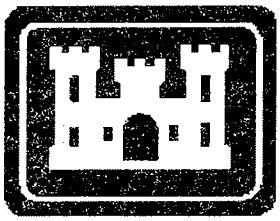
LABORATORY
QUALITY ASSURANCE PLANS

INTERIM REMOVAL ACTION
TNT PIPELINE AND
CHEMICAL WASTE SEWER LINES
FORMER LAKE ONTARIO ORDNANCE WORKS
LEWISTON/PORTER, NEW YORK

PREPARED FOR



UNITED STATES ARMY CORPS OF ENGINEERS
BALTIMORE DISTRICT

PREPARED BY

ROCKVILLE, MARYLAND

AUGUST 1999
USACE CONTRACT NO. DACA31-96-D-0026
DELIVERY ORDER NO. 0025
RADIAN PROJECT NO. 80003625

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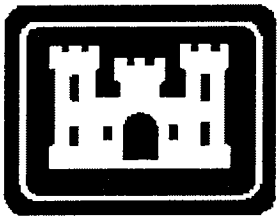

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RAS

Radian Quality Management Program

Analytical Laboratory Systems Manual

SM01/AL Revision 02
September 1, 1998

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INTRODUCTION

This document, *Analytical Laboratory Systems Manual,* describes the quality system for the Radian International Analytical Laboratory System. Radian Analytical Laboratories are located in Austin, TX, at Radian's Summit Park facility:

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Austin, TX 78728

Mailing Address:
P.O. Box 201088
Austin, TX 78720-1088
512-244-0855
Fax: 512-244-0160

Technical Director:
Michael C. Shepherd, Ph.D.

The laboratories that comprise the Radian International Analytical Laboratory System are:

- Sample and Document;
- Trace Metals;
- GC Volatile Organic Compounds;
- Organic Sample Preparation;
- Chromatography;
- Water Quality;
- GC/MS Volatile Organic Compounds (canisters); and
- GC/MS Extractables.

These laboratories are often referred to as the Fixed Protocol Analytical Services (FPAS) Laboratories. The type of analytical work performed by these laboratories is fixed protocol work according to published EPA or other methods, generally in support of regulatory-driven decisions. All analytical work performed by these laboratories is done at the behest of a Radian project team, which is in direct communication with the client.

The purpose of the laboratory quality management program is to ensure that all analytical results produced by these laboratories meet applicable quality specifications that satisfy our clients' needs and expectations.

Scope

The *Analytical Laboratory Systems Manual* describes the overall quality system that has been developed and implemented for ensuring that all data produced by Radian Analytical Chemistry Laboratories meet applicable quality specifications. The quality system encompasses all activities performed within the Analytical Chemistry Laboratories, particularly those that affect quality of results. This system includes:

- A statement of the quality objectives for Analytical Chemistry;
- A description of the specific authority and responsibilities of all personnel within the organization with particular emphasis on those with managerial or quality management responsibilities;
- Descriptions of activities that affect quality with special reference to procedures that detail objectives and performance of these activities;
- Description of the data inspection activity with specific quality assessment procedures that are in effect; and
- A description of quality documentation and records that are maintained.

This document describes the quality management program for Radian Analytical Laboratory Systems. It is one of several systems manuals that have been developed to describe the various quality systems in place at Radian for different business areas. These various manuals collectively comprise Radian's overall Quality Management Program.

Applicability

Radian International's Analytical Laboratory Quality System is designed to ensure the technical quality of all analytical results provided by the FPAS Analytical Chemistry Laboratory to Radian project teams working for clients in industry and government. All personnel working in Analytical Chemistry are required to understand the elements of this system and are expected to follow its guidelines and procedures in the conduct of their work. This quality system does not address quality-related activities for other areas of the company such as Human Resources, Facilities, Analytical Reference Materials, and so forth. These activities are described in detail within the respective systems manuals for the other areas.

Analytical Laboratory Systems Manual Organization

This *Analytical Laboratory Systems Manual* is organized according to the 20 quality system elements defined in the American National Standard, "Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation, and Servicing" ANSI/ISO/ASQC Q9001-1994. Radian considered it important to add a 21st element to this manual, "Safety". This manual was also developed in consideration of the fundamental requirements for a laboratory quality manual, as described in the National Environmental Laboratory Accreditation Conference (NELAC), "Quality Systems" 1997.

At the beginning of each section of this manual is a text box that recites the basic requirement for each quality system, as defined in the ANSI/ISO/ASQC Q9001 standard. As appropriate, the text boxes also recite NELAC basic quality system requirements. These text boxes may also be found in subsections of the manual where it is helpful to clarify the intent of the activity described.

Each section of this manual includes a statement of the basic requirement, the laboratory's quality policy pertaining to that quality system element, the basic responsibilities for fulfilling the policy, and a description of the overall process. Standard Operating Procedures and Quality Management Procedures are referenced, as applicable.

SECTION 1
MANAGEMENT RESPONSIBILITY

This section discusses Radian Analytical Laboratory System's commitment to quality and the organizational structure and management responsibilities for implementing a quality system to fulfill that commitment.

1.1 Quality Policy and Ethics Statement

> ***Supplier's management with executive responsibility shall define and document its policy for quality, including objectives for quality and its commitment to quality. The supplier shall ensure that this policy is understood, implemented and maintained at all levels of the organization.***
> ***—Q9001***

The quality policy for the Radian Analytical Laboratory System is stated as follows:

> **It is the policy of Radian Analytical Laboratories that all analytical data and supporting information generated by the laboratory are produced under strict standards of data integrity, and that all data released by the laboratory are of suitable quality and reliability for environmental management and regulatory decision making.**

This *Analytical Laboratory Systems Manual* constitutes the documentation of the quality program. This program shall be reviewed and approved by Radian management. The enforcement and effectiveness of the quality systems shall be assessed regularly through independent peer reviews. Radian management will commit the resources necessary to fulfill this policy.

Business Policy and Code of Ethical Conduct

The Radian International Business Policy and Code of Ethical Conduct is accessible to all Radian employees, listed under "Manuals" on the RadiaNet Home Page. The Introduction and Quality sections of the *Business Policy and Code of Ethical Conduct Manual* are reproduced below.

> *Radian International's business success depends upon its reputation for integrity and on the trust and confidence of everyone with whom it deals. The commitment of Radian International (Radian) to conduct its business lawfully and ethically is fundamental to its very existence.*
>
> *Ethics deals with the choices that individuals make in their relationships with others, and it also deals with adherence to the rules and standards*

that govern the conduct of institutions and groups in our society. More and more, choices that were once exclusively individual ethical judgments are now governed by laws and regulations. This is especially true in Radian's work for the government where it must comply with an ever-increasing number of stringent procurement rules and regulations.

Since its inception, Radian has had a written set of "values" upon which the company operates. These values are:

1. *We operate on the basis of the highest integrity.*

2. *We are client focused and meet or exceed our clients' expectations.*

3. *We continuously improve our work processes and the quality of services we provide to our clients.*

4. *We are people oriented, emphasizing teamwork and encouraging each person to do what he or she does best.*

5. *We are a good corporate citizen and operate in an environmentally responsible, safe, and socially accountable manner.*

This Code is intended to give each employee a better understanding of Radian's values, its fundamental business policies (particularly those that relate to federal contracting) and its commitment to conduct business at the highest level of ethics, morality, and social responsibility.

Quality

It is the policy of Radian that its services shall be delivered to customers on schedule and in conformance with contractual specifications.

The company will not tolerate professional improprieties--for example, the failure to conduct required reviews or testing, or the manipulation of test procedures or data.

1.1.1 General Quality Objectives

Radian's Analytical Laboratory Quality System is designed to fulfill prescribed requirements for quality management systems in planning, performing, and reporting results of analytical chemical analyses which meet the needs and expectations of our clients. This system is based on guidance provided by the American National Standards Institute (ANSI)/International Standards Organization (ISO)/American Society for Quality Control (ASQC) Q9000-1994 series standards as well as from the National Environmental Laboratory Accreditation Conference (NELAC, July 31, 1997). These standards provide a framework for meeting organizational goals for

managing quality while meeting the customer's needs and expectations for a desired level of quality.

The Analytical Laboratory quality system has three primary objectives:

- Providing analytical results that meet the clients' stated needs and expectations;
- Providing confidence to Radian's customers that the stated needs are being achieved; and
- Providing confidence to Radian corporate management that the desired level of quality is being consistently achieved.

In order to achieve these primary objectives, several specific objectives have been defined.

1.1.2 Specific Quality Objectives

The specific quality objectives of the Analytical Laboratory System are:

- Maintenance of a performance-based system for which our clients set project-specific specifications;
- Communication of basic laboratory specifications for performing analytical work to Radian project teams and our laboratory staff using method-specific Protocol Specifications;
- Consistent performance of all analytical work according to standard Protocol Specifications or Protocol Specifications modified to reflect project-specific requirements;
- Review by the laboratory staff of their own work, correction of any errors, and documentation of any exceptions using the appropriate documents (e.g., the Quality Traveler and the Quality Control Exception Report) before passing on their work;
- Reporting analytical results in a detailed format which allows laboratory staff to verify their work meets specifications for the protocol performed and allows the Radian project teams to validate the results for that protocol; and
- Integrated use of the Protocol Specifications, detailed reporting format, and associated system documents to measure the quality of our services and to continuously improve.

All laboratory staff members are expected to contribute toward meeting these specific objectives.

1.2 Organizational Structure

> ***Resources – Supplier shall identify resource requirements and provide adequate resources, including the assignment of trained personnel for management, performance of work, and verification activities including internal quality audits. Management Representative – The supplier's management with executive responsibility shall appoint a member of the supplier's own management who, irrespective of other responsibilities, shall have defined authority for:***
> ***a) Ensuring that a quality system is established, implemented and maintained in accordance with the Q9001 standard; and***
> ***b) Reporting on the performance of the quality system to the suppliers' management for review and as a basis for improvement of the quality system.***
> ***—Q9001***

This section describes the organizational structure of the Analytical Laboratory System and its relationship within the company organization and specifically with the quality assurance organization. Collectively, these organizational structures allow for control of quality by those performing analytical work and for independent assurance of the adequacy of the quality control program and verification of its implementation. The organization of the Analytical Laboratory System is shown in Figure 1-1.

1.3 Responsibility and Authority

> ***Responsibility and Authority – The responsibility, authority and the interrelation of personnel who manage, perform, and verify work affecting quality shall be defined and documented, particularly for personnel who need the organizational freedom and authority to:***
> ***a) Initiate action to prevent the occurrence of any nonconformities;***
> ***b) Identify and record any problems relating to the product, process and quality system;***
> ***c) Initiate, recommend or provide solutions through designate channels;***
> ***d) Verify the implementation of solutions; and***
> ***e) Control further processing, deliver, or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.***
> ***—Q9001***

Laboratory management shall be responsible for:

a) Defining the minimum level of education, experience and skills necessary for all positions in the laboratory;
b) Assuring that all technical laboratory staff have demonstrated initial and ongoing proficiency in the activities for which they are responsible;
c) Ensuring that the training of its personnel is kept up-to-date by the following:
- ***Evidence must be on file that demonstrates all employees are aware of and are using the latest edition of the laboratory's in-house quality documentation;***
- ***Training courses or workshops on specific equipment, analytical techniques, or laboratory procedures shall all be documented;***
- ***Analyst training shall be considered up-to-date when documentation in the files indicate acceptable performance of a blind sample at least once per year and certification that technical personnel have read, understood and agreed to perform the most recent version of the procedures or method.***

d) Documenting all analytical and operational activities of the laboratory.
e) Supervising all personnel employed by the laboratory;
f) Assuring that all sample acceptance criteria are verified and that samples are logged into the sample tracking system and properly labeled and stored; and
g) Ensuring the production and quality of all data reported by the laboratory.
—NELAC

This section describes the basic responsibilities of laboratory management. Responsibilities associated with specific quality system elements are discussed in each section of this Systems Manual in which the quality system elements are described. The lines of authority are described below, along with the interactive role of the quality assurance/quality control function.

Analytical Chemistry Unit Leader

The Unit Leader of Analytical Chemistry has ultimate authority and responsibility for implementation of the quality system management of personnel involved in activities within the Analytical Laboratory System. In execution of these duties, the Unit Leader is responsible for:

- Assuring that required staffing levels, technical expertise, and resources are provided;
- Assignment of properly trained personnel to the various activities;
- Being available to the Analytical Laboratory System managers reporting to him/her for action on any problem requiring additional management or technical support; and
- Informing Radian's corporate management of activities and developments within the Analytical Laboratory System.

The Unit Leader has the authority to stop any unsatisfactory work at any time and especially when planning and scheduling considerations are overriding quality and/or safety considerations.

Technical Director

The Technical Director is responsible for the technical quality of data produced within the Analytical Laboratory System. The Technical Director is responsible for:

- Review and approval of all standard Protocol Specifications;
- Approving Protocol Specifications modified to meet project-specified needs;
- Final review and approval of Standard Operating Procedures;
- Defining, developing, and approving Quality Management Procedures (QMPs);
- Defining training requirements for specific jobs in the laboratory;
- Ensuring training records are reviewed periodically;
- Attaining and maintaining requisite state and Federal laboratory certifications;
- Being available to all laboratory staff for action on any problem requiring additional technical or management support; and
- Informing the Unit Leader regarding all developments related to quality within the Analytical Laboratory System.

The Technical Director has the authority to stop any unsatisfactory work at any time and especially when planning and scheduling considerations are overriding quality and/or safety considerations.

Operations Manager

The Operations Manager has authority for the individual laboratories and is responsible for implementing the quality system management of personnel within them. The Operations Manager is responsible for:

- Assuring that the required staffing level, technical expertise, and resources are maintained within the section;

- Properly training the staff members in the section;
- Overseeing daily activities within the Analytical Laboratory System including managing and operating the laboratory facilities;
- Overseeing scheduling use of laboratory capacity and assets;
- Tracking productivity measures within the Analytical Laboratory System;
- Being available to all laboratory staff for action on any problem requiring additional management or technical support; and
- Informing the Unit Leader regarding all matters related to developments within the individual laboratories.

The Operations Manager has the authority to stop any unsatisfactory work at any time and especially when planning and scheduling considerations are overriding quality and/or safety considerations.

Client Services Manager

The Client Services Manager has authority for the Client Services Coordinators (CSCs) staffing this section and is responsible for implementing the quality system management of personnel within Client Services. The Client Services Manager is responsible for:

- Assuring that the required staffing level, technical expertise, and resources are maintained within the section;
- Properly training the CSCs;
- Monitoring analytical work subcontracted by Radian;
- Being available to the CSCs for action on any problem requiring additional management or technical support;
- Informing the Unit Leader on all matters related to developments within Client Services; and
- Identifying the laboratory service capabilities, capacities, and certifications required to meet Radian's project and clients needs.

The Client Services Manager has the authority to stop any unsatisfactory work at any time and especially when planning and scheduling considerations are overriding quality and/or safety considerations.

Client Services Coordinators

Client Services is staffed by Client Services Coordinators (CSC) who are responsible for liaison between Radian project teams and the staff of the Analytical Laboratory System. Specifically, CSCs are responsible for:

- Communicating with the Radian project team concerning the analytical needs of the client using Protocol Specifications as the basis for communications;
- Modifying Protocol Specifications to meet client-specified needs for specific projects;
- Identifying relevant safety precautions associated with project samples;
- Identifying certifications required to meet specific project need;
- Communicating client needs and safety precautions to the laboratory staff via standard or modified Protocol Specifications, the Request for Analytical Services (RAS) form, and the Quality Traveler;
- Checking sample logging into LIMS to ensure that samples are logged correctly, that the proper test codes are logged, and that the correct delivery date is logged;
- Maintaining clear lines of communication between and with the project team and the laboratory throughout the project; and
- Approving the draft invoice prior to final invoicing.

The CSCs fulfill these responsibilities through frequent and on-going communications with the project team and the pertinent managers and staff within the Analytical Laboratory System.

Laboratory Managers

Each Analytical Laboratory area is headed by a Laboratory Manager who is responsible for organizing and directing the technical activities within their group. The Laboratory Managers have day-to-day interaction and communication with the technical staff reporting to them. In execution of these duties, the Laboratory Managers are responsible for:

- Maintaining the required staffing levels, technical expertise, and resources for the group;
- Coordinating and scheduling technical staff members within the group;
- Assuring the technical quality of analytical reports produced by laboratories in their groups;

- Conferring with the Operations Manager in the selection of supporting technical staff and for reviewing their performance;
- Informing the Operations Manager on all matters related to developments within the group;
- Approving Protocol Specifications modified to meet client-specified needs for a specific project;
- Maintaining the quality of work performed in their laboratories;
- Developing and maintaining quality laboratory facilities;
- Maintaining equipment located in their laboratories;
- Training their laboratory staff;
- Developing Standard Operating Procedures (SOPs);
- Maintaining laboratory safety, including safety training and waste disposal;
- Implementing quality control procedures; and
- Keeping the Operations Manager informed on all matters related to laboratory operations.

The Laboratory Managers have the authority to stop unsatisfactory work performed within their respective laboratories at any time and especially when planning and scheduling considerations are overriding quality and/or safety considerations. Further, the Laboratory Managers also have authority to approve final laboratory reports generated in their respective laboratories.

Laboratory Quality Officer

The Laboratory Quality Officer is responsible for providing independent quality control/quality assurance guidance to the Analytical Laboratory System. In this capacity, the Laboratory Quality Officer is responsible for:

- Providing independent performance assessment through coordinating laboratory QA/QC audits;
- Serving as an in-house consultant to the Analytical Laboratory System management in defining quality goals or requirements and in developing of a specific internal quality control system; and
- Providing the mechanism whereby quality problems may be brought to the immediate attention of the Laboratory Managers, Operations Manager, and Technical Director for

implementation of corrective action; and Documenting the results of all QA activities to the Radian management through laboratory quality reports.

The Laboratory Quality Officer may be assisted in his/her efforts, by other QA professionals, particularly in performing laboratory QA audits. The Laboratory Quality Officer has the authority to stop any unsatisfactory work at any time and especially when planning and scheduling considerations are overriding quality and/or safety considerations.

1.4 Management Review

> ***Management Review – Management with executive responsibility shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of the Standard and the suppliers stated quality policy and objectives. Records of such reviews shall be maintained.***
> ***—Q9001***

> ***The quality system shall be reviewed at least once a year by management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.***
> ***—NELAC***

This Systems Manual, Laboratory Quality Management Procedures, Standard Operating Procedures, and Protocol Specifications shall be reviewed, updated and approved annually by designated laboratory management.

Self-assessment activities are intended to improve quality by focusing on how well the integrated quality assurance program is working and by identifying problems that hinder the laboratory from meeting its objectives. These reviews involve all levels of laboratory management, and include firsthand participation by senior management, especially in assuring that the activities are productive, with prompt action initiated in response to assessment recommendations and follow-up evaluation of the effectiveness of actions taken.

The Radian Quality Management Plan and the quality system described in this systems manual provide for management evaluation of the quality system as well as other self-assessment activities.

Review and Update of Quality Systems

The primary objectives of the laboratory quality program are to consistently meet accepted performance specifications, to provide confidence to company management that the desired level of quality is being achieved, and to provide confidence to clients that their quality requirements

are being met. As part of the self-assessment program, laboratory management reviews the overall quality system annually and evaluates its suitability and effectiveness for ensuring the continued achievement of its quality objectives. This assessment includes review and, if necessary, revision of quality policies and procedures.

The annual review of the quality system effectiveness consists of a comprehensive evaluation of the policies and procedures as well as an assessment of the results of internal and external audits. The focus of this evaluation is not only on how successful the quality system functions for ensuring achievement of its objectives, but also on whether any organizational, policy, or procedural changes in the system should be made. These changes may ensue from impetus such as new strategic or tactical business decisions, new quality or technical concepts, or changes in client requirements.

This review includes appraisal of this Laboratory *Systems Manual* to determine whether the described policies and procedures are consistent with current practice. Any changes to the quality system, which ensue from the evaluation of the system effectiveness are incorporated in a revision of the *Systems Manual* at this time. Procedures for making changes are the same as for the initial preparation, review, and approval of the systems manual.

As part of this review, laboratory SOPs, QMPs, and Protocol Specifications are reviewed annually, and revised as necessary, by the responsible Laboratory Manager. The process for updating existing documents involves obtaining an edit copy, making the appropriate changes, and submitting the revised document for approval in the same way as new procedures or specifications are approved.

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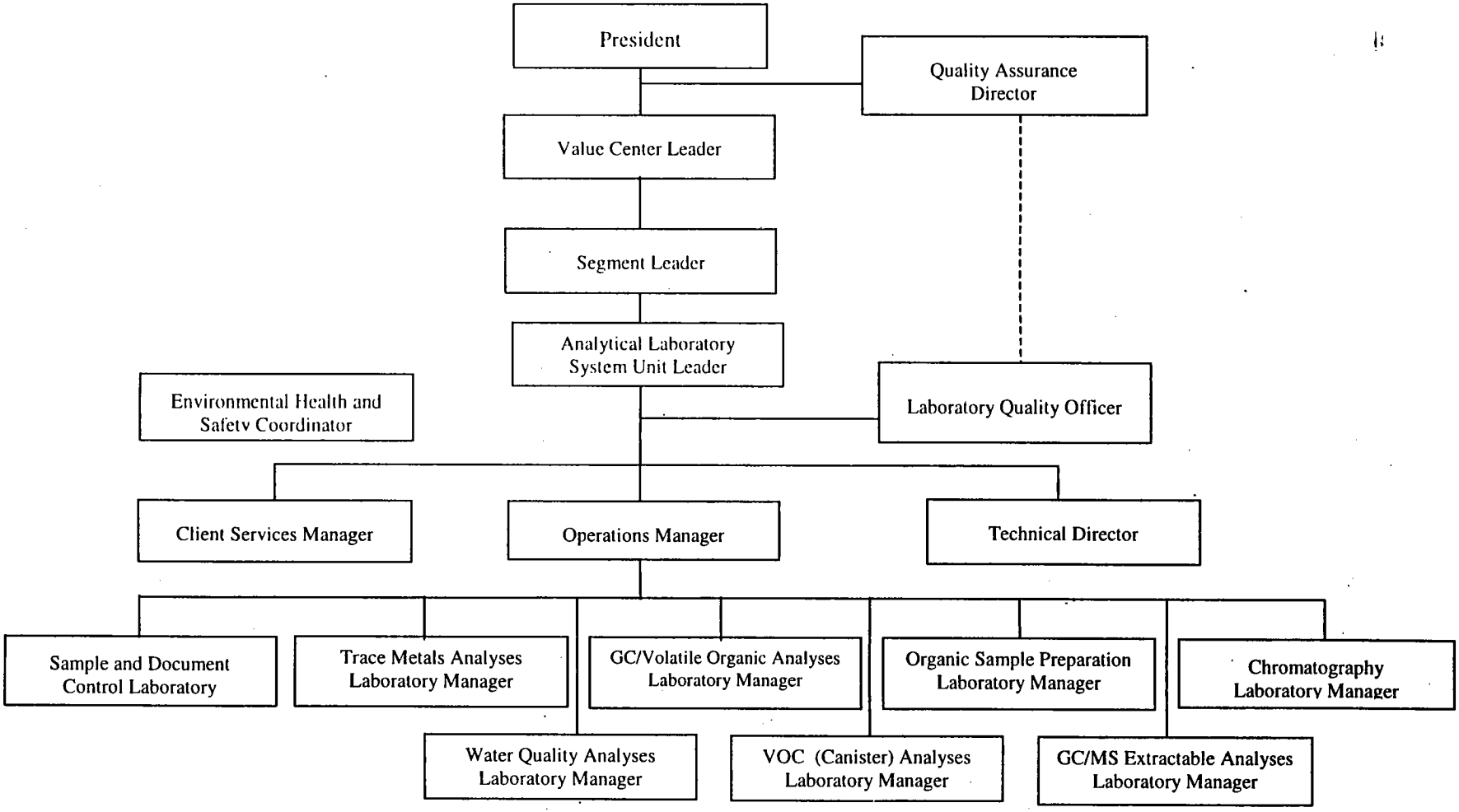

Figure 1-1. Laboratory Organization

SECTION 2
QUALITY SYSTEM

> ***The supplier shall establish, document, and maintain a quality system as a means of ensuring that product conforms to specified requirements. The supplier shall prepare a quality manual covering the requirements of applicable standards. The quality manual shall include or make reference to the quality-system procedures and outline the structure of the documentation used in the quality system.***
> ***—Q9001***

> ***The laboratory shall establish and maintain a quality system appropriate to the type, range and volume of environmental testing activities it undertakes.***
> ***—NELAC***

Policy

Radian Analytical Laboratories shall establish and maintain a quality system, as described in this *Systems Manual*, to ensure that all laboratory activities conform to the requirements of the methods performed, industry standards, project requirements, and agencies authorized to issue certification to perform environmental analyses for state and federal agencies.

