Verify the data meet minimum quality acceptance criteria (e.g., for detection limits, blank contamination, reproducibility, spike recovery).

4. Verify the data were collected under a well-defined, documented quality system (e.g., Standard E-4 ([ANSI/ASQC, 1994)], or Standard 9000 [(ISO, 1987)].

5. Confirm that all pertinent information, such as protocols, test plans, and primary results, are available and use them to verify that the data were collected under appropriate and clearly defined conditions.

7.6 DATA QUALITY OBJECTIVES PROCESS

Environmental data must be of sufficient quality and quantity to establish criteria for making defensible decisions. The Data Quality Objectives Process is a systematic planning tool, based on scientific method, for establishing criteria for data quality and for developing data collection strategies. The DQOs Process is a tool available to Project Managers for structuring the data collection planning process and for developing an appropriate data collection design. The DQOs Process is most appropriate for planning the collection of environmental measurements data.

The Data Quality Objectives Process incorporates seven steps.

1) State the problem.

- Define the problem completely, clearly, and concisely.
- Identify the members of the planning team, including representatives from all groups who are stakeholders in the project and specifically include statistical expertise.
- Designate a decision-maker for the planning team, and assign specific roles to planning team members.
- Identify resources and deadlines pertinent to the project.

2) Develop a decision statement.

- Define the issue(s) that the project will attempt to resolve.
- Identify possible actions that may be taken to solve the problem, including an alternative that requires no action.
- Combine the alternative actions and the principal study question into a decision statement to express a choice among alternative actions.
- If multiple decision statements are required to address the problem, list them in the sequence in which they must be resolved.

3) Identify inputs to the decision.

- Decide what types of information are needed to resolve the decision statement and define the sources for each type of information.
- Decide what information is needed to enable choosing between alternative actions.
- Determine whether there are appropriate environmental measurement methods to provide the necessary data.

4) Define the boundaries of the study.

- Identify any practical constraints that may interfere with the study.
- Determine where and when analytical samples should be taken.

5) Develop a decision rule.

- Combine the results of the previous Data Quality Objectives steps into an "If...then..." decision rule that defines the conditions that enable decision-makers to choose among alternative actions.

6) Specify tolerable limits on decision errors.

- Error in sampling design occurs when the sampling design is unable to capture the complete extent of natural variability that characterizes the true state of the environment. Measurement error relates to the combination of random and systematic error that occurs during the various steps of a measurement process, from sample collection through data handling. The possibility of making a decision error can never be totally eliminated, but there are numerous ways that the decision error can be minimized (e.g., collecting a large number of samples to minimize

sampling design error, analyzing individual samples several times to minimize measurement error, etc.). Because reducing the possibility of making decision errors generally increases costs, it is critical to have an accurate definition of the needs of the decision maker to determine tolerable limits of error.

7) Optimize the design for obtaining data.

- Identify the most effective data collection design that will generate data that satisfy the defined Data Quality Objectives. The goal is to find cost-effective alternatives that balance number of samples and measurement performance, given the feasible choices for sample collection techniques and analytical methods.

SECTION 8

IMPLEMENTATION OF WORK PROCESSES

The types of scientific and technical activities conducted by ERG include collecting and evaluating available information from existing databases and other sources; collecting environmental information through surveys, site visits, and field sampling efforts; analyzing environmental information by database development, data processing, and computer modeling; and preparing written reports and other documents. This section of the QMP describes how work processes are implemented within ERG to ensure that environmental data are of the needed and expected quality for their intended use.

8.1 PROJECT MANAGEMENT: ENSURING THAT WORK IS PERFORMED ACCORDING TO APPROVED PLANS AND SOPS

Project management consists of technical and administrative activities that ensure work assignment objectives are understood and communicated to project staff and that the expected product is provided in a technically sound, cost-effective manner. Work plans, site-specific Sampling and Analysis Plans, and QAPPs communicate this information to the client and to ERG project staff. Communication within ERG also includes project and task instructions, which contain logistical and technical information used to control and coordinate project implementation. These instructions detail the project management, technical review, and QA/QC processes used to implement the work assignment. These instructions include thorough instructions for managing and executing the technical project activities. Large projects may utilize project management software to assist in planning and scheduling. Project instructions

provide logistical and technical information required by project team members to conduct the work. The primary components of project instructions are:

- Project summary and objectives;
- Scope of work;
- Budget and schedule information, including internal deadlines;
- Confidentiality requirements, if any;
- Safety concerns;
- Project staff and responsibilities;
- Standard Operating Procedures (SOPs) to be used;
- Deliverables;
- Deliverable review requirements and other QC procedures;
- Internal and external communication procedures; and
- Travel and procurement requirements.