Responsibilities

The Technical Director, with the assistance of all Laboratory Managers, is responsible for annual review and revision of the *Analytical Laboratory Systems Manual.*

Laboratory Managers are responsible for ensuring that the policies and objectives documented in the *Analytical Laboratory Systems Manual* are understood and implemented by all laboratory personnel.

Process

The elements of the quality system are documented and implemented by way of this *Analytical Laboratory Systems Manual* and related procedures, specifications, and other work instructions.

This document is available to all laboratory personnel. A controlled copy is accessible via the Radian Analytical Laboratory Intranet. Controlled copies of Quality Management Procedures, Standard Operating Procedures, and Protocol Specifications are also available to all laboratory personnel, via either the Intranet or controlled hardcopy documents.

2.1 Quality System Procedures

> ***The supplier shall prepare documented procedures consistent with applicable standards and the suppliers stated quality policy, and effectively implement the quality system and its documented procedures.***
> ***—Q9001***

This *Analytical Laboratory Systems Manual* describes the quality systems for Radian Analytical Laboratories. Associated with this manual are a second tier of documents, which include Standard Operating Procedures, Quality Management Procedures, and Protocol Specifications. The program also includes project-specific documents, such as Project Instructions, Work Plans, Quality Assurance Project Plans, and Health and Safety Plans tailored to address project-specific needs and objectives.

2.2 Quality Planning

> ***The supplier shall define and document how the requirements for quality will be met. Quality planning shall be consistent with all the requirements of a supplier's quality system and shall be documented in a format to suit the supplier's method of operation. These may include items such as:***
> ***a) The preparation of quality plans;***
> ***b) The identification and acquisition of any controls, resources, skill, etc., necessary to achieve the required quality;***
> ***c) Ensuring the compatibility of the design, production process, inspection and test procedures, and the applicable documentation;***
> ***d) The updating, as necessary, of quality control, inspection, and testing techniques, including the development of new instrumentation;***
> ***e) The identification of measurement equipment requirement for the capability to be developed;***
> ***f) The identification of suitable verification at appropriate stages in the realization of product;***
> ***g) The clarification of standards of acceptability for all features and requirements; and***
> ***h) The identification and preparation of quality records.***
> ***—Q9001***

Planning meetings are held by project teams at the beginning of projects to determine analytical requirements. Project-specific requirements for analytical measurement quality are defined in Protocol Specifications for each analytical method. These include requirements for operational, procedural, and technical specifications.

Management planning meetings are held weekly, with the Segment Leader, Unit Leader, Technical Director, and Operations Manager, to determine strategic and tactical plans to achieve quality goals, including the acquisition of equipment, skill, or other resources; the effectiveness of control procedures; recognized performance trends and opportunities for improvement; and the overall suitability of the quality management systems.

2.3 Laboratory Certification

Many state and Federal agencies require that laboratories be certified or accredited to perform chemical analyses. These certifications are generally obtained on a method-by-method basis and involve successful analysis of performance evaluation samples. Often, analysis of performance evaluation samples is supplemented by on-site audit inspection of the laboratories prior to granting certification. Maintenance of certification after initial certification is usually based on continued success analyzing performance evaluation samples and periodic inspection of laboratory facilities by the accrediting body.

A project CSC, in consultation with the Radian project team, is responsible for determining if the proposed project analytical work requires any state or Federal laboratory certifications. If a certification that the laboratory does not already have is required, the CSC and project team work in conjunction with the Technical Director to obtain the necessary certification. Prevailing laboratory certifications are maintained by the Technical Director working in association with the Client Services Manager who is responsible for identifying requisite certifications. A list of current laboratory certifications is kept on the Radian Intranet. This list is updated as certifications are renewed, added or deleted. The Radian Analytical System is currently certified by the agencies listed in Table 2-1.

Table 2-1. Radian International Austin Laboratory Certifications

Federal Laboratory Approvals
US Army Corps of Engineers (USACE) US Air Force/AFCEE
State Laboratory Approvals/Certifications
Arkansas Department of Pollution Control and Ecology California Environmental Laboratory Accreditation Program Kansas Department of Health and Environment Louisiana Department of Health and Hospitals New Jersey Department of Environmental Protection New York State Department of Health North Carolina Department of the Environment, Health, and Natural Resources Oklahoma Department of Environmental Quality Water Resources Board South Carolina Department of Health and Environmental Control Utah Department of Health Wisconsin Department of Natural Resources

SECTION 3
CONTRACT REVIEW

> ***The supplier shall establish and maintain documented procedures for contract review and for the coordination of these activities.***
> ***—Q9001***

> ***a) The laboratory shall advise client in writing of its intention to sub-contract any portion of the testing to another party.***
> ***b) Where a laboratory subcontracts any part of the testing under NELAP, this work shall be placed with a laboratory accredited under NELAP.***
> ***c) The laboratory shall retain records demonstrating that the above requirements have been met.***
> ***—NELAC***

Policy

Project work requirements to which the laboratory is obligated upon acceptance of work shall be reviewed and approved by laboratory management prior to initiation of work.

Responsibilities

The Client Services Coordinator assigned to a project is responsible for reviewing project requirements and for conveying these requirements for analytical services through the use of the RAS and Protocol Specifications. In executing this responsibility, the CSC will:

- Communicate with the Radian project team concerning the analytical needs of the client using Protocol Specifications as the basis for communications.
- Identify relevant safety precautions associated with projected samples.
- Maintain clear lines of communication between the project team and analytical laboratories throughout the project.
- Coordinate with Laboratory Managers and Operations Manager to ensure acceptable capacity and capabilities before committing to the work.
- Notify the project team of any need or intent to sub-contract any portion of analytical testing to a different laboratory.

Process

This section describes the process for reviewing and accepting specifications for analytical work. Typically, the requirements are detailed in project planning documents, such as Quality Assurance Project Plans, Sampling and Analysis Plans, Chemical Data Acquisition Plans, or simple requests for standard reference methods. Legal contracts are managed through Radian's corporate contract review system.

3.1 Review

> ***The supplier shall review statement of requirements (e.g., contract) to ensure that:***
> ***a) The requirements are adequately defined and documented;***
> ***b) Where no written statement of requirements is available for an order received by verbal means, the supplier shall ensure that the order requirements are agreed to before their acceptance;***
> ***c) Any differences between the contract or accepted order requirements and those in the tender are resolved; and***
> ***d) The supplier has the capability to meet the contract or accepted order requirements.***
> ***—Q9001***

Client Services Coordinators (CSC) are the contact with project teams requesting analytical work. As such, the CSC is responsible for determining the analytical requirements and quality specifications, and the laboratory's capacity and capability to meet those requirements. As necessary, the CSC will review the requirements with the Technical Director, Quality Officer, Laboratory Managers, and Operations Manager.

3.2 Amendment to Contract

> ***The supplier shall identify how an amendment to a contract is made and correctly transferred to the functions concerned with the supplier's organization.***
> ***—Q9001***

The responsibility for modifying or amending contracts belongs to the contract specialist on the Radian project team. The CSC may be called upon to provide assistance or documents, such as the Request for Analytical Services (RAS) or Protocol Specifications.

If project's analytical requirements change, the CSC will review and document the changes in modified specifications. These modifications must be approved by the affected Laboratory Managers or Technical Director.

3.3 Records

> ***Records of contract reviews shall be maintained.***
> ***—Q9001***

Records pertaining to review of legal contracts are maintained by Radian's corporate contracts department.

Internal documentation of agreements between project teams and the laboratory, such as the RAS and modified Protocol Specifications, are maintained by Document Control.

SECTION 4
DESIGN CONTROL

> ***The supplier shall establish and maintain documented procedures to control and verify the design of the product in order to ensure that the specified requirements are met. —Q9001***

Policy

Analytical projects performed within the Radian Analytical Laboratory System shall be planned and carried out in a manner such that client needs for these services are translated into technical specifications used by the laboratory.

Responsibilities

Client Services Coordinators are responsible for reviewing and translating pertinent project specifications for analytical services to the laboratory managers and laboratory staff through the RAS and Protocol Specifications.

Laboratory Managers are responsible for ensuring that project requirements, as detailed in the RAS and Protocol Specifications, are communicated and completed by laboratory staff.

The Technical Director and Laboratory Quality Officer are responsible for ensuring that standard Protocol Specifications and SOPs are in place for routine procedures.

The Operations Manager is responsible for ensuring that laboratory capacities and schedules are adequate to meet work projections.

Process

This section describes the tools used for planning an analytical project, including project initiation and scheduling, as well as a description of the systems and procedures for translating objectives into approaches; and the provisions for design review, verification, and approval.

4.1 Project Initiation

Planning begins with the determination of the clients' analytical needs and Data Quality Objectives (DQOs). These analytical needs and DQOs may arise for several reasons such as regulatory requirements or to monitor treatment processes.

There are several key individuals involved in any analytical project. The primary interface between the project staff and the laboratory is the Client Services Coordinator (CSC). The CSC interfaces directly with the project chemist, or other project staff, to establish the analyses required, DQOs, sampling schedule, number of samples/type of matrices requiring analysis, and analytical pricing. The clients' DQOs may be defined in the project-specific Quality Assurance Project Plan (QAPP) along with information such as the analyses required to achieve the project DQOs. The project Sampling and Analysis Plan (SAP), in addition to other information, defines the matrices, number of samples, and sampling schedule. The CSC can also be involved in the peer review of the project QAPP and SAP. With the above listed information, the CSC has all the components needed to meet the objective of processing the project through the laboratory. The CSC and laboratory staff use several tools, as described in the following sections, to achieve this objective.

4.2 Protocol Specifications

The first tool, the Protocol Specification, serves as the basis for defining the analytical needs of the client in terms which are meaningful to the laboratory. This tool also serves as the basis for communicating the project-specific needs to the laboratory staff performing the work. Each method has its own Protocol Specification. The CSC has the responsibility for providing the project chemist with the current standard Protocol Specifications which are used by the laboratory when performing each analytical protocol. Where the standard Protocol Specification does not meet the DQOs of the project, it may be modified to meet the client's specifications. The CSC must obtain approval from the Technical Director or the pertinent Laboratory Manager for proposed modifications to the standard Protocol Specification.

The Protocol Specification includes technical, procedural and operational specifications. The technical specifications represent those items most readily measured and compared against defined performance criteria to measure the quality of the result. The procedural specifications describe things which must be done as part of the analytical process, and includes requirements for calibration and quality control checks, equations to be used to calculate results, and other procedure-oriented specifications. The operational specifications describe systems and conditions under which the analyses must be performed, and includes operational definitions of terminology, training requirements, health and safety requirements, and other system-oriented specifications.

4.3 Project Scheduling and Cost Control

Once the client's needs have been defined through the Protocol Specifications, the CSC will then schedule the samples into the laboratory. This is accomplished by presenting the scope of work (i.e., number of samples/matrices, types of analyses, turnaround time) to the Laboratory Managers and the Operations Manager. They in turn review the laboratory capacity. Scheduling meetings between the CSCs, Laboratory Managers, and the Operations Manager are held two times a week to help facilitate projects through the laboratory. Special scheduling requests can also be addressed by the CSCs and Laboratory Managers on an *ad hoc* basis outside of the normal meetings, when needed. The laboratory staff, CSCs, and Operations Manager use a real-time electronic projection system programmed through the Laboratory Information Management System (LIMS). The projection system contains information such as resource, capacity, samples projected for a resource in any given week, and backlog for a resource from the previous week. The resource is defined as the category under which a specific analysis is performed/projected (e.g., SW-846 Method 8260B is projected under the GCMS volatile resource). The capacity is defined as the number of samples a resource can process on a weekly basis, and still meet the standard regulatory holding times and a standard turnaround time. This tool, available on Radian's Intranet, allows the laboratory to project and view work out as far as one year and is especially useful for long-term monitoring projects. The laboratory may also print out the projections for a 12-week period from the current week, which allows for a convenient view of what is projected in the near future.

The Operations Manager uses several other tools to plan projects and to continually plan and coordinate work in the laboratory such as:

- Daily tracking of sample and analysis backlog;
- Weekly tracking of work to do; and
- Weekly tracking of work projected vs. actual work received.

All of these items are routinely addressed in weekly meetings. With these tools the Operations Manager and Laboratory Managers continually plan for workload increases and decreases by adjusting capacities and shifting staff and/or hiring additional staff.

The LIMS also provides the Operations Manager with the tools needed to measure the laboratory's financial performance by providing a summary of revenue generated. This summary is broken out by functional areas in the monthly financial reports. The Operations Manager also

uses the monthly financial reports to track the budgets for other direct cost and direct labor charges. The LIMS is also used for accounting information such as invoicing the analyses to the project.

4.4 Project Documentation

The CSC has the responsibility for completing a Request for Analytical Services form (RAS) (Figure 4-1) for all work performed by the laboratory. The RAS includes information such as:

- Each analytical protocol to be performed;
- The Protocol Specification (revisions to the standard are stated and approval noted);
- Project identification;
- Number of samples/types of matrices;
- Certification requirements;
- Health and safety information; and
- Project information that may not be included in the Protocol Specification.

The CSC sends the completed RAS form to Sample Control, to the Radian project team, and to the appropriate Laboratory Managers and project staff.

Along with the RAS form, the CSC also initiates a Quality Traveler form (QT) (Figure 4-2). The QT addresses each of the technical, procedural, and operational specifications of the Protocol Specification, and is used by the laboratory staff as a checklist for a specific analytical protocol performed. There are three versions of the QT; one for general use, one for use specifically in the Volatile Organic Compound Laboratory, and one for use in the VOC Canister Laboratory. Any Protocol Specifications that are modified from the standard are attached to the first QT and distributed to the laboratory.

All of the documentation listed above is processed through the laboratory in such a fashion that a peer review is performed at every stage from sample login through final reporting of the data. This flow of work through the laboratory to final reporting is described in further detail in Section 9 of this *Systems Manual*.

Figure 4-1. Request for Analytical Services Form (RAS)

Request for Analytical Services

Original Date:

A. Client-Project Information

Client Code: _____ Work ID: _____

Company/Client: _____ Facility: _____

Charge Number: _____ T&M/FPAS: _____

Invoice to (MKT): _____ CSC (Contact): _____

Surcharges/Discounts: _____

Global Invoicing Comments: _____

Global Reporting Comments: _____

Project Description: _____

Scope/Schedule Description: _____

Project Instructions (Y/N): _____ QAPP (Y/N): _____

Sample Delivery Date(s): _____ Via: _____

TAT (in days)-Verbals: _____ Written: _____

Sampling Location (State Country) _____

Required Certifications: _____

Use of Data (RCRA/Superfund/NPDES/Other): _____

Project Contacts: _____

PjM (Rep): _____ TL: _____

PC/QA:

B. Safety/Disposal Information

Known Compounds Present: _____

Safety Precautions: _____

H&S Data Sheets Available (Y/N): _____

Soil Samples from Restricted or Quarantined Zones (Y/N): _____

(Note: See USDA Soil Movement Regulations.)

Sample Disposal (return/billable): _____

(Note: Dioxin containing samples and samples submitted for dioxin analysis must be returned to the client.)

Disposal Instructions (date/time period):

C. Sample Login Instructions

Work Order/Department/Fraction (specify) Comments:

Invoicing Comments:

Misc. Preparation & Analysis Notes: _____

Reporting Limit: _____

GC 2nd Column Confirmation (Y/N): _____

Other Comments:

No.	Matrix	Spec No	Std. Spec (Y/N)	Test Code	Unit Price	Method Citation

Special Pricing Instructions (MS/MSD, Disposal, Rush TAT, etc.):

Figure 4-1. Request for Analytical Services Form (RAS) (continued)

D. Reporting Instructions
Report To (ATTN): **(Note: Include address for external clients.)**
No. of Reports Required:
Report Format (std/other):
Report Results for Solids as "Dry Weight" or "Received":
Raw Data Packages Required? (Y/N):
Export Electronic File? (Y/N)
File Format:
Path:

Figure 4-2. Quality Traveler

Work Order # _____ **QUALITY TRAVELER** Verbal TAT: __ (days) Report TAT: __ (days)

RAS Number: _____ Client: _____ CSC: _____ Report As: Received

Protocol Spec: _____ Index: ___ Version: _____ Client-only MS/MSD: _ Restricted Soils? _ # Reports: __

Test Codes(s): _____ _____ Class S B T K K K RL __ CIT Method: _____ Comments: _____

_____ _____ _____ _____ Subclass S M C E/D L/D M/D __ __ Health & Safety: _____

_____ _____ _____ _____ Subset __ __ __ __ __ __ __ _ _____

Analyst's/Peer Reviewer's Initials _____/_____ _____/_____ _____/_____ _____/_____ _____/_____ QCER #s

	Client Services		Sample Control		Sample Preparation		Sample Analysis		Document Control		
TECHNICAL	Target Analytes	Y/N-Test/List code(s) verified, inc TICs?		Y/N-Test/List code(s) correct, inc TICs?			Y/N-Calibrated for all target analytes?				
	Precision	Y/N-Std Spec (analytes, conc, tolerances)?			Y/N-Spiking analytes/ conc per Std Spec?		0,M,L,D,E,A-Precision measure(s) different?				
	Accuracy	Y/N-Std Spec (analytes, conc tolerances)?			Y/N-Spiking analytes/ conc per Std Spec?		0,M,L,S,E,A-Accuracy measure(s) different?				
	Detection/Reporting Limits	Y/N-Are the PRDLs standard?					Y,S,P,C,I - Samples have DLs < PRDLs?		Y/N-Correct Reporting Limits used?		
	Holding Times	SP/SA W:___/___ S:___/___		# not meeting Spec		# not meeting Spec		# not meeting Spec			
	Turnaround Times	Specification days		# days TAT in area		# days TAT in area		# days TAT in area		# days TAT in area	
	Lab Completeness	Specification %	NA	Calc'd completeness	NA	Calc'd completeness	NA	Calc'd completeness	NA	Calc'd completeness	NA
	Other	Y/N-Add'l requirements?		Y/N/NA-Add'l req. met?		Y/N/NA-Add'l req. met?		Y/N/NA-Add'l req. met?		Y/N/NA-Add'l req. met?	
PROCEDURAL	Demo of Capability						Date of last complete DOC				
	Statistical Control						Y/R,A,P,T/NYA-Realtime stat control demo for acc/prec/trend rules?				
	Detection Limit Study						Instrument ID/Date of most recent complete DL study				
	Calibration/QC Criteria	Y/N-Standard Spec?			Y/N-Appropriate QC prep'd & deliv'd? Y/N-Initial Prep?		0,C,B,V,M,L,D,S,A,E-Calib/QC analyses not meeting Spec.				

Figure 4-2. Quality Traveler (continued)

SECTION 5
DOCUMENT AND DATA CONTROL

> ***The supplier shall establish and maintain documented procedures to control all documents and data that relate to the requirements of Q9001.***
> ***—Q9001***

> ***Procedures shall be established to ensure maintenance of documentary evidence of quality, including the control of preparation, review, approval, issuance, use, and revision of documents related to policies, work processes, safety requirements, design, and planning.***
> ***—NELAC***

Policy

Radian Analytical Laboratories shall follow established procedures for preparation, review, approval, issuance, use, and revision of documents and data related to the policies and procedures of the laboratory quality system.

Responsibilities

The Document Control Manager is responsible for maintaining and distributing all controlled documents.

The Intranet Custodian is responsible for posting approved, controlled documents on the Radian Analytical Laboratory Intranet.

The Technical Director is responsible for determining the need for, and development of, Quality Management Procedures.

Laboratory Managers are responsible for determining the need for, and development of, Standard Operating Procedures and Protocol Specifications. Laboratory Managers are also responsible for control of software related to generation, calculation, and reporting of data.

Process

Quality documentation includes those specifications and procedures that provide for a systematic and orderly expression of the requirements of the Analytical Laboratory quality system. The primary document that describes the quality system is the *Analytical Laboratory Systems Manual*. This document encompasses all activities that are part of the laboratory operations, particularly those that directly affect analysis quality. Within the *Systems Manual* there are

numerous references to the Protocol Specifications and to the Standard Operating Procedures (SOPs) which describe the specific technical specifications and procedures, respectively, that are to be followed by the laboratory staff when performing various tasks within the Analytical Laboratory System. These documents are maintained in the Document Control File Room. Also referenced in the *Analytical Laboratory Systems Manual* is the Laboratory Quality Report that summarizes the performance of the Analytical Laboratory for the time period covered in that report.

The following Quality Management Procedures are applicable to the document control process:

- QA/QMP002, "Document Control";
- QA/QMP009, "Internal Review of Radian Quality Management System Documents"; and
- AL/QMP001, "Preparation of Radian Analytical Laboratory Standard Operating Procedures and Quality Management Procedures".

The following sections describe the laboratory's process for the control of preparation, review, approval, issuance, use, and revision of documents related to policies, work processes, safety requirements, design, and planning. Specifications for approval, storage media, and archival for quality system documents are shown in Table 5-1.

5.1 Document and Data Approval and Issue

> ***The documents and data shall be reviewed and approved for adequacy by authorized personnel prior to issue. A master list or equivalent document-control procedure identifying the current revision status of documents shall be established and be readily available to preclude the use of invalid or obsolete documents. This control shall ensure that:***
> ***a) The pertinent issues of appropriate documents are available at all locations where operations essential to effective functioning of the quality system are performed;***
> ***b) Invalid or obsolete documents are promptly removed from all points of issue or otherwise precluded from unintended use; and***
> ***c) Any obsolete documents retained for legal or knowledge-preservation purposes are suitably identified.***
> ***—Q9001***

This section describes the procedures to be followed when preparing, reviewing, approving, and issuing the various documents that are part of the Analytical Laboratory quality documents system. These documents include the *Analytical Laboratory Systems Manual*, Protocol Specifications, Standard Operating Procedures, and Quality Management Procedures.