For large projects that incorporate many tasks, task instructions may be developed as part of the technical planning activities. These task instructions provide team members with the technical approach and with schedule and data quality requirements. Task instructions also assign specific responsibilities to each individual.

8.1.1 Responsibilities

The ERG Task Leader is responsible for preparing and implementing project and task instructions. The Project Manager is responsible for ensuring that adequate project and task instructions are prepared and used.

8.2 DEVELOPMENT OF WORK PROCESSES AND PROCEDURES

ERG's processes for identifying operations that require written procedures is presented in this section. Both standard operations and special (critical) operations are discussed.

8.2.1 Standard Operating Procedures

As described in Section 2.2.1, SOPs are written instructions that document a routine or repeated activity. SOPs detail work processes in order to facilitate consistent conformance to technical and quality system requirements. Use of SOPs helps to ensure data quality.

Identifying when new SOPs are needed. As discussed in Sections 1.2.2 and 2.2.1, the Local QA Coordinators are responsible for identifying when SOPs are needed at their location and for designating an appropriate individual to create the needed SOPs. The local QA Coordinators are responsible for developing a standardized form for their location's SOPs.

Use of SOPs. In developing the work plan and project instructions, the ERG Task Leader identifies the SOPs to be used in conducting the work. The Project Manager verifies that the identified SOPs are appropriate to the activity being conducted. As discussed in Section 9.2.7, the corporate quality management staff conducts occasional technical systems audit to evaluate adherence to approved QAPPs and SOPs.

Review, approval, revision, and withdrawal of SOPs. The Local QA Coordinator is responsible for reviewing the draft SOP or designating an appropriate technical reviewer; circulating the approved SOP to technical staff members; and maintaining copies of SOPs pertaining to the ERG location in a central filing system. SOPs are company-confidential. ERG SOPs are prepared and filed by individual ERG locations and maintained in a central filing

system controlled by the Local QA Coordinator. Each SOP has a signed title page and document control format, as depicted in Figure 5-1 found in Section 5 of this QMP. The Local QA Coordinator is responsible for withdrawing obsolete procedures.

8.2.2 Procedures for Special or Critical Operations

Work procedures to be followed for a specific project are presented in a written format in the work plan and project instructions. The ERG Task Leader is responsible for preparing and implementing these plans. The Project Manager is responsible for reviewing the plans and for ensuring compliance with them. For projects the Project Manager considers special or critical, review procedures are developed in consultation with the Local QA Coordinator. See Section 9 of this QMP for available assessment tools.

8.3 CONTROL MEASURES

See Sections 5.2.2 Quality System Records (SOPs and QMP) and 5.2.3 Quality System Document Control for a description of the process used for controlling and documenting the release and changes of the QMP, SOPs, and QAPPs, including needed approvals and removal of obsolete documentation from work areas.

SECTION 9

ASSESSMENT AND RESPONSE

This section of the QMP documents how ERG management determines the suitability and effectiveness of the ERG quality system. This section also documents how ERG evaluates the quality of the projects involved with environmental data collection, generation, or use.

Section 9.1 describes how and when ERG assesses the effectiveness of our corporate quality system and project quality and describes the roles and responsibilities of management and staff in conducting these assessments. Section 9.2 describes available quality assessment tools. Section 9.3 describes QC measures used during the generation of environmental measurements data.

9.1 CONDUCTING ERG QUALITY SYSTEM AND PROJECT QUALITY ASSESSMENTS

Quality System Assessment. As described in Section 2.2.2 of this QMP, the ERG Corporate QA Manager conducts an annual, internal review of the corporate quality system to determine if the quality system is implemented and is operating as prescribed in the QMP. The Corporate QA Manager is responsible for ensuring that independent audits are conducted to determine the effectiveness of the ERG quality system. Local QA Coordinators are responsible for reporting to the Corporate QA Manager results of independent audits they have performed to determine the effectiveness of the ERG quality system, Management Systems Reviews, and independent project quality technical assessments.

Project Quality Assessments. Each Local QA Coordinator is responsible for planning, scheduling, and conducting independent assessments to determine the effectiveness of the ERG

QA/QC program. Local QA Coordinators report the results of these assessments to the Corporate QA Manager and ERG management. Planning of project quality assessments, selection of assessment personnel, reports to management, and responses to assessment findings are discussed in the following sections.

9.1.1 Planning

Planning for project quality assessment is part of the development of a work plan and QAPP (if applicable). The Local QA Coordinator works with the ERG Task Leader during the development of the work plan to identify the QA/QC procedures that are commensurate with the project objectives. The Local QA Coordinator and the ERG Task Leader identify the quality assessment tools that will be used (See Section 9.2 for a description of assessment tools). Quality assessments (e.g., technical reviews, peer reviews, and field sampling audits) are included in the project schedule and budget.

9.1.2 Assessment Personnel

Qualifications of Assessment Personnel. Technical review is the most commonly used tool for assessing ERG project quality. Technical reviewers are proficient in the work area of interest, but are not directly responsible for performing the work. The Project Manager works with the Local QA Coordinator to identify one or more qualified technical reviewers at the start of the project. If special expertise is required, technical reviewers may be ERG consultants or subcontractors.

The ERG staff tasked with assessing the quality of ERG projects have considerable experience in designing and conducting audits of measurement systems (based on internal, but functionally independent, audits of projects and laboratories); external audits of ERG projects

conducted by other organizations; and external audits conducted by ERG staff. This experience contributes to effectiveness and efficiency in auditing performance.

Independence of Assessment Personnel. Personnel conducting assessments are technically knowledgeable but have no direct involvement or responsibility for conducting the work assessed. Thus, they have no conflict of interest (real or perceived).

Authority of Assessment Personnel. Assessment personnel are permitted to access managers, documents, and records, as needed to evaluate the quality of the project. If necessary, the assessment personnel are granted access to CBI, after complying with the provisions of the relevant ERG CBI Plan. As discussed in Section 1.2.3, Stop Work Authority, if assessment personnel find deficiencies in project team quality performance, they notify the Project Manager and Corporate QA Manager. If the deficiencies are not resolved, the assessment personnel, in conjunction with the Project Manager, have full authority to stop work and replace project staff (if necessary) so that the deficiencies are resolved.

9.1.3 Management Review and Response to Assessment Findings

As discussed in Section 1.2.1, the Corporate QA Manager is responsible for implementing corrective actions for quality problems identified by Local and Project QA Coordinators. She is also responsible for recommending required management-level corrective actions which may include stopping work of inadequate quality until identified deficiencies are resolved.

9.1.4 Corrective Actions

Audits, evaluations, and surveillance are the mechanisms used to identify and communicate conditions adverse to quality, to determine a cause for them, and to initiate corrective action. The Project Management Team and senior technical management are responsible for ensuring that when deficiencies are identified, corrective actions are implemented and verified without delay.

Communication. Assessment personnel are responsible for communicating, in writing, any detected deficiencies to the Project Manager and Local QA Coordinator in a timely fashion. The assessment personnel identify the need for corrective action and the Project Manager is responsible for ensuring appropriate action has been taken and documented.

Confirmation of Implementation and Effectiveness. The Local QA Coordinator is responsible for confirming that corrective action has been taken and that the action was effective in remedying the deficiency detected by the assessment personnel.

9.1.5 Resolution of Disputes

On the rare occasion that there is a dispute between the Project Manager and the ERG Corporate QA Manager over proper corrective action or solutions to deficiencies (see Section 1.2.3), the ERG President, David Meyers, resolves the dispute.

9.2 ASSESSMENT TOOLS

ERG executes regularly scheduled audits to verify compliance with all aspects of its quality system and to determine its effectiveness. If inadequacies are identified in the laboratory measurement system and/or in a project's products, audits provide the mechanism for implementing corrective action.

Types of assessment tools applicable to various aspects of scientific and technical activities are described in the following sections:

- 9.2.1 Management Systems Reviews;
- 9.2.2 Peer Reviews;
- 9.2.3 Technical Reviews;
- 9.2.4 Performance Evaluation Audits;
- 9.2.5 Data Quality Assessments and Data Quality Audits;
- 9.2.6 Readiness Reviews;
- 9.2.7 Technical Systems Audits; and
- 9.2.8 Surveillance.

9.2.1 Management Systems Reviews

A management systems review is a qualitative assessment of a data collection operation and/or organization to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate to ensure that the type and quality of data needed are obtained. A management systems review is a qualitative review of the role of QA/QC in project management, where strengths, weaknesses, and problem areas are evaluated. This review is also used to determine the extent to which QA/QC has been established within the organization.