Analytical Laboratory Systems Manual

The *Analytical Laboratory Systems Manual* is one of several developed to describe the various quality systems that are part of Radian's comprehensive Quality Management Program. This manual provides a description of the Analytical Laboratory quality management system. In terms of the Radian International, LLC corporate structure, which consists of various functional units, and the Radian Quality Management Program, which consists of systems manuals for each functional unit, the Technical Director is the Functional Unit Manager for the Radian Analytical Laboratory System, and the Unit Leader is the Systems Manual Sponsor.

The Technical Director has the ultimate responsibility for the preparation and revisions of the manual, which includes input from the Unit Leader, Operations Manager, Quality Officer and various staff members designated by the Unit Leader. Preliminary review and approval authority rests with the Functional Unit Manager. The Systems Manual Sponsor has final review and approval authority.

Following the review and approval by the Technical Director, the manual is forwarded for review to Radian's (QA) Section and company management for final approval by the Quality Assurance Director and Unit Leader. Following final approval, *the Analytical Laboratory Systems Manual* is posted as a controlled document on the Radian Laboratory Intranet.

Table 5-1. Document Approval, Revision and Archival Specifications

Type Of Document	Approval Required	Revision Schedule	Archival
Systems Manual	Functional Unit Manager (Technical Director) Laboratory Quality Officer Company QA Director Systems Manual Sponsor (Unit Leader)	Annual	Indefinitely
Protocol Specifications	Technical Director Laboratory Manager	Annual	Indefinitely
Standard Operating Procedures	Laboratory Manager Laboratory Quality Officer Technical Director Systems Manual Sponsor (Unit Leader)	Annual	Indefinitely
Quality Management Procedures	Functional Unit Manager (Technical Director) Systems Manual Sponsor (Unit Leader) Laboratory Quality Officer	Annual	Indefinitely

Protocol Specifications

Protocol Specifications are documents that specify what the Analytical Laboratory's technical, procedural, and operational requirements are for any given analysis. These documents detail the specifications that the analysis must meet. The Analytical Laboratory management is responsible for the generation of all new Protocol Specifications, as they are needed. Any designated, qualified staff member may write new Protocol Specifications. The Technical Director and the Quality Officer are responsible for reviewing each new Protocol Specification. The Laboratory Manager and Technical Director are responsible for signing each new Protocol Specification once they are approved. Modified Protocol Specifications, containing project-specific modifications to standard Protocol Specifications are initiated by the Client Services Coordinators (CSCs) and require approval by the Technical Director or the pertinent Laboratory Manager.

Once a standard Protocol Specification has been reviewed and approved, the original is stored in the Radian Library and controlled copies are placed in the appropriate satellite files. The Protocol Specification copies are printed on special paper with the words "CONTROLLED DOCUMENT" printed in red across the top of each page. Paper copies of controlled documents reside only at a single laboratory distribution node. Controlled copies are posted on the Radian Laboratory Intranet.

Each staff member is required to read and understand the pertinent Protocol Specification prior to beginning work. Documentation of the use of the specifications is noted on the Quality Traveler (QT), which is a record that travels throughout the Laboratory with a particular set of samples.

Standard Operating Procedures (SOPs)

Standard Operating Procedures (SOPs) are documents that outline how to perform an analysis or a particular activity. The Analytical Laboratory management is responsible for the generation of all new SOPs, as they are needed. New SOPs may be written by any designated, qualified staff member. An activity manager, such as the Laboratory Manager reviews each new SOP. Following this review, each SOP is reviewed by the Quality Officer and the Technical Director. If clarifications or corrections are required, the SOP is returned to the author for resolution. After resolution of problems, the final, approved SOP is signed by the cognizant Laboratory Manager, the Quality Officer, the Technical Director, Systems Manual Sponsor, and Corporate Document Control Custodian.

Once a SOP has been reviewed and approved, the original is placed in the Radian Library and controlled copies are placed in the appropriate satellite files. The copies are printed on special paper with the words "CONTROLLED DOCUMENT" printed in red across the top of the page indicating that the SOP is a controlled document with an effective date. Paper copies of controlled documents reside only at a single laboratory distribution node. Controlled copies are posted on the Radian Laboratory Intranet.

Each staff member is required to read and understand all SOPs that are relevant to their job assignment and are expected to comply with the procedures contained in the SOP. Documentation of this training in new procedures is noted in each individual's training file.

5.2 Document and Data Changes

> ***Changes to documents and data shall be reviewed and approved by the same functions/organizations that performed the original review and approval, unless specifically designated otherwise.***
> ***—Q9001***

All revisions to controlled documentation, software, reference data (such as detection limits), and analytical reports must be reviewed and approved by the original approval authorities, or their successors, prior to implementation.

As part of the quality assessment activities of the Analytical Laboratory, the overall quality system is reviewed on a periodic basis to determine the effectiveness of the system. This assessment includes a review of the *Analytical Laboratory Systems Manual* on an annual basis to determine if any changes or modifications to the manual are needed. These changes may be a result of audit findings of the elements in the system, and to the effectiveness of the system in achieving the overall quality objectives, or in considering updating the system, as a result of changes in strategic or tactical goals of the business unit. Procedures for making changes to the *Systems Manual* are the same as for its initial preparation, review and approval.

In addition to the periodic review of the *Systems Manual*, each Analytical Laboratory SOP and Protocol Specification must be reviewed, and revised if necessary on an annual basis by the Laboratory Manager, or designee, responsible for that document. This review is meant to ensure that each document accurately represents the procedure that is currently being performed.

SECTION 6
PURCHASING

> ***The supplier shall establish and maintain documented procedures to ensure that purchased product conform to specified requirements.***
> ***—Q9001***

> ***Where the laboratory procures outside services and supplies, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's tests.***
>
> ***Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with the specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned.***
> ***—NELAC***

Policy

The purchase of items and services affecting quality shall be planned and controlled to ensure conformance with established requirements.

Responsibilities

Laboratory Managers are responsible for determining quality specifications for equipment and chemical purchases, for communicating those specifications in the purchase requests, and for confirming that the procured items meet the specifications.

Each laboratory manager area is responsible for reviewing and authorizating all purchase requests in their laboratory area.

The Operations Manager is responsible for reviewing and authorizing purchases greater than $500.

The Unit Leader is responsible for reviewing and authorizing purchases greater than $1000.

The Network Administrator must review and approve all software or computer hardware purchases of any amount.

The Technical Director is responsible for reviewing and authorizing all purchases of analytical standards less than $2,500.

The Segment Leader or Value Center Leader is responsible for reviewing and authorizing all purchases greater than $2,500.

Process

This sections describes the procedures used by the laboratory in establishing the quality criteria for purchased items and services, and the provisions for ensuring that purchased items and services meet established quality criteria.

6.1 Evaluation of Subcontractors

> ***The supplier shall:***
> ***a) Evaluate and select subcontractors on the basis of their ability to meet subcontract requirements including the quality system and any specific quality assurance requirements;***
> ***b) Define the type and extent of control exercised by the supplier over subcontractors; and***
> ***c) Establish and maintain quality records of acceptable subcontractors.***
> ***—Q9001***

> ***The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for tests.***
> ***—NELAC***

The final selection of suppliers is based on their qualifications. Considerations in making the selection include the type of product to be purchased, an evaluation of potential suppliers, an evaluation of each product and the product cost. These aspects of the selection process are described below.

6.1.1 Types of Purchased Products

The procurement procedures described in this manual are applicable to all purchased items and services procured by the Analytical Laboratory System. A brief description of the various types of purchased products, the selection criteria to be used, and the person(s) responsible for evaluating suppliers and coordinating the final purchase are listed below.

Laboratory Equipment

One of the most important resources for an analytical service laboratory is laboratory equipment. Radian's investment in this equipment is substantial and its importance to quality service is

critical. This equipment falls generally into four categories: laboratory facility equipment, analytical instrumentation, large support equipment, and smaller miscellaneous equipment. Specific technical specification criteria for the purchase of equipment in each of these categories are defined as part of the purchase justification process. The written specifications are then submitted as part of the purchase order and become part of the purchase order contract. Whenever equipment is purchased having technical specification different than the suppliers' stated specifications, the equipment should be demonstrated to meet those requirements before it is accepted.

Facility equipment, such as laboratory workbenches, chemical fume hoods, and walk-in sub-ambient storage rooms are typically selected for procurement as part of the laboratory design activity. This activity is performed by the company Facilities staff with input from technical managers.

Analytical instrumentation selection is based primarily on technical requirements. The principal evaluation and selection responsibility lies with the Laboratory Managers, with ultimate approval by the Technical Director, Unit Leader, and Segment Leader.

Large support equipment such as analytical balances, ovens, refrigerators, freezers, etc., is typically selected based on performance and cost. The evaluation and selection responsibility lies with the Laboratory Managers. The approval process for the purchase request is the same as that for analytical instrumentation, depending on the cost.

The final category of laboratory equipment is miscellaneous small apparatus used to support routine laboratory activities. These include hot plates, mixers, glassware, etc. The primary selection criteria is typically cost, provided specifications are met. The evaluation, selection, and approval responsibilities are the same of with the large support equipment. However, other laboratory personnel play an active role in the recommendation process.

As mentioned above, written specifications are submitted as part of the purchase order and become part of the purchase order contract.

Computers

A centralized system of acquisition has been developed to take advantage of opportunities for hardware and software to be purchased with volume discounts. Requests for computer-related purchases are directed to Radian's Information Technology Services Team through the Laboratory Network Administrator for approval before processing by Purchasing. Prior to this

submission, evaluation of each purchase justification and final approval, will be made by the Unit Leader and the Segment Leader.

Laboratory Chemicals

Procurement of laboratory chemicals is typically based on specific technical specifications according to the intended use. Specific quality criteria for each chemical must be defined on the Field Purchase Order (FPO), where applicable. Orders of reference materials should be coordinated through the Technical Director or his/her designee, to ensure sufficient lot sizes and appropriate quality standards.

Various chemical solvents and instrument gases (such as helium carrier gas) are also purchased for laboratory use. The selection criteria for these items is primarily purity and cost. The purchase of these items should take advantage of negotiated volume discount contracts. Purchase of these materials is usually initiated by the end user in the laboratory. The Laboratory Manager has final approval authority for these purchases.

Subcontracted Services

Whenever there is a project-specific need to subcontract an analysis or other service through Radian's analytical laboratories, the selection of these subcontractors shall be in accordance with the procedures defined by Radian's Contracts Department. Potential subcontractors will be evaluated based on a number of factors including technical performance, delivery times, and cost. Pre-qualification audits may be performed, as necessary. The Client Services Coordinator or Project Chemist will directly manage and supervise the performance of all items and services contracted through the laboratory.

6.1.2 Supplier Selection

It is the policy of Radian International that suppliers/subcontractors be impartially selected based upon technical, schedule, and price considerations. The technical staff, Purchasing, and Contracts all share the responsibility for identifying sources. The final authority for awarding orders for materials, products, equipment and services rests with Purchasing and Contracts for purchases exceeding $2,500.

The selection of suppliers by the Analytical Laboratory System shall be in accordance with these prescribed guidelines. In selecting sources, emphasis will be placed on technical capability and reliability, quality and capability to produce, ability to meet promised delivery schedules, and

cost. In doing so, procurements shall take advantage, whenever possible, of negotiated national supplier contracts that are in place at Radian. Ultimately, all procured goods and services must meet defined quality standards for purity or performance. Quality standards are given in the analytical SOPs or Protocol Specifications, or in subcontracts for services.

6.2 Purchasing Data

> ***Purchasing documents shall contain data clearly describing the product ordered, including where applicable,:***
> ***a) The type, class, grade, or other precise information;***
> ***b) The title or other positive identification, and applicable issues of specifications, drawings, process requirements, requirements for approval or certification of product, procedures, equipment or personnel; and***
> ***c) The title, number, and issue of the quality system standard to be applied. The supplier shall review and approve purchasing documents for adequacy of the specified requirements prior to use.***
> ***—Q9001***

For commonly used materials (e.g., solvents, latex gloves, glassware, etc.) Radian has established a relationship with a national laboratory supply company to provide on-site stocking and direct procurement of these materials. The laboratory supply vendor maintains an on-site consigned inventory of items, which tend to be used in large quantities. These items are acquired through a counter "check-out" procedure requiring completion of a Materials Requisition request (MRR). The MRR requires employee signature and appropriate account number.

In addition to the above described inventory items, supplier catalog items may also be procured through the on-site supplies vendor. Such acquisitions require completion of the supplier's purchase request form, which includes employee and account number information. Such acquisitions are subject to Laboratory Manager approval and are limited to $2,500.

For items not acquired through the on-site supplier, it is Radian's policy that all purchases less than $2,500 be assigned a Field Purchase Order (FPO) number and be entered in Radian's Automated Purchasing System. Only small item, local purchases of $500.00 or less may be excluded from this requirement. Such purchases shall be accomplished through a Disbursement Request. Additionally, any item over $100 requires an authorizing signature. All purchases by laboratory staff (except those excluded as previously mentioned) shall be initiated with the preparation of an FPO. Since successful technical performance is often critically dependent on the quality of purchased materials, laboratory staff may query potential suppliers to identify essential specifications, availability, suitability, or price, and then recommend the specific item and source on the FPO. All FPOs are submitted to the Laboratory Manager for approval.

Purchase requests for capitalized equipment and computers should be accompanied by a written justification. Final approval for these capital equipment purchases rests with the Unit Leader and Segment Leader.

Each FPO shall be completed in accordance with requirements set forth by Purchasing. In general, the following information, as applicable, is required:

- Supplier's name and address;
- Supplier's stock number and a description of the material;
- Quantity and unit of measure;
- Material specification, such a chemical purity, grade, size, or other technical specification; and
- Required delivery date.

Each FPO will also have the requestor's name, the supervisory approver's name, and the Radian contract or overhead account number that will be charged for the purchase. The portion of the FPO form showing the basis for purchase and justification shall either be completed or a separate justification shall be attached. The specific quality specifications required for the purchased item shall be clearly defined and submitted as part of the FPO.

Inventory

Radian has developed a system to track inventory status of all Federal Government property, office furniture and computers, and laboratory equipment. These procedures are detailed in Radian's Procurement Procedures Manual. This inventory tracking system includes bar coding each purchased item upon receipt for computerized information and location tracking. Additionally, procedures are developed to provide guidance for effective warehouse storage of files, samples, equipment, or other materials. Warehousing of materials is coordinated with Radian's Facilities Dispatcher.

Upon receipt and pick up from Receiving, laboratory chemicals, disposable safety supplies, and other miscellaneous laboratory supplies will be under the control of either the Laboratory Manager or staff member who requested the purchase. General use materials will be stored in designated locations within the laboratories to be available to all staff. All chemical reagents, solvents, and standards will be submitted, as appropriate, to verification procedures, as described below.

6.3 Verification of Purchased Product

> ***Where supplier proposes to verify purchased product at subcontractors premises, the supplier shall specify verification arrangements and the method of product release in the purchasing documents. Where specified in the contract, the supplier's customer or representative shall be afforded the right to verify at the subcontractor's premises and the supplier's premises that subcontracted product conforms to specified requirements. Such verification shall not be used by the supplier as evidence of effective control of quality by the subcontractor.***
> ***—Q9001***

Proper handling, inspection, and requestor notification are important to project scheduling and completion, as well as efficient accounting transactions. All equipment and supplies are received at a central receiving location.

Following initial inspection for damage and completion of receiving records by Receiving personnel, the requestor will be notified of internal receipt. No hazardous substances will remain in the receiving area overnight.

Following the appropriate notification, the requestor will pick up, or arrange for pick up, all received material with the required times. Delivery of office furniture, computer equipment, and instrument gases, is coordinated by those departments responsible for submitting the purchase requests.

All equipment and supplies purchased by Radian shall be visually inspected by both Receiving personnel and the laboratory personnel who requested the purchase to identify any damages, shortages, or overages. Inspection by Receiving personnel shall be in accordance with procedures set forth in Radian's Procurement Procedures Manual. Laboratory personnel will also inspect all received items and report any similar problems to Receiving. Before any purchased equipment is accepted, it shall be demonstrated to meet all defined quality specifications. Specific procedures for verifying chemical reagents and standards are discussed below.

6.3.1 Inspection and Test Procedures

Reagents and standards are inspected upon receipt to ensure that the product delivered meets the quality specifications. Specific criteria for each material are defined according to its intended use, and are delineated in the Field Purchase Order. All records of the results of inspection and analysis for these materials shall be maintained by the appropriate Laboratory Manager. As discussed above, laboratory equipment is inspected to ensure conformity with requirements.

6.3.2 Resolution of Product Quality Problems

Problems relating to damage, shortage, or overage for materials and supplies shall be immediately documented by the requestor. A decision will then be made in consultation with Purchasing, the requestor, and the supplier as to whether the materials will be accepted or returned to the supplier. Most often, Purchasing will have to obtain a Return Authorization from the supplier to do so. In the case of shortages, the shipment will usually be accepted with shipment of additional material made by the supplier. In the case of overages, the supplier will decide if a return of the excess should be made; if so, shipping costs for the return will be handled by the suppliers.

When it is determined that laboratory chemicals that have been inspected do not meet required specifications, the Laboratory Managers shall decide whether the chemical should be returned to the supplier. The Laboratory Manager may consult directly with a technical representative of the supplier to determine how best to proceed. In some cases, the product sold may not be guaranteed to meet certain specifications. If this is the case, the Technical Director and Laboratory Quality Officer should be consulted regarding a course of the action.

SECTION 7
CONTROL OF CUSTOMER-SUPPLIED PRODUCT

> ***The supplier shall establish and maintain documented procedures for the control of verification, storage, and maintenance of customer-supplied product provided for incorporation into the supplier or for related activities. Any such product that is lost, damaged, or is otherwise unsuitable for use shall be recorded and reported to the customer.***
> ***—Q9001***

Policy

Radian Analytical Laboratories shall follow procedures for the handling, storage, preparation, and analysis of samples in such a manner as to ensure the integrity of the samples and the measurement results.

In a sense, the intent of this section in the Q9001 Standard may not be applicable to analytical laboratory operations. As such, the content of this section may be regarded as a special interpretation of "customer-supplied product".

Responsibilities

Sample control personnel are responsible for receiving, inspecting, and logging-in samples. Sample control is also responsible for the disposal or return of any unused samples or portions of samples.

Client Service Coordinators are responsible for resolving any differences between shipment contents and chain-of-custody documentation.

Process

Radian laboratories follow established procedures to control the verification, storage, and maintenance, and disposal of samples. The following QMPs and SOPs pertain to these activities.

- AL/QMP004, "Performance Evaluation Sample Handling";
- AL/QMP006, "Handling of USDA Restricted Soils";
- AL/QMP007, "Hold Alert";

- AL/SOP001, "Sample Check-out and Check-in";
- AL/SOP005, "Sample Storage and Disposal";
- AL/SOP021, "Receipt/Handling of Canisters";
- AL/SOP054, "Sample Log-in"; and
- AL/SOP039, "Unpacking of Samples".

A description of the overall process is provided below.

7.1 Inspection of Contents of Sample Shipments

> ***The laboratory shall have a written Sample Acceptance Policy that clearly outlines the circumstances under which samples will be accepted. Data from any samples, which do not meet the following criteria, must be flagged in an unambiguous manner clearly defining the nature and substance of the variation. This sample acceptance policy shall be made available to sample collection personnel and shall include, but is not limited to the following areas of concern:***
> - ***Proper, full and complete documentation, including Sample ID; location, date and time of collection; collector's name, preservation type, sample type and any special remarks concerning the sample;***
> - ***Proper sample labeling to including unique ID;***
> - ***Use of appropriate sample containers;***
> - ***Adherence to specified holding times; and***
> - ***Adequate sample volume.***
>
> ***Upon receipt, the condition of the sampling, including any abnormalities or departures from standard conditions for the test method shall be recorded.***
> 1. ***Samples requiring thermal preservation shall be considered acceptable if the arrival temp is within 2 degrees Celsius of the required temp, or within the method specified range. For sample with a specified temp of 4 °C, a temp of 0.1 to 6 °C shall be acceptable. Samples that are hand delivered immediately after collection, this criteria may not apply, although there should be evidence that the chilling process has begun such as arrival on ice.***
> 2. ***Laboratory shall check chemical preservation.***
> 3. ***The results of all checks shall be recorded.***
> 4. ***If there is any doubt, the laboratory shall contact the client.***
>
> *—NELAC*

Samples are unpacked and logged-in as described in SOPs, AL/SOP054, "Sample Login" and AL/SOP039, "Unpacking of Samples." On receipt, the contents of all sample shipments are inspected. The number, type, and identities of samples received are compared against those listed on the chain-of-custody form received with the samples. Sample integrity is checked by inspecting for any damage to sample containers and by confirming the samples were properly preserved in the field and that the samples were received at the proper temperature. Any

problems concerning sample identity and sample integrity are communicated to the CSC for subsequent resolution with the project team. If the samples pass inspection, or when problems have been resolved, the samples are logged into the LIMS.

As applicable, the handling of soils regulated under the US Department of Agriculture is described in SOP, AL/QMP006, "Handling of USDA Restricted Soils."

7.2 Use of Hold Alert System

> ***The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the sample, during storage, handling, preparation and testing.***
> ***a) Samples shall be stored according to the conditions specified by preservation protocols, including at the correct temperature range. Samples shall be stored away from all standards, reagents, food, and other potential contamination sources.***
> ***b) Sample fractions, extracts, leachates and other sample preparation products shall be stored according to specifications.***
> ***c) Where a sample or portion is to be held secure, (e.g., for reasons of record, safety or value, or to enable check calibrations or tests to be performed later) the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items.***
> ***—NELAC***

Most regulatory analyses require completion within a given time period following sample collection. The so-called "holding time" for a particular analysis thus establishes an expiration date for each sample being analyzed using that analytical method. Holding times vary from one protocol to the next depending upon the matrix, preservation technique, and analytes being determined. Completing a set of regulatory analyses using a given protocol within the prescribed holding time is required for acceptance of the results as valid data.

Managing the work through the laboratories while continuously performing analyses within the respective holding times is a significant challenge for the laboratory management. To assist in this task, the Hold Alert System was developed to track sample holding times and thus identify any samples in danger of exceeding their holding times. Use of the Hold Alert System is described in the Quality Management Procedure, AL/QMP007, "Hold Alert."

Based upon sample-specific information stored and tracked in the LIMS, a daily report is posted on the Radian Laboratory Intranet listing all samples whose holding times expire within three days. Each Laboratory Manager is required to review the report daily to identify any samples in that area which are in jeopardy of exceeding their holding times and respond with a report as to their status. Furthermore, on the occasion that a sample is within three days of expiration at the time of logging, the LIMS will alert the Sample Control staff until specific remedial actions are

taken. Thus, the Hold Alert System provides an added measure of security against potential loss of data due to invalidation of samples due to exceeding holding times.

7.3 Sample Storage

Samples are stored under conditions prescribed in the reference methods and Protocol Specifications, as described in SOP, AL/SOP005, "Sample Storage and Disposal." Sample storage temperature requirements are monitored daily.

Access to sample storage is controlled as described in SOP, AL/SOP001, "Sample Check-out and Check-in." This procedure provides documentation for all samples removed and consumed or returned to sample storage.