Among the issues addressed in a management systems review are:

- The role of QA/QC as described in management policy;
- The documentation by the program management team of the implementation of QA/QC procedures on the project; and
- The ability to trace the resources allocated to QA/QC management.

Management systems reviews are qualitative evaluations conducted on a regular basis at the corporate level. These reviews do not answer questions involving specific aspects of the QA procedures nor do they address the measurement systems and the data quality indicators.

9.2.2 Peer Reviews

Peer review is a documented critical review of work generally beyond the "state-of-the-art," or work characterized by the existence of potential uncertainty. Peer review is conducted by qualified individuals who are independent of those who performed the work, but who have equivalent technical expertise (i.e., peers). Peer reviewers assess whether the work performed is technically adequate, competently performed, properly documented, and satisfies the technical and quality requirements specified in the Work Plan and/or QAPP. Peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions of a specific work and its documentation. Peer review is typically used in research and development or other activities where quantitative methods of analysis or measures of success are unavailable or undefined.

9.2.3 Technical Reviews

Technical review is a documented critical review of work that has been performed within the "state-of-the-art." Each ERG project has at least one technical reviewer, a person who is proficient in the work area of interest, but not directly responsible for performing the work. One or more technical reviewers are designated at the start of each project at ERG, and the participation of a technical reviewer in the project is budgeted as a line-item cost. The responsibilities of this reviewer include a detailed review of all significant project deliverables and an up-front review of the detailed Work Plan to ensure that:

- The project goals are well-defined, realistic, and appropriate to the needs of the client;
- The approach proposed to meet the goals is reasonable and likely to result in a successful project; and
- The necessary resources in terms of time, dollars, and competent staff are dedicated to the project.

Depending on the needs of the project, the technical reviewer may also function as a senior technical advisor, serving as a resource to project staff during the course of the project. Because of the reviewer's technical experience and proficiency in the work area, the reviewer can make an extremely valuable technical contribution to the program.

A formal project review of all technical work may also be performed by ERG senior technical management who are independent of those who performed the work. This review is done to provide a critical analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that requirements established in the Work Plan or QAPP are satisfied. Technical reviews of ERG projects are maintained as part of the project file.

9.2.4 Performance Evaluation Audits

The purpose of a performance evaluation audit is to quantitatively assess data quality. A performance evaluation audit is applicable to any testing program where reproducibility according to a standard is relevant, as in physical or chemical analysis laboratories, or in field measurement programs such as ambient air monitoring or source emission characterization. The performance evaluation audit provides a direct evaluation of the various measurement systems' capabilities to generate quality data. The performance evaluation audit is accomplished by

challenging the measurement system with accepted reference standards, such as Standard Reference Materials supplied by the National Institute for Standards and Technology (NIST) or by commercial vendors.

Performance evaluation audits review the following:

- Precision and bias of the measurement system;
- Comparison of QC data to actual measurement data collected;
- Function of the measurement system relative to established control limits; and
- Significant deviations from the data quality objectives over time.

Although information collected during a performance evaluation audit will determine when a system is not performing adequately, the nature of appropriate corrective action is not always evident. Questions regarding qualitative issues, such as management policies, sample custody procedures, recordkeeping, and data handling systems are not addressed in a performance evaluation audit.

9.2.5 Data Quality Assessments and Data Quality Audits

Data Quality Assessments. A data quality assessment is a statistical and scientific evaluation of a data set to determine:

- The validity and performance of the data collection design;
- The validity and performance of the statistical test(s); and
- The adequacy of the data set for its intended use.

A data quality assessment can be undertaken only after data have been generated or collected, and is typically performed by a senior project team member, another designated technical reviewer, the Local QA Coordinator, or a combination of staff. A data quality

assessment determines whether the project data meet the Data Quality Objectives and whether they are of the correct type, quality, and quantity to satisfy the objectives specified in the Work Plan or QAPP.

Data Quality Audits. A data quality audit is designed to assess data quality indicators and is applicable to programs in all areas where data are collected. A data quality audit provides information to characterize the data, such as:

- Adequacy of data collection, recording, and transfer;
- Precision and bias of resultant data;
- Adequacy of data calculation, generation, and processing;
- Documentation of all data-handling procedures; and
- Identification of data quality indicators to inform users of limitations and applicability.

A data quality audit will determine whether the data collection procedures need modification and whether the use and documentation of QC procedures are adequate. A data quality audit will not, however, address the overall QA management system of an organization, nor will a data quality audit answer technical questions such as the operating conditions of facilities and equipment.

9.2.6 Readiness Reviews

A readiness review is a systematic, documented review of the readiness for the start-up or continued use of a facility, process, or activity. A readiness review is typically conducted by a project peer reviewer, senior technical management, or Project QA Coordinator, and is performed before proceeding beyond project milestones and prior to initiation of a major phase of work. A readiness review addresses the following questions:

- Has project work of sufficient quality and quantity been completed to allow the project team to proceed with the next phase of work?
- Is the project on schedule and within budget?
- Are appropriate resources (i.e., supplies, materials, analytical instruments, sampling equipment) available for successful execution of the next phase of work?
- Has the project team planned for appropriate support staff (i.e., technical editors, secretarial, or clerical support) for the next phase of work?
- If subcontractors or consultants are required in the next phase of the project, have appropriate arrangements been made and is the necessary documentation available and approved?

9.2.7 Technical Systems Audits

A technical systems audit is an on site, qualitative review of the various aspects of a total sampling and/or analytical system. A technical systems audit provides an assessment of overall effectiveness and represents a subjective evaluation of a set of interactive systems with respect to strengths, deficiencies, and potential areas of concern. Typically, the audit consists of observations and documentation of all aspects of the measurement effort.

A technical systems audit at ERG serves to evaluate adherence to approved QAPPs and SOPs. A technical systems audit reviews the following:

- Sample collection and handling;
- Instrument operation, calibration procedures, and documentation of instrument operation and maintenance;
- Completeness of data forms, notebooks, and other reporting requirements;
- Data review and validation procedures;

- Data storage, filing, and recordkeeping procedures;
- Sample custody procedures, including laboratory sample tracking;
- QC procedures and documentation;
- Operating conditions of facilities and equipment;
- Documentation of maintenance activities in individual instrument maintenance logs; and
- Systems and operations overview.

Technical systems audits do not provide a quantitative measure of quality, but rather an evaluation of the effectiveness of a QC program, both in terms of design and implementation.

9.2.8 Surveillance

Surveillance refers to the continual monitoring and verification of the status of a project and the analysis of records to ensure that specified requirements are being fulfilled. Surveillance is performed by the project's technical management team, who monitor the status of the project and are responsible for the review of records such as laboratory notebooks and other documents. Review of documents and data generated may be performed by the designated technical reviewer, who has a major role in the function of surveillance on the designated program.

9.3 QC MEASURES

ERG QC measures used in field sampling, chemical and physical measurement, and for statistical control and quality calculations are described below.

9.3.1 Field Control Samples

The specific kind and number of control samples and the frequency of collection and analysis are documented in the individual QAPP. Control samples used to document the accuracy and precision of sampling are:

- *Calibration samples*: All instrumentation used for sampling must be calibrated before and after each sampling event. Measurement control for this equipment includes physical inspection for appropriate size and shape, visual inspection for structural integrity, and leak checks. Specific calibration techniques are discussed in the QAPP.

- *Blanks*: Field (equipment) blanks are collected at the start of the sampling program. For water sampling programs, analyte-free water (HPLC-grade) is passed through or over the sampling equipment, into the appropriate sampling containers, and preserved on site according to the analyte-specific preservation methods. The analytical results are used to assess the introduction of contaminants into samples from the sampling equipment. On air sampling programs, field blanks consist of sampling media that are prepared, brought to the field, and installed in the sampling equipment with *no* stationary source matrix passed through the sampling train. Field blanks are used to detect any contamination from the sampling equipment or handling of the sampling medium, cross-contamination from previously collected samples, or contamination from conditions arising during sampling. Trip blanks are samples of sampling media taken from the laboratory to the sampling site and returned unopened to the laboratory. Trip blanks are used to detect any contamination or cross-contamination that might occur during handling and transportation of samples.

- *Field duplicates*: Duplicate samples are collected at the frequency specified in the QAPP and are used to document sampling and analytical precision. This

precision is a function of the variability of the sampling matrix and the variability in the performance of the sampling and analytical techniques.

- *Field spikes*: Field spikes are used to determine the loss of compounds of interest during sampling and shipment to the laboratory. For example, field spikes are designed to show field technicians' precision, possible contamination, and degradation during storage.