SECTION 8
PRODUCT IDENTIFICATION AND TRACEABILITY

> ***The supplier shall establish and maintain documented procedures identifying the product by suitable means from receipt and during all stages of production, delivery, and installation.***
>
> ***Where and to the extent that traceability is a specified requirement, the supplier shall establish and maintain documented procedures for unique identification of individual product or batches. The identification shall be recorded.***
> ***—Q9001***

Policy

Radian Analytical Laboratories shall ensure the unique identification and traceability of samples and all aspects of the measurement process that unambiguously define the measurement result.

Responsibilities

Sample control personnel are responsible for assigning laboratory identification numbers to samples, affixing laboratory sample labels to sample containers, and for peer review of sample identification.

Process

Radian laboratories follow established procedures to for identifying and tracing samples and measurement results. The following QMPs and SOPs pertain to these activities.

- AL/SOP054, "Sample Log-in";
- AL/SOP001, "Sample Check-out and Check-in";
- AL/SOP005, "Sample Storage and Disposal";
- AL/SOP021, "Receipt/Handling of Canisters"; and
- AL/QMP003, "Quality Traveler".

Laboratory records provide the link between sample identification numbers, measurement data, and standard reference materials. This section describes the standard procedures for the identification of samples, standard reference materials, and measurement results. An overall description of the process is provided below.

8.1 Sample Identification

Sample are inspected and logged into the Laboratory Information Management System according to the procedures described in SOPs, AL/SOP054, "Sample Log-in" and AL/SOP021, "Receipt/Handling of Canisters". A Radian label is affixed to each sample bearing the laboratory identification number that corresponds to the original sample identification number.

Samples are assigned a unique laboratory identification number that corresponds to the project sample identification number. Each laboratory sample ID number refers to a unique laboratory workorder number and a sequential number within the workorder. All related quality control data associated with sample preparation and analysis batches are traceable through workorder or batch identification number. The workorder number is based on calendar year and month, and a sequential number within each calendar month. The laboratory sample ID scheme is as follows:

YYMMZZZ-NNX

where YY is the year
MM is the month
ZZZ is the sequential workorder logged in during the month
NN is the sequential sample logged into the workorder
X is an alphabetic identifier for sample fractions

Radian laboratory reports, generated using the Laboratory Information Management System, include a Work Order Summary that lists each Project Sample ID, its Laboratory Sample ID, and the analytical method employed. The laboratory reports also identify the unique sample preparation batch number and analysis batch number associated with each sample. The presentation of analysis results also includes the Project Sample ID and Laboratory Sample ID, as well as a file identification number that relates to the analytical instrument and electronic raw data from that instrument. The laboratory reports show the date of collection, preparation, and analysis for each sample, as well as the analyst and reviewer. All calibration and quality control data, related to the sample measurement through preparation and analysis batch ID numbers, are also presented in each laboratory report.

8.2 Within-Laboratory Traceability

Following log-in, samples are stored in assigned locations. Access is controlled, as described in AL/SOP001, "Sample Check-out and Check-in". The Laboratory Information Management System is then used for sample tracking.

The Quality Traveler (QT) accompanies samples through the laboratory measurement processes, as described in AL/QMO003, "Quality Traveler." The QT is used to measure monitor conformance to specifications, as they relate to the samples.

The source, lot number, and expiration dates of standard reference materials are logged into standards logbooks. The steps and calculations involved in the preparation of working standards are documented in the standards preparation logbook. The unique identification number associated with each unique standard is recorded on the analytical run log, providing a link between the measurement of samples and standards.

Analytical records include the identification of the instrument used, the analyst, date and time of analysis, the source of calibration and quality control standards, and sample ID. The records provide a reliable record of the history of the sample, sufficient to reconstruct the reported results.

SECTION 9
PROCESS CONTROL

> ***The supplier shall identify and plan the production, installation, and servicing processes, which directly affect quality and shall ensure that these processes are carried out under controlled conditions.***
> ***—Q9001***

- ***The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of samples and for calibration and or testing, where the absence of such instructions could jeopardize the calibrations or tests;***
- ***All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-do-date and be readily available to the staff; and***
- ***Laboratorys shall maintain SOPs that accurately reflect all phases of currently laboratory activities such as assess data integrity, corrective actions, handling customer complaints, and all test methods.***

a) These may be equipment manuals, or internally written documents.
b) The test methods may be copies of published methods as long as any changes in the methods are document and included in the methods manual.
c) Copies of all SOPs shall be accessible to all personnel.
d) SOPs shall be logically organized and shall have the signature(s) of the approving authorities.
e) Each SOPs shall clearly indicate the effective date of the document, and the revision number.
—NELAC

Policy

Analytical measurements and activities that directly affect quality shall be performed according to approved procedures, specifications and instructions. Instructions and procedures shall contain sufficient detail and specification to ensure the quality of the work.

Responsibilities

The Laboratory Managers and Technical Director are responsible for identifying which activities require documentation through SOPs and for the subsequent preparation of those documents.

Laboratory Managers have review authority for all Protocol Specifications and Standard Operating Procedures prepared for their areas of responsibility.

The Technical Director has final approval authority for all standard Protocol Specifications and Standard Operating Procedures.

The Document Custodian is responsible for maintaining a master list of approved, current Protocol Specifications and Standard Operating Procedures.

Process

The primary activity of the Analytical Laboratory System is to perform chemical analyses for Radian project teams serving clients in government and industry. These analyses are performed under controlled conditions. Conditions are controlled through laboratory-wide use of:

- Detailed documents which describe the conditions which are to prevail during the analyses; and
- Activities involving review, inspection, and acceptance testing.

The principal documents directing measurement processes are SOPs and Protocol Specifications, which provide the procedure and specifications for each analytical method. Approved SOPs and standard Protocol Specifications are posted as controlled documents on the Radian Laboratory Intranet. These documents are described below in Sections 9.1 and 9.2, respectively.

9.1 Protocol Specification

The Protocol Specification is the tool for communicating the analytical needs of the client to the laboratories in terms that are meaningful to the laboratories. The Protocol Specification lists the specifications for performing an analysis. That is, the Protocol Specification describes the product which is to be delivered to the project at the end of the analytical process. The Protocol Specification is contrasted with Standard Operating Procedures (SOPs) which describe the details of how specific methods or components of methods are to be performed such that they consistently meet the Protocol Specification. The degree of mechanistic detail is far greater in an SOP than in a Protocol Specification.

A set of Protocol Specifications has been developed based on published EPA methods and the most frequent application of these methods for regulatory work. These Protocol Specifications are referred to as standard Protocol Specifications since they list the specifications which are to be met in the absence of other special needs of the client. The Laboratory Manager who is responsible for the protocol generally prepares Protocol Specifications.

On initiation of a project, the CSC provides the representative of the project with copies of the pertinent standard Protocol Specifications. These documents are then modified to meet the

specific analytical requirements of the client. The CSC then coordinates approval of the modified specifications with the Technical Director or the appropriate Laboratory Manager. Copies of the modified Protocol Specification are distributed to the appropriate laboratories before work begins. Modified Protocol Specifications may also be distributed to the project team as a record of the laboratory's understanding of the project expectations. Henceforth, adherence to the Protocol Specification is documented using the QT.

9.2 Standard Operating Procedures (SOPs)

While the Protocol Specifications define what the specifications are, SOPs define what procedures are to be followed and how the laboratories will meet the specifications.

Preparation, review, approval, and distribution of procedural documents are performed according to AL/QMP001 "Preparation of Radian Analytical Chemistry Laboratory Standard Operating Procedures and Quality Management Procedures."

The respective Laboratory Managers and the Laboratory Quality Officer have review authority over all SOPs developed in the Analytical Laboratory System. The Technical Director has final approval authority. Following approval, the original SOP document is stored in a central file maintained by Document Control. Approved SOPs are posted as controlled documents on the Radian Laboratory Intranet.

SECTION 10
INSPECTION AND TESTING

> ***The supplier shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met. The required inspection and testing, and the records to be established, shall be detailed in the quality plan or documented procedures.***
> ***—Q9001***

> ***The laboratory shall establish SOPs to ensure that the reported data is free from transcription and calculation errors. The laboratory shall establish SOPs to ensure that all quality control measures are reviewed and evaluated before data are reported.***
> ***—NELAC***

Policy

Radian Analytical Laboratories shall conduct inspections and tests at designated process check points to ensure that the reported data are free from transcription and calculation errors, and that all quality control measures are evaluated before data are reported.

Responsibilities

Laboratory Managers are responsible for ensuring that all required quality control measures in their respective laboratories are performed, reviewed, and evaluated before data are reported.

Analysts are responsible for documenting review of control measures on the Quality Traveler.

Process

Peer review is the cornerstone of Radian's quality assurance program. Projects are the basis of most Radian work, and all projects are required to have a peer review component. As appropriate for a project or specific work area, items affecting quality are required to be inspected and tested according to established acceptance and performance criteria. Measurement data are reviewed to ensure that the reported data are free from transcription and calculation errors. Likewise, the results of all quality control measures are reviewed and evaluated before data are reported.

The frame of reference used to describe the review, inspection and acceptance testing activities is the flow of work through the Analytical Laboratory System as shown in Figure 10-1. This figure shows the flow of work from initiation of the project, through sample receipt and logging, preparation, and analysis to final reporting of resulting data to the project team. These review activities occur throughout the progression of work through the Laboratory System:

- Review of the standard Protocol Specification by the project team;
- Review and approval of modified Protocol Specifications;
- In-process review of work; and
- Review of final data reports.

Each of these review activities is described below.

10.1 Review of Standard Protocol Specification by the Project Team

Before work can be performed within the Analytical Laboratory System, the analytical requirements of the client must be established for subsequent communication to the laboratory staff using the Protocol Specification. The initial step in this process is the review of pertinent standard Protocol Specification by a representative of the Radian project team against the analytical requirements of the client. In this review, the project team will identify differences between the standard specification and the project's analytical needs. These details are reviewed with the CSC who then prepares a modified Protocol Specification.

10.2 Review and Approval of Modified Protocol Specifications

The CSC makes the project-specific changes by initiating a modification of a Protocol Specification. The CSC initials and dates the modified Protocol Specification using the same color of ink used to make the modifications. If any other people make further modifications, these are made with a different color of ink, with their initials and date. The CSC submits the modified document to the Technical Director or the appropriate Laboratory Manager for review. This review involves:

- Consideration if the laboratory involved is able to meet the client's needs as described in the modified Protocol Specification;
- Consideration of alternative specifications if the laboratory cannot meet one or more of the client's specifications; and
- Consideration if additional changes should be made in order to meet the client's analytical requirements.

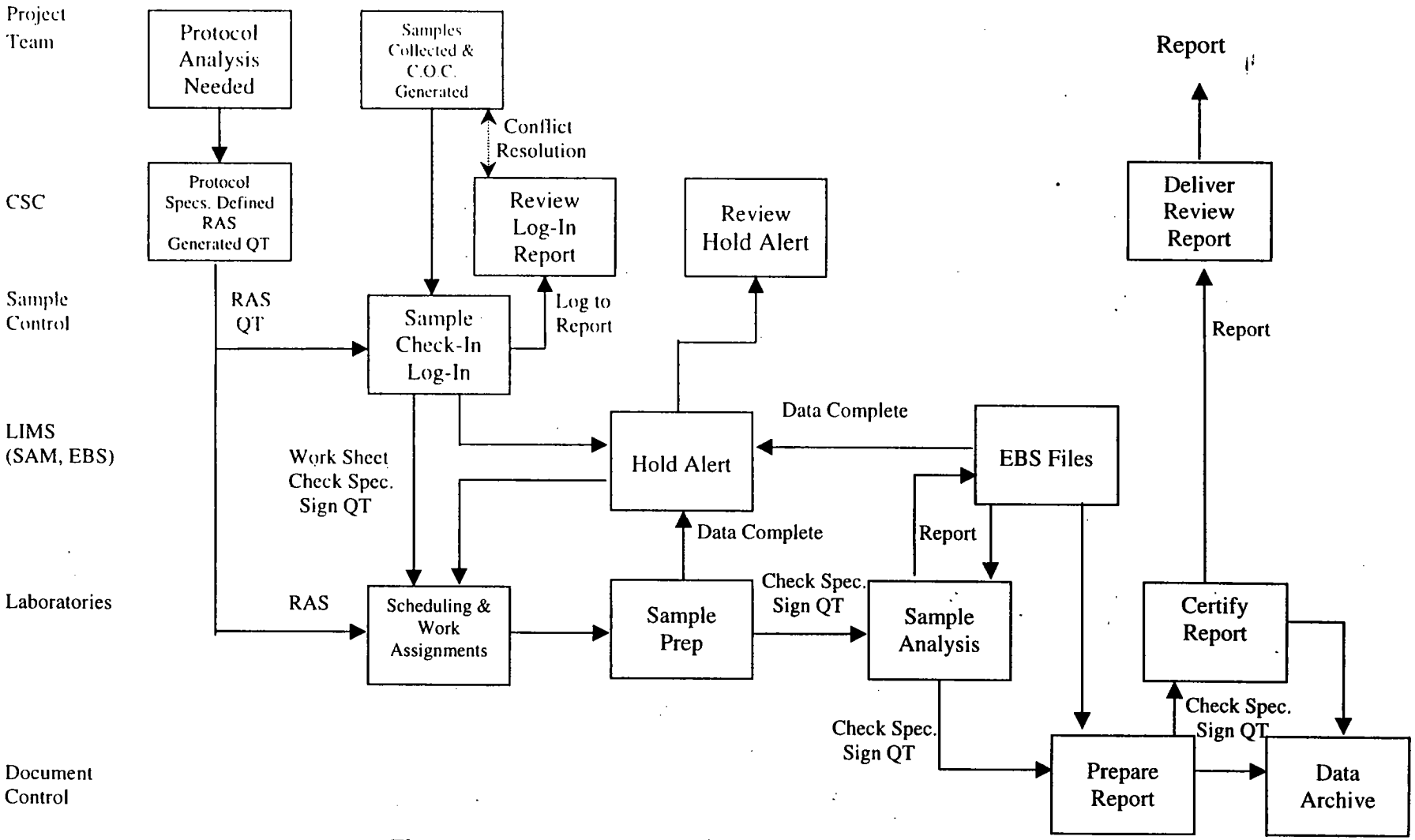

Figure 10-1. FPAS Operations Flow Diagram

If the laboratory can meet the client's needs, the reviewer approves the modifications by initialing and dating the Protocol Specification using a color of ink different from those used to make the suggested modifications. The modified Protocol Specification is then distributed to the appropriate laboratories. If the modified Protocol Specification cannot be approved as written, the CSC communicates the problem specifications to the project team for subsequent discussion, further modification of the Protocol Specification, and final review and approval of the modified Protocol Specification. The original copy of the modified Protocol Specification is given a unique number and filed in Radian's Document Control.

10.3 Receiving Inspection and Testing

> ***The supplier shall ensure that incoming product is not used or processed until it has been inspected or otherwise verified as conforming to specified requirements. Verification of the specified requirements shall be in accordance with the quality plan or documented procedures.***
> ***—Q9001***

Sample receipt, inspection and acceptance are discussed in Section 7, Control of Customer Supplied Product.

10.4 In-process Inspection and Testing

> ***The supplier shall carry out all final inspection and testing in accordance with the quality plan or documented procedures to complete the evidence of conformance of the finished product to the specified requirements. No product shall be dispatched until all the activities specified in the quality plan or documented procedures have been satisfactorily completed and authorized.***
> ***—Q9001***

Procedures for in-process inspection and testing are described in the analytical method SOPs and Protocol Specifications. In process review of acceptance testing is conducted by the analyst and documented on the Quality Traveler (AL/QMP003, "Quality Traveler"). Situations that do no meet the quality specifications are documented on the Quality Control Exception Report.

In-process inspection and testing within the Analytical Laboratory System is on-going, in-process review as work progresses through the system. The purpose of in-process review activities is to:

- Review work that has been performed prior to the current task(s) to ensure preceding work meets specifications;

- Review one's own work for the current task; and
- Review by second party (or peer review) of work for the current task against specifications before passing the work on to the subsequent step.

Thus, the on-going, in-process review activities bridge between each step in the analytical process.

During the in-process review, work is reviewed against the technical, procedural, and operational specifications within the Protocol Specification. Particular attention is paid to the technical specifications since meeting these specifications is critical to the defensibility of the final data. The review activities are documented using the Quality Traveler (QT). The QT progresses through the analytical system with the samples. Review of prior work and review of one's own work are documented when the analyst places his/her initials in the fields for just completed current analysis task on the QT. These review activities are supplemented by peer review. Peer review is the process whereby a technically qualified staff member who is not the primary person responsible for a specific task provides an independent technical review of the work to determine if the task product meets the Protocol Specification.

Peer review is performed and is documented on the QT five times during the analytical process:

- Review of the initial work of the CSC (e.g., QT, RAS form) by a representative of Sample Control;
- Review of the logging information from Sample Control by the CSC;
- Review of the work performed by the sample preparation analyst by a colleague in the sample preparation laboratory;
- Review of the analytical work performed by the sample analyst by a colleague in the laboratory involved; and
- Review of the work performed in Document Control by a colleague in Document Control.

The peer reviewers' initials in the peer reviewer fields on the QT documents indicate that peer review occurred at each step.

During the review process, the reviewers also document any time they determine that the work does not, or in their opinion cannot be performed in a manner that meets the Protocol Specification. These cases are documented by completing a Quality Control Exception Report (QCER). The QCER number is also entered onto the QT and a copy of the document

accompanies the QT through the remainder of its trip through the laboratory. The QCER system is described in Section 14.2.

10.5 Final Inspection and Testing

> ***The supplier shall:***
> ***a) Inspect and test the product as required by the quality plan or documented procedures; and***
> ***b) Hold product until the required inspection and tests have been completed or necessary reports have been received and verified.***
> ***—Q9001***

Measurement data are reviewed for compliance with requirements detailed in the Protocol Specification prior to release of data.

Laboratory Managers have overall responsibility for ensuring that all specifications for work performed in their laboratories have been met. The pertinent Laboratory Manager, or designee, reviews the completed QT and documents this review by signing the final analytical report and a file copy, which is subsequently filed in Document Control. The original report and the file copy are passed to the CSC.

An additional cursory review of all analytical reports is also performed by the CSC. This review step is documented in a work order logbook, which lists each work order, the initials of the CSC, and the date the file copy was returned. If errors are found in the report, the CSC notifies the Operations Manager that the associated work order needs to be reopened and states why this action is necessary. The Operations Manager tracks the number and causes for all reopened work orders.

10.6 Inspection and Test Records

> ***The supplier shall establish and maintain records which provide evidence that the product has been inspected or tested. These records shall show clearly whether the product has passed or failed the inspections or tests according to defined acceptance criteria. Where the product fails to pass any inspection or test, the procedures for control of nonconforming product shall apply.***
> ***—Q9001***

The results of QC tests are documented in raw measurement records and are presented with the analytical data reports. The Quality Traveler and QCER provide records of inspection of QC criteria, problems identified and corrective actions taken.

SECTION 11
CONTROL OF INSPECTION, MEASURING, AND TEST EQUIPMENT

> ***The supplier shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment (including test software) used by the supplier to demonstrate the conformance of product to the specified requirements. Inspection, measuring and test equipment shall be used in a manner that ensures that the measurement uncertainty is known and is consistent with the required measurement capability.***
> ***—Q9001***

> ***Each item of equipment, including reference materials, shall, when appropriate, be labeled, marked or otherwise identified to indicate its calibration status. Records shall be maintained of each major item of equipment and all reference materials significant to the test performed.***
> ***—NELAC***

Policy

Measurement equipment shall be used and maintained in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability. The calibration or standardization of equipment or materials that are related to sample measurements or measurement quality shall be unambiguously documented and directly traceable to the measurement results.

Responsibilities

Laboratory Managers are responsible for maintaining SOPs and Protocol Specifications that define requirements for equipment performance characteristics. These include, as appropriate, instrument tuning and calibration; linear range, retention time, and method detection limit studies; and contamination and recovery checks.

Laboratory Managers are also responsible for specifying calibration and maintenance requirements for ancillary equipment, such as thermometers, pipettes, and balances.

Laboratory Managers are responsible for assigning equipment maintenance duties to laboratory staff.

Designated laboratory staff are responsible for performing and documenting equipment maintenance.

Process

Radian Analytical Laboratories follow standard procedures to ensure that all measurement equipment are properly calibrated, inspected and maintained, Analytical instruments and reference materials are uniquely identified. Calibration records identify the calibration status of each instrument.

Equipment or instrumentation which gives suspect or unacceptable results, are taken out of service, until repaired and demonstrated by calibration, verification or other appropriate tests to perform satisfactorily. Instruments and equipment that are out of service are identified according to SOP325-AD-009, "Laboratory Tagging System".

The effect of any calibration or other quality defect in the analytical instrumentation on associated measurement results is evaluated and indicated in Quality Control Exception Reports (QCERs).

Records are maintained of all reference materials significant to the tests performed. Maintenance records include documentation on all routine and non-routine maintenance activities and reference material verifications.

Control Procedure

Radian Analytical Laboratories follow standard operating procedures to ensure that the performance of measurement devices and instruments is tested, verified and adjusted if necessary to meet the measurement performance criteria.

The activities that apply include calibration, on-going QC checks, inspections and maintenance. The requirements for performance are detailed in the applicable standard operating procedures and protocol specifications.

Calibration, quality control, and maintenance requirements are described in analytical method SOPs and Protocol Specifications. Maintenance of ancillary equipment, such as the calibration and verification of thermometers and pipettes are described in separate SOPs. A master list of approved SOPs and Protocol Specifications is maintained by the Document Control Officer. Project-specific SOPs and modified Protocol Specifications are maintained in the project file, but are not maintained as standard, controlled procedures and specifications.

The overall control processes are described below.

11.1 Calibration of Instrumentation

The supplier shall:

- ***Determine the measurements to be made and the accuracy required;***
- ***Identify all inspection, measuring and test equipment that can affect product quality and calibrate and adjust them against acceptable standards;***
- ***Define the process used for the calibration of measuring and test equipment, including details of equipment type, unique ID, location, frequency of checks, check method, acceptance criteria, and corrective actions;***
- ***Identify measuring and test equipment with a suitable identifier to show calibration status;***
- ***Maintain calibration records;***
- ***Assess and document the validity of previous test results when test equipment is found to be out of calibration;***
- ***Ensure that the environmental conditions are suitable for the calibration tests being carried out;***
- ***Ensure that the handling, preservation and storage of measuring and test equipment is such that the accuracy and fitness for use are maintained; and***
- ***Safeguard measuring and test equipment facilities, including both test hardware and software, from adjustments that would invalidate the calibration setting.***

—Q9001

Equipment and Reference Materials:

*a) **The laboratory shall be furnished with all items of equipment (including reference materials) required for the correct performance of tests;***

*b) **All equipment shall be properly maintained, inspected and cleaned; and***

*c) **Defective equipment shall be taken out of services and tagged until repair.***

—NELAC

Documented calibration procedures are required to provide consistency in preparing instrumentation for performing analyses or measurements. This subsection provides information regarding calibration of two categories of measuring and test equipment: measurement equipment and analytical instrumentation. Table 11-1 provides examples of the general types of equipment in each category.

Measurement Equipment

Calibration procedures are described in the SOPs and tolerances are described in the Protocol Specifications. Typically, new measurement equipment is calibrated upon receipt prior to use in the laboratory. Calibration verifications are performed periodically thereafter. All calibration events performed are documented in laboratory notebooks which the Laboratory Managers are responsible for maintaining. Verification of calibration events is documented during internal and external audit activities. Table 11-2 lists some typical measurement equipment used in the laboratory with their calibration requirements and frequency.