9.3.2 Chemical and Physical Measurement Control

Control samples are used as an internal evaluation of how the measurement system performed. Control samples are intended to check contamination, precision, and accuracy within previously established limits. The type of control samples used depends on the laboratory procedure, but frequency, acceptance criteria, and corrective action must all be considered. Requirements for control samples must be written and unambiguous corrective action procedures specified whenever a control sample does not meet acceptance criteria. Control samples typically include calibration checks, QC check samples such as second source reference materials, blanks, spiked samples, and replicates. Project-specific control samples are specified in the QAPP.

Laboratory control samples are blanks that have been spiked with the analytes of interest from an independent source to enable monitoring of the execution of the analytical method. These samples are used to verify that the analytical instrument is calibrated correctly. The two types of blanks used in chemical and physical measurements include:

- *Laboratory blanks*: A laboratory blank is an aliquot of an analyte-free matrix that is taken through the preparation steps prior to analysis. The results from laboratory blanks are used to identify any contamination from reagents, sample preparation equipment, or analysis; and

- *System blanks*: A system blank is an artificial sample designed only to monitor instrument contamination. System blanks are reagent water or pure solvent that is taken only through the analytical process.

Four types of laboratory spikes are routinely used in the analytical laboratory:

- *Laboratory control samples* are spikes of a reagent grade matrix that are taken through the preparation and analysis steps. Laboratory control samples are used to document accuracy and precision of the entire analytical process.
- *Analytical spikes* are spikes added to the samples after preparation but before analysis; analytical spikes are used to document analytical accuracy.
- *Matrix spikes* are spikes added to a sample matrix prior to extraction, digestion, or other preparative steps, and analysis. Matrix spikes are used to assess precision and bias in actual samples, as well as to identify matrix effects.
- *Surrogate spikes* are organic compounds that are similar to the analytes of interest in chemical composition, extraction behavior, and chromatographic behavior, but that are not normally found in nature. The surrogate spike compounds may be isotopically labeled analogs of the compounds of interest or homologs of the compounds of interest. Surrogate compounds are spiked into all blanks, standards, samples, and spiked samples prior to preparation and analysis. Surrogate spikes are used to assess precision and bias.

Instrumentation used for measurement must be calibrated before and after each analytical series. Measurement control for this equipment includes visual inspection for structural integrity, leak checks for vacuum equipment, checks of chromatographic properties, etc. Specific calibration procedures are specified in the QAPP.

9.3.3 Statistical Control and Quality Calculations

Statistical methods are applied to establish and monitor control in analytical processes and to calculate precision and accuracy for measurement data during data validation. The statistical procedures and calculations to be used for a specific measurement process or project are identified and presented in the QAPP or in appropriate SOPs. These statistical calculations follow EPA or other recommended procedures.

Statistical control must be demonstrated for each analytical process before the measurements can be considered reliable. Statistical control is usually determined by calculating the mean and standard deviation of a series of measurements of the same control sample or parameter, analyzed over a period of time. Warning and control limits are generally set at two or three times the standard deviation of the measurement. Control charts are maintained to provide visual demonstration of statistical control and are updated periodically to monitor the process. Corrective action must be taken if the measurement exceeds the control limits. Parameters or measurements that are monitored include method spike recoveries for organic and inorganic analytes, surrogate spike recoveries, and the relative percent difference between matrix spike/ matrix spike-duplicate sample recoveries. The frequency requirements for updating control charts and control limits, the parameters or measurements to be monitored, and corrective actions are defined in the QAPP. Statistical control calculations and control charts are reviewed as part of Technical Systems Audits and Data Quality Audits.

Data validation procedures are presented in every QAPP and follow standard statistical calculations for precision and accuracy. Specific calculations used to assess precision include the relative percent difference (RPD) and average RPD for duplicate samples or analyses, and coefficient of variation (CV) and pooled CV for measurements of three or more replicates. Confidence intervals may be established for specific parameters or analytes for use in data interpretation applications. Accuracy is evaluated by calculating the percent recovery or

standard error for Performance Evaluation Audit samples, or the percent recovery of matrix, method, or analytical spike samples.

Blank sample results may also be evaluated by statistical methods, such as calculating the average blank contaminant concentration. These results are compared to field sample results to assess whether blank contamination has influenced or biased the results.

Precision and accuracy results are compared to the established control limits or project-specific Data Quality Objectives. This comparison provides the basis for assessing whether the data are valid for use in the intended applications, whether any data must be flagged to indicate limitations in their use, or whether any corrective action is warranted.

SECTION 10

QUALITY IMPROVEMENT

This section of the QMP documents how ERG works to continuously improve our corporate quality system and the systems we use to ensure the quality of our work.