Analytical Instrumentation

Calibration of an analytical instrument involves measuring instrument response at several known concentrations of the analyte to be determined. Each analytical instrument must be properly calibrated before performing a chemical analysis. An effective calibration procedure specifies:

- The reference standard(s) to be used during calibration;
- The frequency with which calibration must be performed; and
- Acceptance criteria.

The specifications for calibrating analytical instruments are listed in each Protocol Specification while the operational details of the calibration process are described in the corresponding SOP.

Table 11-1. Analytical Laboratory Equipment Types

Category	Type
Measurement	Analytical balances Top-loading balances Hamilton liquid dispenser Pipetts Thermometers
Analytical	Gas chromatographs (GC) Gas chromatograph/mass spectrometer (GC/MS) High performance liquid chromatographs (HPLC) Atomic absorption spectrophotometers (AA) Inductively coupled plasma emission spectrometer (ICPES) Water Quality Laboratory instruments

The cognizant Laboratory Manager is responsible for ensuring that all measurement equipment are properly calibrated. The Laboratory Manager is also responsible that traceability of all calibration standards is properly documented. Traceability of standards is documented from receipt from the manufacturer through subsequent handling steps (e.g., dilution) to calibration of the instrument by assigning a unique standard identification to solutions. These standard identifications and, therefore, the chronological use of the calibration material is documented in standards logbooks.

11.2 Quality Control Analyses

Each analytical method includes a series of quality control analyses that are performed to assess and document performance. Some typical quality control analyses include:

- GC/MS mass scale calibration;
- GC/MS tuning using DFTPP;
- Daily calibration verification;
- Analysis of method blanks;
- Daily continuing calibration verification;
- Determination of internal standards;
- Determination of surrogate compounds;
- Analysis of laboratory control samples and laboratory control sample duplicates; and
- Analysis of matrix spikes and matrix spike duplicates.

The specific quality control analyses required for each method are listed in the pertinent Protocol Specification. Quality control analyses are described in greater detail in Section 14.1.3.

Table 11-2. Measurement Equipment Calibration

Measurement/Equipment	Calibration Requirement	Frequency
Balances (Analytical and top-loading)	Calibration and maintenance by outside vendor	Annually
	Calibration verification using Class S or S-1 weights	Daily, or before use
Drummond Pipettes (and all other non-Class A pipettes)	Calibration	Upon receipt
	Calibration verification	Quarterly
Thermometers	Calibration against NIST traceable thermometer	Annually
Weights	Calibration and maintenance by outside vendor	Annually

11.3 Acceptance Testing Activities

Acceptance testing activities are performed within the Analytical Laboratory System in support of the chemical analyses being performed according to specifications listed in the Protocol Specifications. These activities involve:

- Inspection of reagents and standards;
- Instrumentation receipt and setup;
- Routine instrument maintenance; and
- Non-routine instrument maintenance.

Each of these acceptance testing activities are described below.

11.3.1 Reagents and Standards

All laboratory reagent chemicals are inspected upon receipt to ensure proper identity and quantity. On transfer to the laboratory, the laboratory staff member who requested the purchase inspects the purchased product to determine that the stated product specifications meet those listed on the purchase order. If the product's stated specifications do not meet the specifications required, the procedures described in Section 6.3.2 are followed to resolve the problem. In some cases, however, chemicals may be purchased that are sold with no stated specifications. Selection of these chemicals for purchase will be made only when either the chemical's importance to final product quality is minimal or when the purchase of an alternative product is prohibitive due to extreme cost or availability problems.

Most laboratory reagents are purchased in lots that can be used over six to twelve months. Some examples of these reagents are solvents and column material used in the Organic Sample Preparation Laboratory as well as most analytical reagents. Bulk purchasing is done to minimize variability between different lots of material due to slight changes in composition. If a new lot of reagents or materials is found to be unacceptable on testing, the entire lot is returned to the vendor for replacement.

Testing of sorbent material (e.g., XAD-2 resin) used in sample collection for some organic analyses provides an example of this process. The sorbent material is tested by extracting an aliquot from each new lot received and analyzing the resulting extract using gas chromatography.

The results of this analysis must meet the acceptance criteria defined for the sorbent material (e.g., absence of contamination) in the pertinent SOP or the entire lot is returned to the vendor.

New lots of standard materials must be of known quality and origin. Such materials include those used to prepare initial and continuing calibration standards and spiking solutions used as laboratory control samples and matrix spikes. The quality and traceability of all standards are critical since all analyses refer back to the calibration standards and all quality control analyses must provide reliable data for assessing laboratory performance. Upon receipt of new standard material, the laboratory staff performs chemical analyses of the standard to verify that the new standard meets the criteria defined by the Analytical Laboratory System.

11.3.2 Instrument Receipt and Set-Up

Instruments purchased and incorporated into the Analytical Laboratory System also undergo acceptance testing to document that the instrument can perform up to the required specifications. On receiving new instrumentation, the vendor is called to notify him/her that the instrument has arrived at Radian. Specific dates are set to have the vendor visit the laboratory to unpack and install the instrument. Typically, the laboratory staff does not unpack or install a new instrument unless the instrument is small and relatively unsophisticated (e.g., benchtop visible spectrophotometer). During the laboratory visit, the vendor must demonstrate to the satisfaction of the responsible Laboratory Manager that the instrument meets the required performance specifications by analyzing test solutions and performing other diagnostic tests. Radian does not officially accept the instrument until acceptable performance is documented.

Performing a Demonstration of Capability (DOC) is part of the acceptance testing performed on new instrumentation. The instrument is calibrated and four identical laboratory control samples are analyzed sequentially. The accuracy and precision data for these DOC analyses must meet the specifications listed in the Protocol Specification. If these specifications are not met, the sources of potential problems are investigated with particular suspicion placed on performance of the new instrument.

11.3.3 Routine Maintenance

The objective of routine maintenance is to perform continuously on-going acceptance testing to minimize downtime to crucial analytical instruments and other equipment due to unexpected failure. The Laboratory Managers are responsible for maintenance of instrumentation and equipment located in their respective laboratories. Often, specific responsibilities for routine

maintenance on certain instruments are delegated to the laboratory staff. The Laboratory Manager retains, however, ultimate responsibility for routine maintenance.

Each instrument has a dedicated log located near the instrument to document all maintenance activities. Routine maintenance, changes in configuration, and replacement of parts is recorded in the maintenance log. As is the case for laboratory notebooks, the Laboratory Manager is responsible for periodically reviewing maintenance logs.

The effectiveness of the routine maintenance program depends largely on adherence to specific maintenance schedules for each instrument. Laboratory Managers are responsible for developing maintenance schedules for all critical instrumentation and equipment. Recommended maintenance schedules provided by the manufacturer often provide the basis for these schedules.

Service contracts are in place for the major instrumentation assigned to the Laboratory Analytical System. These instruments include:

- Hewlett-Packard GC/MS instruments (both software and hardware);
- Perkin-Elmer atomic absorption instruments (Models 4100 and 5100);
- Dionex ion chromatographs (Model 300);
- Bran & Luebbe autoanalyzer (Model TRAACS 800); and
- Jarrell-Ash Trace ICP (Model 61E).

Routine maintenance provided by trained service technicians under service contracts is crucial to minimizing downtime of sophisticated analytical instrumentation.

Routine maintenance also includes maintaining an adequate inventory of spare and expendable parts to maximize efficient instrument utilization and minimize downtime. This inventory emphasizes those parts and supplies that are subject to frequent failure, have limited useful lifetimes, or cannot always be obtained in timely manner should failure occur.

11.3.4 Non-Routine Maintenance and Repair

Despite comprehensive routine maintenance, malfunction or failure of instrumentation or equipment does occasionally occur which requires immediate repair. All non-routine maintenance of instruments in the Analytical Laboratory System is recorded in the appropriate

maintenance logs. If an instrument cannot be used pending repair, the instrument is tagged following the procedures described in SOP 325-AD-009. These procedures ensure that all laboratory staff is aware that the instrument is currently unusable. After repair, an instrument may still not be immediately usable pending recalibration. Procedures for tagging instruments under these conditions are also described in SOP 325-AD-009.

SECTION 12
INSPECTION AND TEST STATUS

> ***The inspection and test status of product shall be identified by suitable means, which indicate the conformance or nonconformance of product with regard to inspections and tests performed. The ID of inspection and test status shall be maintained, as defined in the quality plan or documented procedures, throughout production, installation, and servicing of the product to ensure that only product that has passed the required inspections and tests are used.***
> ***—Q9001***

Policy

Radian Analytical Laboratories will identify, track, review and report the status of work as it proceeds through the laboratory, until the final report is issued.

Responsibilities

Client Services Coordinators are responsible for tracking the status of work in-house for their assigned projects.

Laboratory Managers are responsible for scheduling work for completion, tracking work through their laboratory, and for ensuring that work is completed on time and in accordance with project requirements.

The Operations Manager is responsible for tracking overall laboratory capabilities and capacities, and for tracking on-time performance.

Process

Radian's analytical reports include all results related to measurement performance, such as calibration results, laboratory control sample results, spiked samples, and replicate analyses. The results for the performance indicators are compared with acceptance criteria and documented on the Quality Traveler. Any exceptions are noted on Quality Control Exception Reports, as described in Sections 13 and 14.

Analytical report status is documented in the following intermediate reports:

- Work Not Complete Report; and

- Quality Traveler Sign-Off.

Additionally, the Laboratory Information Management System provides for the following levels of status reports:

- Written;
- Transmitted;
- Complete;
- Reported; and
- Invoiced.

SECTION 13
CONTROL OF NONCONFORMING PRODUCT

The supplier shall establish and maintain documented procedures to ensure that product that does not conform to specified requirements is prevented from unintended us. This control shall provide for identification, documentation, evaluation, segregation, disposition of nonconforming product, and for notification to the functions concerned..

The responsibility for review and authority for the disposition of nonconforming product shall be defined. Non-conforming product shall be reviewed in accordance with documented procedures. It may be:
a) Reworked to meet the specified requirements;
b) Accepted with or without repair by concession; and
c) Regraded for alternative applications, rejected or scrapped.
—Q9001

The results of each test(s) carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, in accordance with any instructions in the test methods. The results shall normally by reported in a test report and shall include all the information necessary for the interpretation of the test results and all information required by the method used.
—NELAC

Policy

Radian Analytical Laboratories shall follow established procedures to ensure that test results are reported accurately and in accordance with method and client specifications. Results that do not conform to specified requirements shall be identified and qualified, as appropriate. This applies to both hardcopy and electronic data deliverables.

Responsibilities

Analysts are responsible for performing work that meets the project specifications. The analysts are also responsible for adding data qualifiers and report comments, completing QCERs, and notifying the CSC in the event of a nonconforming situation that requires a project decision.

Peer reviewers are responsible for ensuring that appropriate data qualifiers (flags and comments) and QCERs have been included with the data reports.

Laboratory Managers are responsible for ensuring that the data reports are complete and properly assembled and submitted by the analyst.

Client Service Coordinators are responsible for communicating any data problems with the project team and for obtaining project team approval for actions pertaining to the nonconforming data.

Process

Radian analytical reports are constructed using standard laboratory procedures to ensure that measurement data that do not conform to specified requirements are appropriately qualified, reworked, or prevented from unintended use. This process provides for identification and documentation of the nonconforming characteristic, evaluation and qualification of the affected data, and notification of the client, as appropriate.

The systems for documenting deviations in quality specifications are described in Section 14 and include use of the Quality Traveler and Quality Control Exception Report.

The documentation of conformance to quality specifications is further assessed through peer review of laboratory measurement results, as well as peer review of the final analytical report. Peer review processes are based on requirement described in the Protocol Specifications.

Review and Disposition of Nonconforming Product

Quality problems associated with measurement data are documented. The data are qualified according to protocols outlined in the method SOPs and Protocol Specifications. Problems, anomalies, or limitations in the usability of the data are discussed with the client (project team) to determine appropriate action.

Analytical reports include calibration data, as well as and results for analysis of quality control samples (e.g., blanks, spikes, replicates, etc.). The analytical reports also include Quality Control Exceptions Reports (identifying deviations from quality specifications, affect on data quality, and actions taken), Report Comments (additional information from the analysts that helps with data interpretation) and Report Flags (qualifiers applied to data based on quality exceptions).

SECTION 14
CORRECTIVE AND PREVENTIVE ACTION

> ***Supplier shall establish and maintain documented procedures for implementing corrective and preventive actions.***
> ***—Q9001***

> ***In addition to providing acceptance criteria and specific protocols for corrective actions in the Method SOPs, the laboratory shall implement general procedures to be followed to determine when QC data are out of control. These procedures shall include but are not limited to the following:***
> ***1) Identification of person responsible for assessing each type of QC data;***
> ***2) Identification of the person responsible for initiating or recommending corrective action;***
> ***3) Define how the analyst should treat a data set if the associated QC measurements are unacceptable; and***
> ***4) Specify how out-of-control situations and subsequent corrective actions are to be documented.***
> ***To the extent possible, samples shall be reported only if all QC measures are acceptable. If a QC measure is out-of-control, all samples associated with the failed QC measured shall be reported with the appropriate data qualifier(s).***
> ***—NELAC***

Policy

Radian Analytical Laboratories shall establish measurement performance criteria and procedures for implementing and documenting corrective and preventive actions.

Responsibilities

Laboratory Managers are responsible for developing Protocol Specifications to include appropriate performance criteria and corrective actions.

Analysts are responsible for documenting adherence to performance criteria (Quality Traveler) or corrective actions (Quality Control Exception Report).

Peer Reviewers are responsible for verifying corrective actions taken.

Client Service Coordinators are responsible for defining project-specific performance criteria and corrective actions.

Process

The following procedures are applicable to the corrective and preventive action systems:

- AL/QMP007, "Hold Alert";
- AL/QMP003, "Quality Traveler";
- Scheduled, "Control Chart Usage"; and
- 300-QA-003 "Use of the Recommendation for Corrective Action (RCA) System".

The overall process is described below.

The Analytical Laboratory System has developed and implemented several procedures to detect, identify, control, and document potential quality issues. The fundamental mechanism for documenting exceptions to quality specifications in the measurement process, and actions taken in response to the identified quality exception, is the "Quality Control Exception Report," or QCER.

Quality control checks are fundamental tools in the laboratory to monitor analytical performance. The use of statistical methods to identify trends is also very important for quality improvement initiatives in the laboratory. Corrective action procedures are taken to document problems and aid in root cause assessment, as well as make recommendations for procedural changes, if appropriate, to prevent recurrence. Finally, systems are in place that promote continuous improvement within the Analytical Laboratory System.

14.1 Control Procedures

Most of the control procedures used in the laboratory involve quality control checks associated with all analytical measurements. These control checks are used to assess the conformance to the criteria outlined in the Protocol Specifications. In addition, control procedures have been implemented to ensure that sample logging occurs in a timely manner and that analyses are performed within holding times. Finally, the QT provides documentation that these control procedures were performed, and if there were any nonconforming events. These control procedures are described in the following subsections.

14.1.1 Sample Receipt Control

The Analytical Laboratory handles a large volume of samples and analyses on a daily basis. Samples are tracked through the laboratory using the Laboratory Information Management System (LIMS). This system is activated after samples are logged in. As a means to document and track samples that have been received in the laboratory, but not yet logged in to the LIMS, a procedure is used to communicate these situations. Samples may not be immediately logged because required documentation (RAS form, QT, specific Protocol Specification) has not been received from the CSC, questions concerning the receipt of the samples needs to be addressed (discrepancy in chain-of-custody, improper receipt temperature, pH, etc.), late arriving samples or a large sample receipt volume on a given day, or other situations that may arise. This procedure provides a mechanism to rectify problems associated with the samples, and serves as a reminder to log all samples as quickly as possible.

The Sample Control Laboratory Manager, or designee, is responsible for sending a message via electronic mail listing all samples not yet logged into the LIMS. This electronic message is sent to the entire laboratory staff. The message is sent daily whether or not all samples received have been logged in by the Sample Control staff. Specific information in the message includes the project name, date of receipt in Sample Control, and reason(s) the samples have not yet been logged into the LIMS. Samples remain on this list until they have been logged into the LIMS. CSCs use this information as a reminder to obtain missing information from the project staffs and/or communicate this information to Sample Control. The Sample Control staff uses this procedure as a reminder to log any samples on this list as quickly as possible.

14.1.2 Holding Time Control

Sample holding times are controlled within method and Protocol Specification requirements by means of the Hold Alert system. This computerized sample tracking system ensures that sample preparation and/or analytical holding times are met for all samples. Satisfying holding time specifications is very important since regulatory agencies use this measure as a primary consideration for validating analytical data. Having a routine procedure to track potential holding time exceedances allows for prompt corrective action before holding times are missed.

After logging into the LIMS, the current status of all samples is tracked in the laboratory. The Hold Alert output lists all samples that will exceed either preparation or analysis holding time within the next three working days. This is accomplished by searching all analyses not-yet-complete in the LIMS and keying off of sample collection date and the specific holding time in the analytical method (or Protocol Specification).

All Laboratory Managers or designees must respond daily to the Hold Alert message and document the status of all samples listed. If holding times are allowed to be exceeded, this is stated by the CSC, based on client approval. Planned or actual analysis dates are given by the Laboratory Managers. A response to the Hold Alert message is required even if no samples are listed, or no problems exist for the samples listed. The status response is sent to the Operations Manager, Unit Leader, Technical Director, Quality Officer, and CSCs, to communicate any potential holding time exceedances.

14.1.3 Analytical Control

Various quality control checks are performed to assess and document analytical performance in the laboratory. Checks applicable to a particular protocol are listed in the Protocol Specification, including a description, frequency, acceptance criteria, and corrective action. Control checks are used to assess whether each analytical batch has met its quality objectives. As an example, Table 14-1 lists the types of quality control checks that are routinely performed with each analytical batch for Method 8270C, and gives a brief definition for each.

Table 14-1. Example: Laboratory Limits and Tolerances for Method 8270C

QC Activity	Definition
GC/MS Mass Scale Calibration	Calibration of GC/MS instrument mass scale by analysis of perfluorotributylamine (PFTBA)
DFTPP Tuning	Tuning of GC/MS instrument by analysis of decafluorotriphenylphosphine (DFTPP)
GC Performance Check	Check of GC performance based on degree of degradation of DDT and response and tailing of pentachlorophenol and benzidine
Method Blank Analyses	Laboratory-pure water extracted and analyzed as a sample to assess potential contamination arising during sample preparation or analysis
Initial Calibration Verification	Verification that daily instrument response and GC retention times meet specifications before beginning analyses
Continuing Calibration Verification	Periodic verification that instrument response and GC retention times continue to meet specification as analyses proceed during an analytical sequence

Table 14-1. Example: Laboratory Limits and Tolerances for Method 8270C (continued)

QC Activity	Definition
Surrogate Spike Analyses	Determination of six compounds spiked into all samples extracted and all QC solutions analyzed to assess on-going analytical performance through recovery of the spiked compounds
Laboratory Control Sample/Laboratory Control Sample Duplicate (LCS/LCSD) Analyses	Two aliquots of laboratory-pure water, spiked with a subset of target analytes, extracted and analyzed as a sample to measure accuracy and precision for the analytical system through the recovery data obtained for the spiked compounds
Matrix Spike/Matrix Spike Duplicate (MS/MSD) Analyses	Two aliquots of a sample which are spiked with a subset of target analytes and then extracted and analyzed as a sample to document potential matrix interferences through the recovery data obtained for the spiked compounds

Specific acceptance criteria for each quality control check are found in the Protocol Specifications. When these criteria are not met for a particular analytical batch, the required corrective actions are prescribed. In most cases, changes to the analytical system and/or reanalysis are required (holding time permitting). In some cases, documentation of the quality control check, exceedance is all that is possible. In all cases where quality control check criteria are not met, documentation of the situation is required using a Quality Control Exception Report (QCER).

The QT is used to document any technical, procedural, or operational specification of the analyses that are not met, following the criteria in the Protocol Specification. As described earlier, the QT is completed by the person performing the task/analysis in each area of the laboratory, and is peer reviewed by an appropriate laboratory staff member. This procedure provides essential quality control of each step in the analytical process, and provides documentation that the control checks were performed.

14.2 Corrective Action

Various systems are in place to identify and document problems requiring some sort of corrective action. Root cause analysis of quality problems is used to understand the underlying

causes of these problems and to prevent recurrence. The corrective action systems and procedures used in the Analytical Laboratory System are discussed in this subsection.
There are two mechanisms for identifying and documenting nonconformance to the Protocol Specifications and/or to technically sound analytical practices and procedures. The QCER system and the company QA Recommendation for Corrective Action (RCA) system are used by the laboratory staff to identify, document, and recommend appropriate corrective actions. The Laboratory Quality Report and Performance Evaluation Responses are also used to communicate the results of quality assessment activities.

The QCER system is a three-tiered hierarchical system comprising forms and procedures used to identify and document all exceedances of QC criteria found in the Protocol Specifications. Each tier, or level, has an associated electronic form that addresses a type of laboratory problem:

QCER System

- The Level 1 QCER form is used to document problems, which do not affect the quality of clients' data, and to describe the corrective action(s) taken. For example, a Level 1 QCER form is completed for an unacceptable calibration standard that was remade prior to analyzing samples. The Level 1 QCER form is not distributed but electronically retained for use by the Laboratory Managers, Quality Officer, and Technical Director;

- The Level 2 QCER form is used to document problems which potentially affect the quality of clients' data, to propose the probable cause of the problems, and to describe the corrective action(s) taken. Unacceptable matrix spike or surrogate recoveries attributed to a matrix effect would require completion of a Level 2 QCER form. The Level 2 QCER form is distributed to the pertinent Laboratory Manager, CSC, and Project Chemist; and

- The Level 3 QCER form is used to document systematic one-time or recurring problems, which require high-level attention to correcting the problems and verification of resolution. For example, a Level 3 QCER form would be completed if a high concentration sample was mishandled resulting in contamination of other samples, indicating a need for an approach to handling high concentration samples in the future. A Level 3 QCER form can be initiated by any member of the laboratory staff by identifying the problem, proposing a probable cause, and proposing corrective action(s). At this stage, the form is distributed to pertinent Laboratory Manager and the Technical Director. The Technical Director responds to the proposed corrective action(s), identifies the person responsible for resolution, and identifies the person responsible for verifying resolution. The Technical Director then distributes the

form as he/she sees fit. Typically, the form is sent to the Unit Leader, Operations Manager, Quality Officer, Client Services Manager, the pertinent Laboratory Manager, and CSC. After the problem is verified to be resolved, the completed Level 3 QCER form is again distributed to the persons previously selected by the Technical Director.

QCER forms are completed by the analyst immediately after a QC tolerance is exceeded. Since the QCER system is in an electronic format, problems identified and corrective actions taken can be electronically tabulated regardless of level involved. Tabulation of QCER responses facilitates monitoring whether appropriate corrective actions were taken and categorization of problems encountered for subsequent quality improvement. A status report of active Level 3 QCERs is sent by the Quality Officer to all laboratory managers monthly.