10.1 MANAGEMENT COMMITMENT

ERG's goal is to meet or exceed our customers' expectations for quality products. ERG is committed to allocating the necessary resources for implementing, maintaining, and improving our quality management program, as well as preventing problems before they occur.

ERG senior management communicate these expectations to staff during employee training, project planning, review of work plans, and staff performance reviews. Technical capability, work quality, and adherence to QA/QC procedures are the most heavily weighted factors in staff performance reviews.

ERG management and project staff consider the Project QA Coordinators as team members whose goal is to help achieve the common goal of producing complete and accurate data.

10.2 IDENTIFICATION AND REMEDIATION OF CONDITIONS ADVERSE TO QUALITY

ERG uses audits, evaluations, and surveillance (described in Section 9 of this QMP) to identify and communicate conditions adverse to quality, to determine a cause for them, and to

initiate corrective action. A QA/QC system functions to save time, improve procedures, communicate the need for additional support and resources to management, and to improve the overall effectiveness of systems and the quality of the data. Systematic deficiencies identified by audits are reported to the Corporate QA Manager so that she can address these deficiencies in her annual quality improvement plan.

Any project team members concerned about problems or events that affect data quality, sample integrity, or laboratory or field safety, communicate their concerns to the Project Manager or his designee. The team members identify the problem and make recommendations for solutions. As directed by the Project Manager, the team members implement the recommended solution and document the result. Timely identification is vital to solving problems and thorough documentation is vital to preventing their recurrence.

An example of ERG's quality problem identification procedures is the Request for Corrective Action system used to track quality deficiency issues in the Morrisville chemistry laboratory. Problems signaling significant and systematic deficiencies are addressed with a Request for Corrective Action. A Request for Corrective Action is issued by a member of the QA staff or by his/her designee for a particular project to the associated manager. Each Request addresses a specific problem or deficiency, usually as a result of an external or internal QA audit. These requests are designed to identify a specific problem, to recommend a course of action, to identify the person responsible for implementing the corrective action, to verify implementation, and to document the resulting corrective action taken. Each Request for Corrective Action requires a written response from the responsible party, typically the person to whom the Request was issued.

As discussed in Section 2.2.3, ERG also asks our clients directly if they are satisfied with the quality of our work. Each client, Contract Officer, and WAM is contacted by ERG President

David Meyers or another ERG senior manager every year and asked to provide an assessment of the technical quality of our work. Clients are also asked if there are areas they would like ERG to improve. Any identified systematic deficiencies are addressed in a quality improvement plan.

10.3 QUALITY IMPROVEMENT ACTIVITIES

All ERG employees are encouraged to identify opportunities to improve the quality of our work. They are encouraged to :

- Identify problems;
- Investigate the root cause;
- Develop solutions to the problems; and
- Communicate their concerns to management, including ERG President David Meyers.

10.4 ENCOURAGING STAFF PARTICIPATION

ERG management encourages staff participation in quality improvement by taking a "no-fault attitude." Through our quarterly achievement award program, management recognizes individual and group contributions to ERG's success, including contributions to quality improvement.

APPENDIX A

ERG STANDARD OPERATING PROCEDURES FOR SCIENTIFIC AND TECHNICAL ACTIVITIES

APPENDIX A

ERG STANDARD OPERATING PROCEDURES FOR SCIENTIFIC AND TECHNICAL ACTIVITIES

SOP No.	SOP Title
1	Documentation of Field Recovery Activities
2	Gravimetric Determination for Particulate Emissions Measurements
3	Field Procedure for Collecting Ambient Air Toxics and Carbonyl Compounds Samples using the ERG:AT/C Sampling System
4	SOP for Preventive Maintenance in the Gas Chromatography/Mass Spectrometry Laboratory
5	SOP for the Concurrent GC/FID/MSD Analysis of Canister Air Toxic Samples
6	SOP for the Analysis of Tenax® Tubes According to EPA Method TO-1/TO-17
7	SOP for the Preparation of Review Packages for Mass Spectrometry Data Sets
8	Procedure for Preparation of Standard Operating Procedures
9	SOP for the Operation of the Documentation System
10	SOP for the Determination of Method Detection Limits in the GC/MS Air Toxics Laboratory
11	SOP for Sample Storage and Checkout from Freezers/Refrigerators at the Laboratory
12	SOP for Basic Training Requirements for Sample Preparation Laboratory Personnel
13	Field Procedure for Collecting Ambient Air Hexavalent Chromium Samples using the ERG:CR6 Sampling System
14	SOP for Sample Preparation QC
15	SOP for Documentation Procedures for the Sample Preparation Laboratory
16	SOP for the Varian 9000 Series High Performance Liquid Chromatography (HPLC)
17	SOP for Developing, Documenting, and Evaluating the Accuracy of Spreadsheet Data