RCA System

The RCA system is administered and tracked by the company QA Director. While any laboratory staff member can issue QCERs, RCAs are issued only by the QA Director, Radian QA staff, or the Laboratory Quality Officer. RCAs are issued as a result of performance audits, systems audits, or other QA activities. The use of RCAs is restricted to the following situations:

- A systematic deficiency, inadequacy, or inappropriate action, which is clearly at odds with accepted QA practice;

- A clear and present risk of major data loss or invalidation, or of failure to achieve specified data quality objectives for a significant portion of a measurement effort; or

- Opportunities for systematic improvement of a particular QC system or procedure for which the recommended action is not urgent, but would bring the overall system more in line with generally accepted QC practice.

The originator of the RCA provides a description of the problem and recommended corrective action. The individual responsible for action responds by describing the planned and/or implemented corrective action. The originator reviews this response to make sure it adequately addresses the QA concern, and if they agree with the resolution, verifies that it has been fully implemented in the laboratory. If there is no response from the individual responsible for action, or the QA staff does not agree with appropriateness of the response, the resolution is pursued to successively higher management levels until the issue is resolved.

Performing root cause analysis of quality problems goes on in tandem with the mechanisms to identify and document QA problems and implement appropriate corrective actions. Root cause analysis is used to identify and correct the underlying causes of quality problems and to prevent recurrence. Root cause analysis should be used whenever a trend is identified that is currently outside tolerance, or leading to tolerance exceedance. Also, when systematic or recurring problems are observed that suggest an underlying assignable cause, root cause assessment of these problems should be used. Root cause assessment is made by Laboratory Managers in their input to both the Laboratory Quality Report and in responses to unacceptable performance evaluation sample results. Other uses include assessments by analysts and Laboratory Managers of trends shown by control charting activities, or repeated tolerance exceedances. The Technical Director and Quality Officer are kept informed on all QC problems requiring root cause analysis.

Laboratory Quality Report

The Laboratory Quality Report is assembled semi-annually by the Quality Officer, with Laboratory Managers providing information for their laboratories. Control charts are also provided for appropriate parameters for various Protocol Specifications. Each month, Laboratory Managers assess trends and try to identify the underlying cause of all unacceptable trends or out-of-tolerance events.

PE Response

Responses are written for all unacceptable performance evaluation (PE) sample results for both internal and external PE samples. In preparing the response, the Laboratory Manager and analysts thoroughly review the analytical systems and data for the particular analytical batch and batches analyzed prior to and after the batch in question. Raw data, sample preparation, sample analysis, and assessment of conformance to the Protocol Specifications is reviewed. Through this effort, the root causes for unacceptable PE sample results are investigated. Corrective actions are suggested and implemented as part of this review and response. Review of control charts to observe unacceptable trends and any repeated nonconformance to particular Protocol Specifications also suggest that a root cause analysis is warranted. This should be performed by analysts as they observe these trends and also by Laboratory Managers during periodic reviews of laboratory performance. Other situations may arise in the laboratory which may indicate a root cause assessment is appropriate. All laboratory personnel are responsible to bring attention to any potential problem and pursue the cause of the problem until any appropriate corrective action has been implemented.

14.3 Continuous Improvement

The goal of the Analytical Laboratory is to provide analytical services that consistently meet the clients needs and expectations. To maintain technical superiority and performance in the marketplace, the focus must be on continuous improvement. The four keys to achieving quality improvement are:

- Total involvement by everyone in the organization, including management;
- Communication to staff at all levels in the organization so everyone understands the clients' requirements and how the organization is meeting the clients' needs;
- Removal of barriers so procedures that ensure quality systems can be implemented effectively; and
- Continuous evaluation and improvement of processes by looking for better ways to do things.

One continuous quality improvement initiative implemented in the Analytical Laboratory is weekly quality assurance meetings held with the Laboratory Quality Officer by each of the Laboratory Managers and their laboratory members. These meetings are regularly scheduled, and all staff members in a laboratory area attend. A full range of laboratory quality issues are discussed in the meetings, including specific technical questions from staff members, review of various control check data, and review of the Protocol Specifications, etc. The agenda is flexible and responsive to current concerns and initiatives. Meeting notes are distributed by the Laboratory Managers to the attendees with a copy to all Laboratory Managers, the laboratory management and company Quality Assurance Director. These meeting notes document the quality issues discussed, and also communicate these issues with the entire laboratory management team so that all may benefit from the ideas discussed.

Another weekly meeting of the Unit Leader, Technical Director, all Laboratory Managers, senior staff, the Client Service Coordinators, and the Quality Officer is a forum to discuss various continuous quality improvement issues. New quality improvement initiatives are presented and discussed with the laboratory management team. Special problems and concerns are openly addressed, and issues to be addressed in subsequent meetings are outlined. Final resolution of these new quality improvement initiatives then become topics for the weekly QA meetings with all laboratory staff members.

SECTION 15
DELIVERY OF TEST REPORTS

> ***The supplier shall establish and maintain documented procedures for handling, storage, packaging, preservation and delivery of product.***
> ***—Q9001***

> ***Laboratory Report Format and Contents.***
> ***1) Title, e.g., "Test Report" or "Test Certificate" or "Laboratory Results"***
> ***2) Name and address of laboratory; location where tests were conducted, if different; phone number with name of contact person for questions.***
> ***3) Unique identification for the certificate or report (such as serial number) and of each page, and the total number of pages.***
> ***4) Name and address of client, and project name.***
> ***5) Description and unambiguous identification of the tested sample including the client identification code.***
> ***6) Identification of test results derived from any sample that did not meet NELAC sample acceptance requirements, such as improper container, holding time, or temperature.***
> ***7) Date of receipt of sample, date and time of sample collection, date(s) of performance test, and time of sample preparation and analysis if the required holding time for either activity is less than or equal to 48 hours.***
> ***8) Identification of the test method used.***
> ***9) If the laboratory collected the sample, reference to sampling procedure.***
> ***10) Any deviations from (such as failed quality control), additions to or exclusions from the test method (such as environmental conditions), and any other information relevant to a specific test, such as environmental conditions including the use of relevant data qualifiers and their meaning.***
> ***11) Identification of whether data are calculated on a dry weight or wet weight basis; identification of the reporting units such as •g/L or mg/kg, and for whole effluent toxicity, identification of the statistical package used to provide data.***
> ***12) When required, a statement of the estimated uncertainty of the test results.***
> ***13) A signature and title, or an equivalent electronic identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue.***
> ***14) At the laboratory's discretion, a statement to the effect that the results relate only to the items tested or to the sample as received by the laboratory.***
> ***15) At the laboratory's discretion, a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory.***
> ***16) When reported, clear identification of all data provided by outside sources, such as air temperature or ambient water temperature.***
> ***17) Clear identification of numerical results with values below 3.18 times the MDL (10 times the standard deviation as determined by the method detection limit study).***
> ***—NELAC***

Policy

Radian Analytical Laboratories shall deliver analytical reports having suitable content and format that meet that client's needs. Test results shall be reported accurately and unambiguously in accordance with method or project requirements. Test reports shall include all the information

necessary for the interpretation of the test results and all information required by the method used.

Responsibilities

Client Service Coordinators are responsible for conveying project-specific reporting requirements via project-specific Protocol Specifications, and for issuing the reports to the project team.

Reporting personnel are responsible for ensuring that all report information is correct and in accordance with project-specific requirements.

Laboratory Managers are responsible for and review and approval of all laboratory reports issued from their respective laboratories.

Process

Project-specific reporting requirements are delineated and communicated to the laboratory staff via project-specific modified Protocol Specifications, as described in Section 4.

Data are reviewed during the work process, documented on the Quality Traveler. This process is described in Section 10.4. Laboratory Managers review and approve final data reports before issue.

Use and interpretation of Radian Analytical Reports is described in the "Guide to FPAS Report Format." The procedure, AL/SOP013, "Data Export" describes the process for electronic data deliverables.

The standard Radian Analytical Laboratory Report includes the following information:

- Title: Radian Analytical Services FPAS Report;
- Laboratory address and identification of Client Services Coordinator;
- Unique Workorder Number and Table of Contents identifying the total number of pages in the report;
- Client code, client name, facility or site of sample collection, and a project identification name and number;

- A listing of the project sample identification number or description, the corresponding laboratory sample identification number, identification codes and descriptions of tests performed;
- Chain of custody record and Addendum identifying any sample discrepancies in identification or preservation;
- Identification of any samples analyzed outside specified holding times;
- Date of sample collection, receipt, and preparation;
- Date and time of sample analysis;
- Flag definitions and report comments;
- Identification of reporting basis for sample, i.e., "as received" or "dry weight";
- Results for analysis of quality control samples, and comments on any uncertainties in measurement accuracy evidenced during analysis;
- Identification of analysts, reviewer, and signature of Laboratory Manager;
- Identification of project-provided data relevant to derived quantities, such as impinger or air sample volumes;
- Identification of sample-specific detection limits with each measurement result, and qualifiers appropriate to the data quality objectives and reporting limits specified by the client.

The standard format, from which the project team may select sections to be included in the reports, includes the following:

- Work Order Summary
  - Flag Definitions
  - Protocol Summary
  - Results Summary
  - Initial Calibration
  - TCLP Batch Summary
  - Extraction/Digestion Batch Summary
- Analysis Batch Summary
  - Detailed Sample Results
  - Laboratory Blanks
  - Laboratory Control Samples
  - Matrix Spikes
  - Collection Medium Spikes
  - Analytical Spikes

  - Calibration Verification
  - Analytical Duplicates
  - Serial Dilution Checks
  - Endrin/DDT Breakdown
  - Detectability Check Samples
  - Reporting Limit Check Standard
- Comments/Narrative

Full data packages including, as applicable, raw data such as chromatograms, mass spectra, and quantitation reports are available upon request from the project team.

SECTION 16
CONTROL OF QUALITY RECORDS

> ***The supplier shall establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality records.***
>
> ***Quality records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Retention times of quality records shall be established and recorded.***
> ***—Q9001***

> ***The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. The system shall produce unequivocal, accurate records which document all laboratory activities. The laboratory shall retain, on record, all original observations, calculations and derived data, calibration records and a copy of the test report for an appropriate period.***
> ***—NELAC***

Policy

Radian Analytical Laboratories shall maintain a records management system. The laboratory shall maintain records of all original observations, calculations and derived data, calibration records, sample custody or tracking documentation, and copies of test reports.

Responsibilities

The Document Control Officer is responsible for indexing and maintaining laboratory records.

Laboratory Managers are responsible for submitting all raw data, archived electronic data, laboratory notebooks, and all quality studies (such as MDL, linear range, retention time etc.) to Document Control.

Process

This section describes the procedures used within the Analytical Laboratory System to control records generated during the normal course of its activities. These items include raw analytical data, logbooks, notebooks, certification and performance evaluation results, procedures and specifications related to the work performed, chain-of-custody forms, training records, and quality control measurements. This section also contains a description of other miscellaneous records that are maintained.

Data handling and archiving procedures are described in SOP 325-AD-010, "Data Handling and Archiving".

Project-specific requirements for records generation and management are delineated in project-specific quality documents. Specifications for review, approval, and issuance are also determined by project requirements.

16.1 Records

Records are those documents that demonstrate achievement of the required quality and verify effective operation of the quality system. These include raw data, chain-of-custody forms, logbooks, laboratory notebooks, electronic media, Quality Travelers, reports, report files, training records, certification and performance evaluation files, method detection limits study data, and demonstrations of capability. This section describes the procedures that are to be followed when identifying, collecting, indexing, filing, storing, and disposing of records. Table 16-1 shows the distribution for each documentation and record type.

16.2 Generation and Identification

Records are generated during the technical activities that are performed as part of the Analytical Laboratory operation. This information is organized in the laboratories and the Document Control file room so that it can be readily retrieved while maintaining security and confidentiality. The generation and identification of each type of quality record is described in Table 16-2. The control of each record is described in Table 16-3. Electronic media are generated by various laboratory instruments and the LIMS utilized by the laboratory. The types of electronic media used to store data are; magnetic tape, floppy diskettes, and CD-ROM optical discs.

16.3 Storage and Disposition

Inactive files and certain files that are over one year old (see Table 16-2), are archived in labeled cartons at designated warehouse locations. The contents of each carton is listed on warehouse inventory forms that identify:

- Sender's name and employee number;
- Name and employee number of person receiving carton for storage;
- Date of receipt at the warehouse;

- Contents category (e.g. workorders, raw laboratory data); and
- Contents description (using unique numbers when possible).

Files containing the quality records described previously are retained for a designated period of time. If not contractually established, these records are retained for five years. Prior to disposition, the Document Control Laboratory Manager reviews contents of each file carton and is responsible for obtaining approval for disposal.

Table 16-1. Documentation and Record Types

Type Of Document	Storage Media	Archive Duration
Documents		
Systems Manual	Hardcopy, Electronic	Indefinitely
Protocol Specifications	Hardcopy, Electronic	Indefinitely
Standard Operating Procedures	Hardcopy, Electronic	Indefinitely
Records		
Raw Data	Hardcopy Electronic	5 years
Chain-of-Custody Forms/ Addendum	Hardcopy	5 years
Reports	Hardcopy Electronic	5 years
Logbooks	Hardcopy	5 years
Laboratory Notebooks	Hardcopy	5 years
Training Records	Electronic	Indefinitely
Method Detection Limits	Hardcopy Electronic	5 years
Demonstration of Capabilities	Hardcopy Electronic	5 years
Calibration Data	Hardcopy Electronic	5 years

Table 16-1. Documentation and Record Types (continued)

Type Of Document	Storage Media	Archive Duration
Certifications/ Performance Evaluation Files	Hardcopy	5 years
Work Order File Documentation	Hardcopy Electronic	5 years

Table 16-2. Generation and Distribution of Quality Records

Type of Record	Preparation/ Initiated	Distribution	Retrieval	Storage/ Archiving
Hardcopy Raw Data	Individual laboratory instrument	Labs to Document Control	Document Control/ electronic media	Document Control 1 year/warehouse for duration
Chain-of-Custody Forms	Sample Control	Sample Control to Document Control	Document Control	Document Control 1 year/warehouse for duration
Laboratory Notebooks/ Logbooks	Document Control to Labs	Labs to Document Control	Document Control	Document Control 1 year/warehouse for duration
Electronic Raw Data	Individual Laboratory instruments/ LIM systems	Lab to Document Control	Document Control	Document Control/off-site storage for this media
Quality Travelers	Client Service Coordinator	Travels with samples through labs to Document Control	Document Control	Document Control 1 year/warehouse for duration
Reports	Document Control	Document Control to Laboratory; then back to DC	Document Control	Document Control 1 year/warehouse for duration
Training Files	Individual laboratory	Individual to Document Control	Document Control	Document Control permanent storage
Certifications/ Performance Evaluations	Client Services Coordinator	Travels with samples through labs to Document Control	Document Control	Document Control permanent storage

Table 16-3. Control of Records

Type of Document	Type of Control	Type of Identifier
Standard Operating Procedure	Sign-off of management	Unique numbering system
Protocol Specification	Sign-off by Technical Director and Laboratory Manager	Unique numbering system
Type of Record		
Raw method detection limit, demonstration of capability data	Laboratory approval	Preparation and analytical batch-unique identifications
Chain-of-custody forms, reports, work order files, Quality Travelers	Laboratory approval	Filed by work order number
Logbooks	Binder lock, issued by Document Control	Unique number on each binder lock
Laboratory notebooks	Issued by Document Control	Unique number on each notebook
Electronic raw data	Laboratory approval	Unique numbering system
Training files	Laboratory management approval	Filed in Document Control by individual
Certifications/Performance Evaluations	Laboratory management approval	Filed in Document Control by type or agency

SECTION 17
INTERNAL QUALITY AUDITS

> ***Supplier shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.***
>
> ***Follow-up audits shall verify and record the implementation and effectiveness of the corrective action taken.***
> ***—Q9001***

> ***The laboratory shall arrange for annual quality systems audits of its technical activities. Audits shall be carried out by QA Officer or designee, who are trained and qualified as auditors, and who are independent of activity being audited. Where audit findings cast doubt on data validity, lab shall take immediate corrective action and notify clients whose work may be affected.***
> ***—NELAC***

Policy

Radian Analytical Laboratories shall conduct internal quality audits annually of every laboratory area. The audits shall be designed to verify whether quality activities and related results comply with established procedures and specifications and to determine the effectiveness of the quality system. The audits shall be conducted by Radian QA staff, who are trained and qualified as auditors, and who are independent of the activity being audited.

Responsibilities

The laboratory Quality Officer is responsible for arranging for the annual internal quality audits to be conducted by independent Radian QA auditors.

Radian QA auditors are responsible for preparing audit plans, scheduling and conducting audits, submitting audit findings in a written audit report to Laboratory Management, tracking Recommendations for Corrective Action, and conducting follow-up audits to verify the effectiveness of corrective actions.

Laboratory Managers are responsible for cooperating with the QA auditors and the audit schedule, providing such information as necessary to facilitate the audit, initiating corrective actions in response to audit findings, and responding in writing to the audit report.

Process

Radian's Analytical Laboratory participates in a variety of planned and periodic assessment activities. These include self-assessments conducted by laboratory management, and independent assessments (i.e., audits), both internal and external, conducted by Radian's QA staff or by third party auditors on behalf of Radian clients or certification bodies. These activities are discussed in the following subsections.

17.1 Self-Assessment

Self-assessment activities are intended to improve quality by focusing on how well the integrated quality assurance program is working and by identifying problems that hinder the laboratory from meeting its objectives. Self-assessment involves all levels of laboratory management, and includes firsthand participation by senior management, especially in assuring that the assessment activities are productive, with prompt action initiated in response to assessment recommendations and follow-up evaluation of the effectiveness of actions taken.

The Radian Quality Management Plan and the quality system described in this systems manual provide for management evaluation of the quality system as well as other self-assessment activities.

17.1.1 Review and Update of Quality Systems

The primary objectives of the laboratory quality program are to consistently meet accepted performance specifications, to provide confidence to company management that the desired level of quality is being achieved, and to provide confidence to clients that their quality requirements are being met. As part of the self-assessment program, laboratory management reviews the overall quality system annually and evaluates its suitability and effectiveness for ensuring the continued achievement of its quality objectives. This assessment includes review and, if necessary, revision of quality policies and procedures.

The annual review of the quality system effectiveness consists of a comprehensive evaluation of the policies and procedures as well as an assessment of the results of internal and external audits. The focus of this evaluation is not only on how successful the quality system functions for ensuring achievement of its objectives, but also on whether any organizational, policy, or procedural changes in the system should be made. These changes may ensue from impetus such

as new strategic or tactical business decisions, new quality or technical concepts, or changes in client requirements.

This review includes appraisal of this *Analytical Laboratory Systems Manual* to determine whether the described policies and procedures are consistent with current practice. Any changes to the quality system which ensue from the evaluation of the system effectiveness are incorporated in a revision of the *Systems Manual* at this time. Procedures for making changes are the same as for the initial preparation, review, and approval of the *Systems Manual.*

As part of this review, laboratory SOPs and Protocol Specifications are revised annually by the responsible Laboratory Manager. This revision is intended to ensure that each SOP and Protocol Specification accurately represents the procedure and specification that are currently in use. The process for reviewing and revising existing SOPs involves obtaining an edit copy of the activity, making the appropriate changes, and submitting the revised document for approval in the same way as new procedures or specifications are approved.

17.1.2 Evaluation of Audit Findings

Radian's Analytical Laboratory participates in internal and external audits on a regular basis, as described in Section 17.2. Findings from audits are compiled by the Laboratory Quality Officer and reviewed semi-annually in the laboratory Quality Reports. This review is intended to determine if the planned and implemented corrective actions indicated by the audits have been effective in eliminating the root cause of identified problems. This evaluation is a retrospective review of previously implemented corrective actions and is independent of the analysis and root cause assessment associated with corrective actions at the time of the independent audit.

17.1.3 Quality Report

The Laboratory Quality Officer compiles a semi-annual Laboratory Quality Report recounting the status and progress on Protocol Specification development and use, control charting, external quality control requirements, QCERs, laboratory certifications and performance evaluation results. The report includes recommendations for improvement, if required.

17.2 Independent Assessment

A quality audit is a systematic and independent examination and evaluation to determine whether quality activities and results comply with planned arrangements and whether these arrangements

are implemented effectively and are suitable to achieve objectives (ANSI/ASQC A3-1987). Radian's Analytical Laboratory participates in planned and periodic independent assessments conducted by both Radian QA auditors (internal audits) and by third-party auditors (external audits). Internal audits may be conducted as part of the Radian Quality Audit Program, a routine schedule of independent assessments performed throughout the year in the various laboratories, or on a project-specific basis, scheduled as required. External audits may also be project-specific, or part of a certification or prequalification process. The types of quality audits normally conducted and the responsibilities of laboratory staff regarding audits are discussed in the following subsections.

17.2.1 Types of Audits

The types of audits typically conducted by Radian QA auditors and, according to their needs, by external auditing organizations include Management Systems Audits, Technical Systems Audits, Performance Evaluation Audits, and Data Quality Audits. Each of these is described in the Quality Assurance Systems Manual. Brief descriptions are presented below.

Management Systems Audits

The purpose of a Management Systems Audit is to evaluate the organization's quality management system. It is a qualitative review of the role of quality assurance in management. The strengths, weaknesses, and problem areas are evaluated. The audit is used to determine the extent to which quality assurance has been established within the organization.

Technical Systems Audits

Technical Systems Audits (TSAs) address compliance with specified procedures and overall effectiveness of the laboratory operations. A Technical Systems Audit 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 a measurement system. The TSA is based on adherence to approved methods, SOPs, policies, project plans, and systems plans. It does not provide a quantitative measure of quality, but does provide an evaluation of the effectiveness of a quality program. This type of audit addresses questions regarding items such as:

- Calibration procedures and documentation;

- Completeness of forms, notebooks, etc.;
- Data review and validation procedures;
- Data storage, filing, and recordkeeping procedures;
- Sample custody and handling procedures;
- Quality control procedures and documentation;
- Operating conditions of facilities and equipment; and
- Documentation of maintenance activities.

Performance Evaluation Audits

Performance Evaluation Audits provide a quantitative assessment of a system or process. These audits are applicable to any testing program where comparability to a standard is relevant. It provides a direct evaluation of the various measurement systems' capability to generate accurate data. This is accomplished by challenging the measurement systems with accepted reference standards.

Data Quality Audits

The purpose of Data Quality Audits is to assess data quality indicators. These are applicable in all areas where data are collected and will address the data trail supporting final results. Data Quality Audits provide information required to characterize data quality. These audits answer questions as to whether the data collection efforts need modifications, whether the use and documentation of quality control procedures are adequate, and whether sufficient documentation is maintained. In general, these audits provide information regarding:

- Adequacy of data recording and transfer;
- Precision and bias of resultant data;
- Adequacy of data calculation, generation, and processing;
- Documentation of procedures; and
- Identification of data quality indicators (e.g., flags) to inform users of limitations and applicability.

17.2.2 Audit Scheduling

Internal audits of each laboratory area are conducted annually under the Radian Quality Audit Program. These audits are scheduled by the Laboratory Quality Officer and Laboratory Managers. Client Service Coordinators work with the Quality Officer and Laboratory Managers to schedule project-specific audits.

Internal audit plans are prepared by the auditor prior to conducting the audit. The audit plan should identify the scope, requirements, personnel, activities to be audited, applicable documents, schedule, and procedures or checklists. The notification should be made to the cognizant activity manager, Quality Officer, and, for project-specific audits, the Client Service Coordinator.

Unscheduled audits may be conducted, but are uncommon. Normally, the laboratory may expect the following considerations with respect to audits:

- Notification of a forthcoming audit;
- A kickoff meeting to arrange audit activities within the laboratory;
- An audit wrap-up meeting to discuss findings;
- A copy of the audit findings, or final report;
- The opportunity to concur with or dispute audit findings before they are reported; and
- Limited interference with normal laboratory activities.

The laboratory has the following responsibilities with respect to audits:

- Designating an escort for the auditor;
- Furnishing access to facilities and information;
- Furnishing ample workspace for the auditor;
- Cooperating with the auditor;
- Attending audit meetings;
- Evaluating the correctness of audit findings;

- Initiating prompt corrective action; and
- Refraining from interfering with the audit.

17.2.3 Responses to Audit Findings

Following each internal audit, and typically for external audits, a wrap-up/debriefing meeting is held between the auditor(s), Laboratory Quality Officer, and the appropriate Laboratory Manager to review and discuss any preliminary recommendations. At a later date, the auditor prepares a formal report detailing the audit activities. The principal laboratory contact with the auditor responds to the audit report. Responses to audits should be submitted to the lead auditor within 30 days of receipt of the audit report and should include the following, as applicable:

- Action to correct the deficiency;
- Root cause identification;
- Actions to prevent recurrence;
- Lessons learned; and
- Actions to be taken for improvement.

The Laboratory Quality Officer tracks the results of all audits, including findings, recommendations for improvement, corrective actions implemented, and evaluation of the effectiveness of actions taken.

Systematic problems or significant deficiencies identified via internal audits are reported and tracked using the Recommendation for Corrective Action (RCA) system. All RCAs are issued in accordance with the Quality Management Procedure QA/QMP006, "Procedure for the Recommendation for Corrective Action (RCA) System". The RCA system is designed to identify a specific problem, to recommend a course of action, to identify a person responsible for implementing the corrective action, to verify implementation, and to document correction taken as a result of the RCA. Each RCA requires a written response from the responsible party to whom it was issued.

SECTION 18
TRAINING

> ***The supplier shall establish and maintain documented procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality.***
> ***—Q9001***

> ***Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory, including records on demonstrated proficiency for each laboratory method.***
> ***—NELAC***

Policy

Individuals performing work directly or indirectly related to Radian projects shall have a combination of education, training, and experience appropriate to perform their assigned duties. Radian Analytical Laboratories shall identify training needs and provide for the training of all personnel performing activities affecting quality. Training records shall be maintained by laboratory management. The training records shall document the relevant qualifications, training, skills and experience of technical personnel, including records of demonstrated proficiency for each laboratory method.

Responsibilities

The Technical Director and Laboratory Managers are responsible for establishing the training requirements, and for conducting and documenting the training for all technical personnel.

The Document Control Officer is responsible for maintaining training records of laboratory personnel.

Process

The general requirements for training at the laboratory are described in the Quality Management Procedure, AL/QMP005, "General Training." A description of the corporate training program, as well as a discussion of the details of laboratory-specific training, is presented below.

For Radian's laboratory to achieve and maintain the kind of responsive, reliable services that are necessary to meet the Radian project needs, we must have staff who are highly qualified and well trained. Laboratory staff managers meet this need through regular planning to make sure that

they have a thorough understanding of the staff needs for the laboratory operation. This is coupled with a commitment to hiring only qualified candidates for all positions. Finally, staff training and development is given priority so that staff can grow to meet the changing laboratory needs.

18.1 Determination of Initial Capability and Qualification

Technical staff managers determine the staff needs of the area for which they are responsible. This requires a thorough understanding of the technical requirements of the tasks performed in their areas as well as projected needs dictated by project requirements. Selection of new staff in Radian Analytical Laboratories is made based upon certain general qualifications, the requirements of the specific job, and upon the technical capability of the potential staff member.

Prior to selection of new staff, either as a new hire to Radian or from another position in the company, the technical capability of the potential staff members must be assessed. Potential staff shall have the educational training or work experience commensurate with that required for the staff level that they would be assigned. Also, each candidate for a position with Radian Analytical Laboratories shall have the educational training, skills, and/or job training defined for that specific position. Job descriptions and responsibility for job categories that are common to multiple project or functional areas of Radian are provided in the Corporate Systems Manual and its referenced documents. A description of the staff levels and general expectations for each is included in Tables 18-1 and 18-2.

18.2 Training

It is Radian's objective that the quality of its products and technical services be consistent regardless of who does the work. This degree of standardization requires a training program which is flexible enough to meet the diverse needs of a number of different technical service areas, while ensuring that all employees receive the training necessary and appropriate to their specific work area. This is achieved through initial indoctrination upon arrival at Radian followed by a two-tiered training program which includes a centrally administered general program of regularly scheduled courses of broad applicability, supplemented by additional job- and task-specific procedural training.

18.2.1 Indoctrination

Provisions for indoctrination of employees depend on employee work assignments. All new employees in Radian Analytical Laboratories attend general orientation, laboratory safety, and hazard awareness sessions. General orientation addresses the motivating principles and concepts underlying Radian's approach to quality, as well as technical and managerial precepts fundamental to conducting business at Radian.

It is the responsibility of the Technical Director to define the training requirements for the specific jobs in the laboratories. The requirements are communicated upon initial assignment through the Laboratory Managers who ensure that their analysts are adequately indoctrinated in the standards and regulations necessary to perform the work. Additionally, all new employees will be required to read this manual as soon as possible following their hiring to familiarize them with the overall Analytical Laboratory's Quality System and to introduce them to its policies, procedures, and guidelines for producing at a quality product.

Table 18-1. Expectations of Research Assistants at Radian

Area	RA I	RA II	RA III	RA IV	RA V	R Assoc.	Sr. R. Assoc.
Technical Skills/Abilities	Comprehends written instructions and maintains a notebook, as required in the performance of standardized procedures	Performs semi-routine procedures and is familiar with the resources used to perform them. Develops graphs, charts, and tables, and performs basic mathematical calculations required to carry out such procedures.	Performs non-routine procedures and is familiar with the standards of operation used to perform them. Recognizes and reports inconsistencies in data.	Has a thorough knowledge of techniques and basic technical literature, required to complete more complex task assignments.	Analyzes problems associated with task assignments and modifies procedures to successfully meet the objectives of the task. Recognizes and addresses the quality control aspects of these tasks.	Plans, executes and/or manages a project or tasks of limited scope, but which may require non-routine judgements and decisions. Is recognized internally as an expert in the procedures associated with their work.	Develops and/or adopts operational procedures and the associated quality control to allow other people to accomplish projects or tasks of limited scope.
Communications -Internal	Communicates with supervising scientists/engineers and research assistants as required to complete assigned tasks	Comprehends detailed written or oral communications from a variety of scientists/engineers and research assistants as required to complete assigned tasks	Reports results of laboratory or field tests in standard written formats.	Reports data and operational procedures both orally and in writing to supervising scientists/engineers.	Contributes to the report writing phase of projects. Communicates to train and supervise less experienced research assistants or scientists/engineers.	Communicates effectively at all levels of the company regarding scheduling and performance of work. Prepared written reports on laboratory or field test findings and recommendations.	Actively promotes the technical and personal development of less experienced staff in his/her technical area.
Communications -Client	None expected.	None expected	None expected.	Presents a professional, responsive image when interfacing with the client.	Communicates effectively with clients on a technical level.	Communicates effectively with clients on both technical and project management issues.	Communicates independently with clients on both technical and project management issues.
Knowledge of Radian	Knows Radian's objectives, goals, and policies, including Quality Specifications, safety procedures, and practices.	Knows the policies and operational procedures applicable to his/her work area.	Knows the capabilities of his/her group.	Knows Radian's organizational structure.	Knows Radian's policies and procedures. Knows the capabilities and resources of his/her section or department.	Knows Radian's overall capabilities and resources, as required to staff and perform projects for which he/she is responsible.	Knows Radian's capabilities and resources, and can market them effectively to clients.
Personal and Project Management Skills	Performs work under close supervision.	Performs work under general supervision.	Meets deadlines with high quality work. Assists less experienced RAs.	Sets and meets personal deadlines associated with the performance of tasks. May supervise other less experienced staff.	Performs work independently. Plans and conducts tasks consistent with the PQS.	Accountable for the quality, timeliness and efficiency of all work conducted.	Actively involved in the close supervision and training of others.
Years Experience (Since High School)	0 minimum; 0-4 typical; (entry level for High School Graduate).	1 minimum; 2-6 typical; (entry level for AA degree in related field).	3 minimum; 4-10 typical; (entry level for BS in related field or AA degree in specific field).	5 minimum; 6-16 typical	8 minimum; 10+ typical.	15 minimum; 15+ typical.	25 minimum; 25+ typical.

These expectations are considered typical for the job description of each specific classification; in the course of a year, individuals will have some assignments that will have higher and lower expectations than those listed for their job classification.

Table 18-2. Expectations of Exempt Technical Professionals at Radian

Area	Assoc. E/S/S	Engr/Sci/Spec	Staff E/S/S	Senior E/S/S	Sr. Staff E/S/S	Principal E/S/S
Technical Skills/Judgement/ Creativity	Applies fundamentals to solve well-defined problems; seeks assistance when needed.	Completes well-defined tasks accurately (can quality-assure own work).	Plans as well as executes tasks, assures the quality of others' work; identifies follow-on tasks to ongoing work.	Develops technically sound, innovative, and cost effective solutions to ill-defined problems.	Is recognized internally as an expert in key Radian business area; is used extensively in peer review roles.	Is recognized externally by key clients as an expert in his/her technical area; develops SOPs and peer review guidelines applicable to his/her work area.
Communications	Communicates clearly and effectively with TS supervisors and project managers	Interacts maturely with supervisors, peers and peer reviewers; communicates problems promptly.	Gives clear instructions and timely/constructive feedback to personnel working on his/her tasks; proposes solutions when problems are identified	Anticipates and communicates effectively in order to solve problems; is an effective peer reviewer of proposals and project deliverables.	Works with technical staff managers to motivate and train junior staff with developmental interests in his/her work area.	Actively promotes internal technical development programs to keep Radian at the forefront of his/her work area.
Knowledge of Radian	Works to acquire a basic understanding of Radian's policies and procedures, organization, approach to performing projects, etc.	Knows what is expected of a Radian professional; knows Radian policies and procedures applicable to his/her work area	Knows the capabilities of his/her group/work unit.	Knows the capabilities of his/her section or department and effectively promotes them internally.	Is aware of Radian's corporate capabilities and effectively represents those capabilities externally.	Understands Radian's CBD process; leads CBD projects to develop viable new products and services.
Project Management Skills	None – the focus at this level is on learning to manage oneself.	Manages own time effectively to meet commitments.	Effectively directs their own and others efforts to accomplish required tasks.	Directs substantial projects or tasks with minimal support using the PQS	Independently plans and manages very large projects or tasks using the PQS.	Independently plans and manages very large projects or tasks using PQS
External Visibility/Credibility	None.	None	Limited.	Is recognized by clients as a key Radian performer; gives occasional technical papers.	Publishes regularly.	Publishes extensively; chairs technical sessions at national symposia.
Required Training for Promotion to Next Level	New Employee Orientation; Safety Orientation.	Time Management; Technical Writing.	Project Direction I; Proposal Writing.	Project Direction II; Program Manager.	Delivers in-house seminars in his/her area of technical expertise.	Presents external seminars and training courses in his/her area of expertise.
Years Experience (since BS)	0 minimum; 0-2 typical.	1 minimum; 2-6 typical.	3 minimum; 4-12 typical.	6 minimum; 8-18 typical.	10 minimum; 15+ typical.	15 minimum; 20+ typical.

18.2.2 General Training

At the company level, Radian offers a broad program of training courses which are applicable to staff across various departments and locations. These courses cover a variety of development areas, including:

- Health and Safety;
- Administrative areas (G&A, procurement, subcontracting, for example);
- Management and leadership development; and
- Technical.

Individual courses range in duration from single classes (e.g., Hazard Communication Training and CPR Training) to classes which meet weekly for several months (e.g., Introduction to Statistics and Excellence in Leadership). Through these courses, Radian ensures that managers and technical personnel develop not only the technical skills to do their job, but also the management and communication skills needed to perform their jobs with excellence.

The current course list comprising this program is disseminated by means of a training calendar distributed through Radian's managers to the staff and posting on the Radian e-mail system. These courses include personal development courses, management courses, technical skills courses, and health and safety courses. While participation in many of the courses is elective, specific training expectations are delineated for each technical level on the technical staff achievement ladder.

18.2.3 Procedural Training

While general training gives the staff an overview of company procedures and policies as well as provides for training in areas that are applicable to staff development across all of Radian International (e.g., Technical Writing), specific procedural training is required prior to execution of any of the tasks performed in the Analytical Laboratory System. Adequate training ensures that procedures are done in accordance with the method, in a safe manner, and in compliance with the quality specifications required for the job.

It is the responsibility of the Technical Director to develop and ensure implementation of the training programs required to meet this need.

General training specific to the laboratory can include health and safety training, statistical process control, laboratory documentation, environmental requirements (i.e., "room checks"), and operation of general laboratory equipment (balances, ovens, etc.).

Procedural training is typically carried out by the employee's immediate supervisor or a senior analyst and consists of a combination of reading (methods, Protocol Specifications, SOPs), observation, and carrying out a task under supervision.

The final procedural training step is for the analyst to carry out a Demonstration of Capability prior to the performance of any specific protocol on client samples. This typically consists of quadruplicate analyses on an appropriate matrix. Requirements for the Demonstration of Capability and any other procedure specific training requirements are documented in the Operational Specifications of each Protocol Specification.

18.2.4 Training Documentation

Documentation of attendance at company training courses is maintained by the Corporate Training Coordinator. Attendance sheets are used to document individual employee participation and this information is transferred to a computerized training database. A summary of this training is distributed to managers annually (at a minimum) or on an as-needed basis.

Certification for the OSHA Health & Safety 40-hour training, CPR, and other health and safety training as needed will be provided by Environmental Affairs Systems.

Training records that are specific to Analytical Chemistry and the procedures performed within that area are kept in individual training files which are maintained electronically. It is the responsibility of employee's immediate supervisor to make certain that individual training files are current and complete. The Technical Director is responsible for ensuring that department training records are periodically reviewed.

18.3 Evaluation of Performance

Another important component of Radian's quality management program is the annual performance evaluation process. Through this process, Radian managers recognize the good work of their employees and identify areas that need improvement. New employees are evaluated less formally and sooner to alert them to potential areas of improvement. In private

performance evaluation discussions, training needs are identified and personal performance goals for the coming year are established.

Additionally, routine technical review and surveillance of the tasks performed by members of Analytical Chemistry are carried out by the Laboratory Managers to ensure that the highest quality work possible is being performed. Through this process, the managers are able to identify additional training that may be needed by individual staff members and correct deficiencies in performance as they are occurring.

SECTION 19
SERVICING

> ***Where servicing is a specified requirement, the supplier shall establish and maintain documented procedures for performing, verifying, and reporting that the servicing meets the specified requirements.***
> ***—Q9001***

> ***The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of NELAC Standard or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those involved areas of activity and responsibility are promptly audited .***
>
> ***After issuance of the report, the laboratory report shall remain unchanged. Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Test Report or Test Certificate, serial number [or as otherwise identified], or equivalent form of wording. Such amendments shall meet all the relevant requirements of the Standard.***
>
> ***The laboratory shall notify clients promptly, in writing, of any event, such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report or test certificate or amendment to a report or certificate.***
> ***—NELAC***

Policy

Radian Analytical Laboratories shall follow established procedures for the resolution of defects in Radian analytical reports, or complaints related to laboratory activities pertaining to measurement procedures, protocol, or reported data.

Responsibilities

Client Service Coordinators are responsible for initiating requests for reanalysis or reissuance of reports, either electronic or hardcopy.

The affected Laboratory Manager is responsible for ensuring that the defect was corrected and that the service was effective in meeting the client specifications.

The Operations Manager is responsible for tracking problems requiring rework and with reporting those problems to management.

Process

Radian Analytical Laboratories produce analytical reports. Reports are reviewed and approved through laboratory processes prior to release of the reports. In the event that the analytical procedures, quality system activities, or report deliverables (hardcopy or electronic) do not meet client requirements, Radian will initiate corrective actions to resolve the deficiency and deliver a conforming product to the client.

SECTION 20
STATISTICAL TECHNIQUES

> ***The supplier shall identify the need for statistical techniques required for establishing, controlling, and verifying process capability and product characteristics.***
> ***—Q9001***

Policy

Radian Analytical Laboratories shall identify the need for and establish procedures addressing the use of statistical techniques for establishing, controlling and verifying measurement process capabilities and characteristics.

Responsibilities

The Technical Director, Quality Officer, and Laboratory Managers are responsible for establishing control limits and tolerances and making sure they are updated as needed using appropriate statistical methods.

Process

The use of statistical methods is an important tool in the Analytical Laboratory System as part of the quality improvement process. Statistical methods are used both to evaluate and control technical parameters, as well as to monitor operational aspects of the laboratory. Further, trends in analytical data or laboratory performance are monitored over time. Trend analysis is used to prompt changes to Protocol Specifications or particular laboratory systems to improve overall laboratory quality.

One use of statistical methods in the Analytical Laboratory is defining various laboratory limits and tolerances. Examples and short definitions of some of these limits and tolerances are given in Table 20-1.

Statistical control is assessed in the Analytical Laboratory System using real-time control charts. Specific performance measures are charted as defined in each Protocol Specification by the analyst immediately after analysis. The control limits and trend rules are established using applicable statistical methods. Statistical control compliance for both accuracy and precision is tracked on the Quality Traveler (QT), as described in the Quality Management Procedure, AL/QMP003, "Quality Traveler."

Protocol Specification compliance is monitored on the QT and reviewed by all Laboratory Managers on a regular basis as part of their input to the Laboratory Quality Report. All areas of laboratory performance are assessed: technical, procedural, and operational. QCER frequency and problem identification are also reviewed regularly by the Laboratory Managers as input to the Quality Report.

In addition to these quality control data which are addressed statistically to effect overall quality improvement, various operational data are also tracked in the same manner. Efficient operation of the laboratory is also important. Examples, with short descriptions of operational data tracked in the Analytical Laboratory, are listed in Table 20-2. Each is tracked by the Operations Manager on a weekly basis. Information, with graphical presentations, are given to pertinent laboratory staff members in the weekly scheduling meeting. These data are tracked over time to monitor trends in laboratory operational performance. Any appropriate measures are taken, as indicated by these trends in performance.

Table 20-1. Representative Limits and Tolerances

Laboratory Limit/Tolerance	Definition
Method Detection Limit (MDL)	Determined annually (or more often if specified by the method) for each analyte in each Protocol Specification and documented to be less than or equal to the Protocol Required Detection Limit (PRDL). The MDL study is performed following procedures in 40 CFR Part 136 Appendix B.
Reporting Limit	Performance specification for reporting data to a specific project. The Reporting Limit is the concentration below which numerical data are not reported to the project. The default Reporting Limits are numerically equivalent to the PRDLs. A project team may establish alternative Reporting Limits for their project. The project team may choose Reporting Limits greater than, less than, or equal to the PRDLs depending on the analytical needs of their client.
QC Tolerances	Protocol Specification QC tolerances (e.g., LCS/LCSD, MS/MSD, surrogate recovery) are reviewed annually and updated as needed based on historical data using statistical methods
Instrument Control Limits	Individual instrument control limit based on historical data using statistical methods

Table 20-2. Statistical Methods Used For Laboratory Operations

Laboratory Operational Tool	Definition
On-Time Delivery	All workorders tracked per turn-around-time requirement in Protocol Specification by laboratory area. Laboratory tolerance is 90% on-time delivery with no more than 5% overdue work in the whole laboratory.
Reopened Workorders	Frequency of type of problem causing reopened workorders in each laboratory area.
Laboratory Sample Capacity/Sample Projections	Sample capacity per week for each laboratory area determined from available personnel and equipment/instrumentation. Sample projections use laboratory capacity figures to schedule samples into the laboratory for analysis.
Samples Received vs. Samples Projected	A projections tool that is monitored weekly.
Completed Work vs. Sample Capacity	Check of each laboratory area to assess laboratory throughput on a weekly basis.

SECTION 21
SAFETY

Policy

Radian International believes that employee safety and the prevention of property loss are as important as product quality, responsiveness to clients, and cost control. Radian is committed to complying with all federal, state, and local occupational safety and health regulations applicable to Radian work sites. Where regulations inadequately address workplace hazards, Radian is committed to complying with consensus standards and/or recognized good health and safety practices.

Responsibilities

All employees are responsible for working safely and for reporting any safety problems or potential problems to management.

The Laboratory Environmental Health and Safety Coordinator is responsible for implementing the health and safety program for the laboratory. Responsibilities for Environmental Health and Safety staff are described in the following sections.

Process

The following sections summarize Radian's company-wide approach to health and safety, the Analytical Laboratory Section requirements, and selected references in the area of health and safety.

21.1 General Company Requirements

The general company requirements in regard to health and safety are described in the Environmental Affairs Systems Manual, which is part of Radian's Quality Management Plan. The Corporate Director of Health and Safety (CDHS) is responsible for the preparation, implementation, and revision of the Environmental Affairs Systems Manual and the supporting documents that it references, which detail the policies and procedures that are established in regard to health and safety.

Radian is committed to providing a safe and healthful workplace for its employees. Each Radian employee has a role in maintaining safe working conditions and in performing work safely. A

detailed discussion of particular responsibilities of Radian staff appears in Radian's Health and Safety Manual. This manual also describes the hazard communication programs which are developed in response to the requirements in the Hazard Communication Standard (29 CFR 1910.1200) for employers to provide information to their employees about hazardous chemicals in the workplace.

The Health and Safety Manual documents Radian's Respiratory Protection Program, which ensures proper selection, use, and maintenance of respirators as required by federal regulatory standards (29 CFR 1910.134); Radian's hazardous waste minimization program; and guidelines that are designed to ensure proper dangerous goods shipment according to Department of Transportation (DoT) Hazardous Materials Regulations (49 CFR) and the International Air Transport Association (IATA) Dangerous Goods Regulations. The Health and Safety Manual also serves as the Chemical Hygiene Plan mandated by 29 CFR 1910.1450, which is designed to ensure the protection of Radian laboratory workers from health hazards associated with hazardous chemicals.

In addition to the Health and Safety Manual, the Medical Monitoring Manual documents Radian's Medical Monitoring Program, which is established for employees engaged in potentially hazardous activities. This program provides medical examinations for employees in certain jobs. Finally, the Radiation Protection Manual defines Radian's Radiation Protection Program. The three objectives of this program are to maintain worker radiation exposure at a level which is as low as is reasonably achievable, to contain radioactive materials in areas in which their presence is intended, and to document the components to ensure compliance with license and registration requirements.

21.2 Analytical Laboratory Requirements

This section describes the specific health and safety requirements for the Analytical Laboratory System. It is expected that all laboratory operations will be carried out in accordance with principles and procedures described in Radian's Environmental Affairs Systems Manual and its referenced documents. In addition, laboratory operations must meet the rules and regulations of federal, state, and local authorities. Specific Standard Operating Procedures (SOPs) have been developed and implemented for certain safety related topics such as glass crushing and hazardous waste operations.

21.2.1 Health and Safety Responsibilities

Each laboratory staff member has a role in maintaining safe working conditions and in performing work safely. Radian's Health and Safety Manual describes the general responsibilities of the company staff. Particular responsibilities of the laboratory staff are delineated below.