SOP No.	SOP Title
18	Maintaining and Recording Data Records
19	SOP for Transferring, Storing, and Using Confidential Business Information (CBI)
20	SOP for Conducting a Laboratory Systems Audit
21	Calibration and Operation of Analytical Balances
22	SOP for the Preparation of Standards in the ERG Organic Preparatory Laboratory
23	SOP for the Use of Significant Figures and Rounding Off Numbers When Reporting Data
24	SOP for Preparing Aldehyde Derivatizing Reagents and Extracting Derivatized Samples
25	SOP for the Operation of the Rainin High Performance Liquid Chromatography System
26	SOP for Documentation: Labeling of Samples and Standards Prepared in the Laboratory
27	SOP for the Operation of a Gas Chromatograph
28	SOP for QA/QC in the Gas Chromatography/Mass Spectrometry
29	SOP for Concentration of Sample Extracts Using the Kuderna-Danish Concentrates
30	SOP for Canister Sampling System Certification Procedures
31	SOP for Cleaning Glassware and Syringes for Organic Analysis
32	Statistical Manual Standard Operating Procedure
33	SOP for Solid and Hazardous Waste Disposal
34	Analytical Chemistry Training at PPK Laboratory
35	SOP for QA/QC
36	SOP for Laboratory Security
37	SOP for Chemical Inventory

SOP No.	SOP Title
38	SOP for Personal Protective Equipment Program
39	SOP for Maintaining Laboratory Notebooks
40	SOP for Chemical Storage Facilities
41	SOP for Tracer Gas Release and Integrated Bag Sampling for Analysis by FTIR Spectroscopy
42	SOP for the Dionex-300 Ion Chromatograph
43	SOP for the Analysis of Semivolatile Organic Compounds in Gaseous Emissions using the SemiVOST Method
44	SOP for Method 8270C - GC/MS Analysis of Semivolatile Organics
45	SOP for Sample Log-in at the ERG Chemistry Laboratory
46	Field Procedure for Collecting Speciated and/or Total Nonmethane Organic Compounds Ambient Air Samples using the ERG:S/NMOC Sampling System
47	Field Procedure for Collecting Ambient Carbonyl Compounds Samples using the ERG:C Sampling System
48	SOP for Cleaning XAD-2® with QC Measures to Assure Cleanliness
49	SOP for the Extraction and Analysis of PAH's from XAD-2® Traps
50	SOP for Separatory Funnel Liquid-Liquid Extraction by EPA SW-846 Method 3510C
51	SOP for Continuous Liquid-Liquid Extraction by EPA SW-846 Method 3520C
52	SOP for Acid-Base Partition Cleanup by EPA SW-846 Method 3650B
53	SOP for Soxhlet Extraction by EPA SW-846 Method 3540C
55	SOP for Maintenance of NANOpure-A Deionized Water System
56	SOP for Daily Maintenance of Cold Storage Units
57	SOP for Project Peer Review
58	SOP for Preparing Method 25 Audit Samples Using the Transfill System

SOP No.	SOP Title
59	SOP for High Performance Liquid Chromatography
60	SOP for PDFID Sample Analysis
61	SOP for Standard Preparation Using Dynamic Flow Dilution System
62	SOP for UATMP & NMOC Canister Cleaning
64	SOP for Shipping Method 6, 7, 8, and 26 Audit Samples
66	Cylinder Recycling
67	SOP for Producing Standard Mixtures of Organic Compounds in Air by Liquid Injection
69	SOP for Shipping Method 23 Audit Samples
70	SOP for Storing and Shipping Method 13A, 13B, and 29 Audit Samples
71	SOP for Documentation Requirements for the GC/MS Laboratory and for GC/MS Systems in the VOC Laboratory
72	SOP for Stack Sampling using FTIR Spectroscopy
73	SOP for the ECD Wipe Test
74	SOP for the Preparation of Spiked Sorbent Samples Using Liquid Spiking into Tenax-GC® Tubes
75	SOP for the Preparation of Spiked Sorbent Samples Using Liquid Spiking onto XAD-2®
76	SOP for the Preparation of Spiked Sorbent Samples Using Flash Evaporation Spiking onto XAD-2®