Staff Managers

The Analytical Laboratory staff managers include the Unit Leader, Technical Director, Operations Manager, and Laboratory Managers. These individuals, working in concert with the Laboratory Environmental Health and Safety Coordinator (EHSC) and the laboratory safety team, are responsible for ensuring that all activities under their control are conducted in a safe, professional manner. Further, they ensure that sufficient resources to allow the staff to perform work safely. They are also responsible for identifying and properly managing hazards that may be encountered. The staff managers will review each employee's job profile to assure that proper health and safety training is provided. Specifically, the staff managers:

- Review the scope of any planned project to identify potential health and safety issues;
- Conduct hazard assessments, with the assistance of the local Environmental Health and Safety Coordinator (EHSC), of laboratory operations to identify problem areas;
- Ensure compliance with applicable regulations, corporate guidelines, and specific laboratory health and safety procedures;
- Address and resolve all health and safety concerns expressed by the staff; and
- Report accidents, near misses, and unusual safety problems promptly to the EHSC or CDHS.

Environmental Health and Safety Coordinator (EHSC)

As described in the Health and Safety Manual, most Radian offices have a designated Environmental Health and Safety Coordinator (EHSC) who shares responsibility with the CDHS for implementing all company health and safety programs at the local level. The analytical laboratory is an area that is deemed to have significant health and safety issues which are faced on a daily basis. As such, the laboratory has a designted EHSC.

The EHSC directs monthly meetings of the laboratory safety team, which comprises a representative (who is not a laboratory manager) from each laboratory. The EHSC is also responsible for:

- Conducting annual safety inspections, with representatives of the safety team, of each laboratory area;
- Conducting specific hazard assessments as required by the Analytical Laboratory staff managers;
- Notifying the Technical Director of any specific safety training needs for the staff;
- Communicating the adequacy or deficiency of the health and safety performance, as well as the effectiveness of specific health and safety procedures, to the staff managers; and
- Assisting the staff managers in modifying health and safety procedures to adjust for deficiencies and to deal with new needs.

Staff Members

All Radian employees, including staff members of Radian Analytical Laboratories, are responsible for maintaining and promoting safety awareness. They must familiarize themselves with all company programs, policies, and procedures, as well as specific requirements of the Analytical Laboratory System. In doing so they must be able to identify and deal properly with hazards they may encounter.

All staff members also have a responsibility to know and use available company resources. They should know when and how to use appropriate personal protective equipment and be familiar with health and safety resources, emergency procedures, and available training programs. Each staff member must read, understand, and comply with the guidelines set forth in this manual and any specific health and safety procedures that are implemented.

21.2.2 Hazard Communication

All Analytical Laboratory personnel take part in Radian's Hazard Communication Program. This program is designed to meet the requirements of the Hazard Communication Standard (29 CFR 1910.1200) and ensure that each employee is aware of the hazards and safe handling procedures of the chemicals with which they work. This program is described in the Radian Health and Safety Manual. Each employee must read, understand, and comply with the program plan. Also, each employee must work safely and be aware of any unsafe conditions and report those to their immediate supervisor.

In addition to the general components of the corporate program, the Analytical Laboratory program includes specific policies in regards to hazard information. Chemical hazard information is collected for each product procured by the laboratory and documented in the form of a Material Safety Data Sheet (MSDS). Copies of MSDSs are maintained in central locations for easy access by all personnel. Original copies of each MSDS are also maintained in a central file. Any staff manager or staff member who procures any unusual or potentially hazardous chemicals or a shipment of samples which are out of the ordinary or potentially hazardous, has the responsibility of notifying the EHSC who will prepare a suitable Project Health and Safety Plan for the situation.

21.2.3 Respiratory Protection Program

The Radian Respiratory Protection Program was developed to ensure respirators are properly selected, used, and maintained by Radian employees according to federal regulatory standards (29 CFR 1910.134). The principal personal protection system within the laboratory is the engineering controls, such as general and local ventilation.

Laboratory Managers determine whether respiratory protection is required for an employee when they complete their Medical Monitoring Evaluation sheet with the employee. This is done whenever there is a change in job assignment and reviewed annually. If the employee requires respiratory protection, they are assessed for their physical and psychological fitness to wear a respirator as part of the corporate Medical Monitoring Program. Staff members must be fit-tested and trained by the EHSC before using respirators.

21.2.4 Waste Management

The requirements set forth in the Radian Health and Safety Manual for minimizing the generation of liquid and solid wastes (particularly hazardous wastes) apply to all laboratories. All Laboratory Managers and their staff periodically review laboratory operations to determine if all reasonable measures are being taken to minimize wastes. All staff members must be aware of all regulations and company guidelines to manage wastes in their area in addition to the specific requirements instituted within the Analytical Laboratory System.

21.2.5 Dangerous Goods Shipping

The shipment of dangerous goods according to either DoT regulations (49 CFR) or IATA regulations is an integral part of laboratory operations. All members of the laboratory staff are indoctrinated to company policies and procedures in regards to shipping dangerous goods through the participation in corporate training courses. These courses include the corporate S-2 Course for anyone involved in routine dangerous goods shipments, the S-3 Course which is a general shipping awareness course, or the health and safety orientation course which introduces employees to the basic issues involved in shipping dangerous goods.

In addition to this general training requirement for all laboratory staff, the laboratory also maintains a group of staff members who have completed training (S-1) as company Shipping Specialists. Shipping Specialists give guidance in proper shipping techniques. In the Analytical Laboratory System, the Shipping Specialists have primary responsibility to ensure that:

- All materials and samples are approved for shipment by the selected mode of transportation;
- All materials and samples are properly classified, packed, marked, and labeled;
- Shipper's declaration of dangerous goods has been properly completed and signed; and
- Requirements for overpacks and freight containers have been met.

21.2.6 Laboratory Operations

The Laboratory Operations section of Radian's Health and Safety Manual serves as the Chemical Hygiene Plan (mandated by 29 CFR 1910.1450). The Chemical Hygiene Plan defines general health and safety practices applicable to all Radian laboratories. This plan is augmented by various laboratory-specific SOPs.

The SOPs implemented within the Analytical Laboratory System detail specific work practices for laboratory operations. These include SOPs covering general work practices, emergency procedures, personal protective equipment, and laboratory inspections, hazardous waste and glass crushing operations. Also included are SOPs discussing training with particular emphasis on laboratory training. Each worker must read and understand each SOP pertaining to a particular operation before beginning that operation. All workers become familiar with all health and safety SOPs relating to their work area.

21.2.7 Medical Monitoring

Radian has established and maintains a Medical Monitoring Program as described in the Radian Health and Safety Manual and the Medical Monitoring Manual. This program provides for baseline medical exams for employees in specified jobs, periodic medical exams over the course of employment at Radian to assess the worker's long-term medical status, and exams or consultations in the event of an exposure or suspected exposure. Inclusion in this program is based upon the employee's job profile that describes work activities and potential exposures for typical Radian work environments. All laboratory workers in the Analytical Laboratory System are assigned a job profile.

The Medical Monitoring Manual describes each job profile category and lists potential physical and chemical hazards as well as personal protective equipment. The manual also describes the medical monitoring protocol and schedule that has been developed for each job profile. Records of medical examinations are maintained in a manner that is consistent with OSHA regulations and medical ethics relating to confidentiality of patient information.

21.2.8 Health and Safety Training

It is a goal of Analytical Laboratory System that all staff members be able to recognize and understand the potential risks associated with their work. The health and safety training requirements for each job profile, is detailed in Radian's Medical Monitoring Manual and described generally in the Health and Safety Manual. The Analytical Laboratory managers have the primary responsibility for ensuring that the staff members have the appropriate training and will maintain copies of training records for all employees under their supervision.

In addition to the specific training protocol detailed for each subprofile in the Medical Monitoring Manual, all laboratory personnel receive training regarding the proper work practices required within the laboratory. This training is provided by the Laboratory Managers and is a one-time requirement upon initial assignment to the Analytical Laboratory System. The location and use of personal protective equipment are described as well as emergency equipment, potential chemical hazards and risks. The Laboratory Managers maintain records of initial training.

21.2.9 Accident Reporting

All Radian employees have a responsibility to report accidents, injuries, work-related illness, and near misses under the Radian Accident Reporting Program. Supervising personnel have a responsibility to ensure that unsafe working practices or conditions affecting personnel under their supervision are promptly corrected. The Analytical Laboratory System handles the reporting of accidents in a manner consistent with the corporate program.

Specifically, all laboratory personnel have the responsibility to initiate the accident reporting sequence by communicating with their supervisors as soon as possible after an incident they observe or to which they fall victim. The Laboratory Managers are the primary persons responsible for completing and submitting the required written accident reports for their staff members. The specific procedures to be followed in determining what is a reportable incident and in completing the necessary reports are described in the Radian Accident Reporting Program in the Health and Safety Manual. Additionally, any incident occurring in a laboratory should have the required reports include the cognizant Laboratory Manager in the distribution.

21.3 Safety References

This section describes several references available to laboratory employees that describe health and safety policies, procedures or guidelines. These references are available both to provide direction to employees in the conduct of their work and as resources for addressing questions regarding health and safety issues. They are meant to define Radian's company health and safety policies and to provide information and guidance in complying with applicable regulations and recognized good work practices.

21.3.1 Environmental, Health, and Safety Systems Manual

The Radian *Environmental, Health, and Safety Systems Manual* is a document specifically prepared and implemented to define Radian's company policies in the area of health and safety. It is meant to be used by both Radian employees and managers as guidance in complying with government regulations and establishing good work practices. The Corporate Director of Health and Safety (CDHS) is responsible for the periodic review and updates to this document. The *Environmental, Health, and Safety Systems Manual* is posted on the Radian intranet and is accessible to all employees.

21.3.2 Radian International Medical Monitoring Manual

The Medical Monitoring Manual serves as documentation of the Radian Medical Monitoring Program. This program is maintained for employees engaged in potentially hazardous activities. It provides for medical exams for employees in certain job categories. The manual details the specific monitoring protocols and schedules for each of the job profiles at Radian, as well as the basic health and safety training requirements for each profile. The CDHS is responsible for auditing the program and for periodically evaluating the overall program effectiveness.

21.3.3 Radian International Radiation Protection Manual

The Radiation Protection Manual is a document prepared to define Radian's Radiation Protection Program. The three objectives of this program are to maintain worker radiation exposure at a level that is as low as is reasonably achievable, to contain radioactive materials in areas in which their presence is intended, and to document the components to ensure compliance with license and registration requirements. The Analytical Laboratory System has instituted a radiation screening program in Sample Control to survey incoming samples for radioactivity so that they may be handled safely. Electron capture detectors are also wipe-tested on a semi-annual basis to verify no leakage of radioactive Ni-63. Radian maintains a radioactive materials license issued by the Texas Department of Health to handle various radionuclides in specified laboratories.

21.3.4 Material Safety Data Sheets

The Hazard Communications Program implemented by Radian requires that Material Safety Data Sheets (MSDSs) be obtained or developed for each hazardous chemical it produces or imports. MSDSs obtained from outside vendors or suppliers are maintained as part of a master MSDS file at each Radian office. Data included on the MSDSs are chemical and physical properties, toxicological properties, hazards, safety and handling information, exposure and first aid instructions, and spill response instructions.

21.3.5 Regulatory Documents

One of the key elements of the company health and safety program is regulatory compliance. Regulatory compliance is the responsibility of every Radian employee. Ensuring that the facilities and personnel are in compliance with the applicable regulations is a management responsibility. Several federal and state regulations as well as certain federal agency guidelines provide specific direction or guidance in the safe handling of hazardous materials. A few of the

primary documents, which have direct effect on Analytical Laboratory operations, are briefly summarized below.

OSHA Safety and Health Standards (29 CFR 1910)

OSHA regulations specify the general industry safety standards applicable to all workplaces. In addition, they contain one subpart specifically applicable to work involving hazardous materials. Subpart Z - Toxic and Hazardous Substances contains standards for handling specific chemicals. A generic form of these standards has been developed by Radian and is the basis of all procedures for handling toxic chemicals.

Occupational Safety and Health

The State Department of Occupational Safety and Health administers the Texas occupational safety and health statutes (General Statute 95-121(1)). These statutes closely resemble the federal OSHA statutes, and Radian's Texas-based facilities including the Analytical Laboratory are in full compliance with both.

Resource Conservation and Recovery Act (RCRA)

The RCRA regulations define the requirements for management, storage, transportation, and disposal of hazardous wastes. In many states, administration of the RCRA waste management system has been transferred to individual state governments, with the federal regulations serving as minimum standards. Radian's facilities must comply with all RCRA generator requirements. Compliance with RCRA is the responsibility of the Environmental Health and Safety Coordinators.

Hazardous Wastes

In Texas, the Texas Natural Resources Conservation Commission (TNRCC) administers the RCRA-mandated waste management system on behalf of U.S. EPA. The Analytical Laboratory operates in full compliance with these requirements.

Department of Transportation (49 CFR 100-199)

The Department of Transportation (DoT) regulations govern the methods and modes of shipping hazardous materials within the United States. Shipment of bulk chemicals to and from the

Radian facilities is subject to the DoT regulations. Compliance with DoT shipping regulations is the responsibility of the Shipping Specialists.

International Air Transport Association (IATA)

The IATA regulations govern shipments of hazardous materials in national and international airspace. These regulations impact the laboratory operation when samples are shipped by air. Air shipments with both national and international routes must comply with both DoT and IATA regulations. Specific airline tariffs also impact such shipments. Compliance with the IATA regulations is the responsibility of the Shipping Specialists.

Nuclear Regulatory Commission (NRC)

The NRC regulations apply to two aspects of laboratory operations associated with the Analytical Laboratory System. The operation and monitoring of equipment containing radioactive sources (e.g., electron capture detectors for gas chromatographs) must be performed according to NRC regulations. Secondly, use and storage of radioactively labeled chemicals are regulated by NRC, DoT, and state regulations.

Radioactive Materials

The State of Texas is an NRC "agreement state"; activities involving radioactive materials are permitted and monitored by the Texas Department of Human Resources, Division of Radiation. The state regulations are virtually identical to the NRC regulations discussed above.

United States Department of Agriculture (USDA)

Handling of USDA-restricted soil samples at Radian Analytical Laboratories is described in the laboratory Quality Management Procedure, AL/QMP006, "Handling of USDA Restricted Soils for Analysis." This procedure addresses restricted domestic and foreign soils, in accordance with the Animal and Plant Health Inspection Service quarantine regulations. Parts 330.300 and 330.302.

UNCONTROLLED

Quality Assurance Manual

Prepared for:

ECOLOGY AND ENVIRONMENT, INC.
Analytical Services Center
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List of Tables and Illustrations

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Figure

List of Acronyms

% D	percent difference
% R	percent recovery
AA	atomic absorption spectrophotometers
APHA	American Public Health Association
ASC	Ecology and Environment's Analytical Services Center
ASTM	American Society for Testing and Materials
AWWA	American Water Works Association
BFB	bromofluorobenzene
BOD	biochemical oxygen demand
BOD_5	5-day biochemical oxygen demand
CAD	computer-aided design
CFR	Code of Federal Regulations
CLP	Contract Laboratory Program
COC	chain-of-custody
COD	chemical oxygen demand
DFTPP	decafluorotriphenylphosphine
DOT	United States Department of Transportation
DQOs	data quality objectives
E & E	Ecology and Environment, Inc.
EDD	electronic data deliverables
EPA	United States Environmental Protection Agency
GAC	general analytical chemistry
GB	gigabyte
GC/MS	gas chromatography/mass spectrometry
HMTA	Hazardous Materials Transportation Act
HP	Hewlett Packard

List of Acronyms (Cont.)

HPLC	high performance liquid chromatography
IC	ion chromatography
ICP	inductively coupled plasma
ICS	interference check samples
ICV	initial calibration verification
IPR	initial precision and recovery
KCl	potassium chloride
LCS	laboratory control sample
LIMS	laboratory information management system
LRS	Laboratory Report System
MB	megabyte
MDL	method detection limit
mg/L	milligrams per liter
MS	matrix spike
MSD	matrix spike duplicate
MSDS	material safety data sheets
NELAC	National Environmental Laboratory Accreditation Conference
NELAP	National Environmental Laboratory Accreditation Program
NFPA	National Fire Protection Association
NIST	National Institute of Standards and Technology
NYCRR	New York Code of Rules and Regulations
OSH	Occupational Safety and Health Act
OSHA	Occupational Safety and Health Administration
PARCC	precision, accuracy, representativeness, completeness, comparability
PE	performance evaluation
ppm	parts per million
PQL	practical quantitation limit
QA	quality assurance
QAM	Quality Assurance Manual
QAPP	quality assurance project plan
QC	quality control
RAM	random access memory

List of Acronyms (Cont.)

RCRA	Resource Conservation and Recovery Act
RPD	relative percent difference
SOP	Standard Operating Procedure
SOW	statement of work
TKN	total Kjeldahl nitrogen
TOC	total organic carbon
TOX	total organic halogen
TRPH	total recoverable petroleum hydrocarbons
UPS	uninterruptible power source
VIM	International Vocabulary of Basic and General Terms in Metrology

Quality Assurance Manual
for
Ecology and Environment, Inc.
Analytical Services Center
4493 Walden Avenue
Lancaster, New York 14086

Authorization – Revision 1

The quality assurance system described in this Quality Assurance Manual has the support of the management at Ecology and Environment, Inc., Analytical Services Center. Every member of the Analytical Services Center staff is tasked to provide quality data to our clients. It is the responsibility of all personnel to use and follow this manual as a guide for quality improvement.

Signature:	**Date:**
Gary Hahn Gary Hahn Laboratory Director	11-24-98
Ray Piccione, Ph.D. Quality Assurance Coordinator	Nov. 24, 1998
Marcia Meredith Galloway Quality Assurance Officer	11-24-98
Joseph Forti Joseph Forti General Manager	11-24-98

Distribution Policy

The Quality Assurance Manual (QAM) distribution is controlled by the Ecology and Environment, Inc. (E & E) Analytical Services Center (ASC) Document Control Officer. The document is not released without approval by the Quality Assurance (QA) Officer or QA Coordinator. Uncontrolled copies are generally released to outside clients or agencies. Internal copies are controlled and maintained by the Document Control Officer.

When this QAM is revised and approved, it is distributed to each laboratory section. The distributed copies are recorded, along with the current revision number, in a distribution logbook or database maintained by the Document Control Officer. The names of the QAM recipients outside the laboratory are also recorded in the logbook. The recipients will be sent all revisions for a period of one year.

The attached revision table lists the revision type, date, applicable revision number, and distribution.

Revision Table

Description	Revision Type	QA Approval	Revision Date	Revision Number	Distribution
Development of new QAM	Not applicable	—	11/97	0	Initial controlled copies
Updated Appendix D, E, and F	Minor	—	2/98	0	All controlled copies
MDL description pages 4-9/10	Minor	—	5/98	0	All controlled copies
Sample Preservation Temperature pages 10-3/4	Minor	—	5/98	0	All controlled copies
Clarification of Responsibilities pages 3-5/6, 3-7/8	Minor	—	6/98	0	All controlled copies
Balance Calibration 8-5/6	Minor	—	6/98	0	All controlled copies
Update new organization and NELAC standards	Major	See Authorization Rev. 1	10/98	1	Reissue copies to internal and all current clients
Frequency of QAM and QA/QC training, 5-3	Minor	Authorization Document Control Form	12/98	1	Internally controlled copies
~~Presentation~~ Preservation check page 10-4	Minor	—	12/98	1	All controlled copies
Responsibilities, Section 3.2.1	Minor	Document Control Form	6/99	1	Internally controlled copies
PE Samples, Section 4.4.3	Minor	Document Control Form	6/99	1	Internally controlled copies
QC Hierarchy, Section 4.6.3	Minor	Document Control Form	6/99	1	Internally controlled copies
MS Analytes, Control Section 4.6.3 MS Sample	Minor	Document Control Form	6/99	1	Internally controlled copies
Duplicate sample, Section 4.6.3	Minor	Document Control Form	6/99	1	Internally controlled copies
Glassware, Section 7.5	Minor	Document Control Form	6/99	1	Internally controlled copies
Calibration Documentation, Section 8.2	Minor	Document Control Form	6/99	1	Internally controlled copies
Raw Data Information, Section 11.2.3	Minor	Document Control Form	6/99	1	Internally controlled copies
Archives, Section 11.2.5	Minor	Document Control Form	6/99	1	Internally controlled copies

Only most recent revisions shown.

1 Introduction

This manual describes the quality assurance (QA) program employed by Ecology and Environment's Analytical Services Center (ASC). It is intended to provide employees, accrediting agencies, and clients with an understanding of how ASC maintains an effective QA system. The Quality Assurance Manual (QAM) is divided into 16 sections. The sections provide general descriptions of ASC objectives, policies, facilities, organization, personnel, services, and specific QA and quality control (QC) procedures as practiced within each area of operation. Referenced figures, tables, and standard operating procedures (SOPs) support the descriptions in the QAM sections and related documentation. The content of the QAM sections is not modified for specific clients or agencies unless the requirements of these clients become standard policy. Client-specific requirements are included in project-specific documents or in the client-specific sections of the operational SOPs, as appropriate.

SOPs are maintained written procedures for implementing the activities described in this manual. The SOPs are made available to the staff in hard copy or as electronic documents as defined in the Document Control Procedure (see Section 11). All laboratory personnel assigned responsibilities outlined in this QAM adhere to the procedures and policies described here and in the laboratory SOPs.

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2 Definitions

Definitions for this QAM are taken from the National Environmental Laboratory Accreditation Conference (NELAC) *Quality Systems Manual* (NELAC 1998); "Test Methods for the Evaluating of Solid Waste, Physical/Chemical Methods," United States Environmental Protection Agency (EPA) SW-846, Update III, June 1997; and other relevant state and federal guidance. The NELAC manual quotes relevant definitions from ISO/IEC Guide 2; ISO 8402; ANSI/ASQC E-4, 1994; the EPA "Glossary of Quality Assurance Terms and Acronyms"; and the *International Vocabulary of Basic and General Terms in Metrology* (VIM). These definitions are provided in Appendix A. The list of standard definitions is referenced in internal SOPs. SOPs include any definitions related specifically to that procedure.

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3 Organization and Management

3.1 Company

The location, mailing address, and phone numbers for ASC are:

Ecology and Environment, Inc.
Analytical Services Center
4493 Walden Avenue
Lancaster, New York 14086
(716) 685-8080
(716) 685-0852
ASC@ENE.COM

Ecology and Environment, Inc. (E & E) is a publicly held corporation registered and incorporated in the State of New York. E & E has been in business since 1970; ASC is a division of E & E. ASC serves environmental businesses; local, state, and federal agencies; industry; and various international projects.

3.2 Organization

ASC's core services include analysis of samples and interpretation of results. The primary contact at ASC for analytical testing is the Laboratory Director. In addition to standard laboratory analyses, ASC provides other services in conjunction with E & E's corporate staff.

The QA and management structure at ASC is presented on Figure 3-1. ASC is divided into the following production sections: sample management, reporting, gas chromatography/mass spectrometry (GC/MS) semivolatiles, volatiles, GC semivolatiles, high performance liquid chromatography (HPLC), metals, and general analytical chemistry (GAC). Project management, information systems, QA, and administrative units operate in conjunction with production work groups but report independently to the Laboratory General Manager.

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FIG.3-1-CDR-11/01/98-GRA

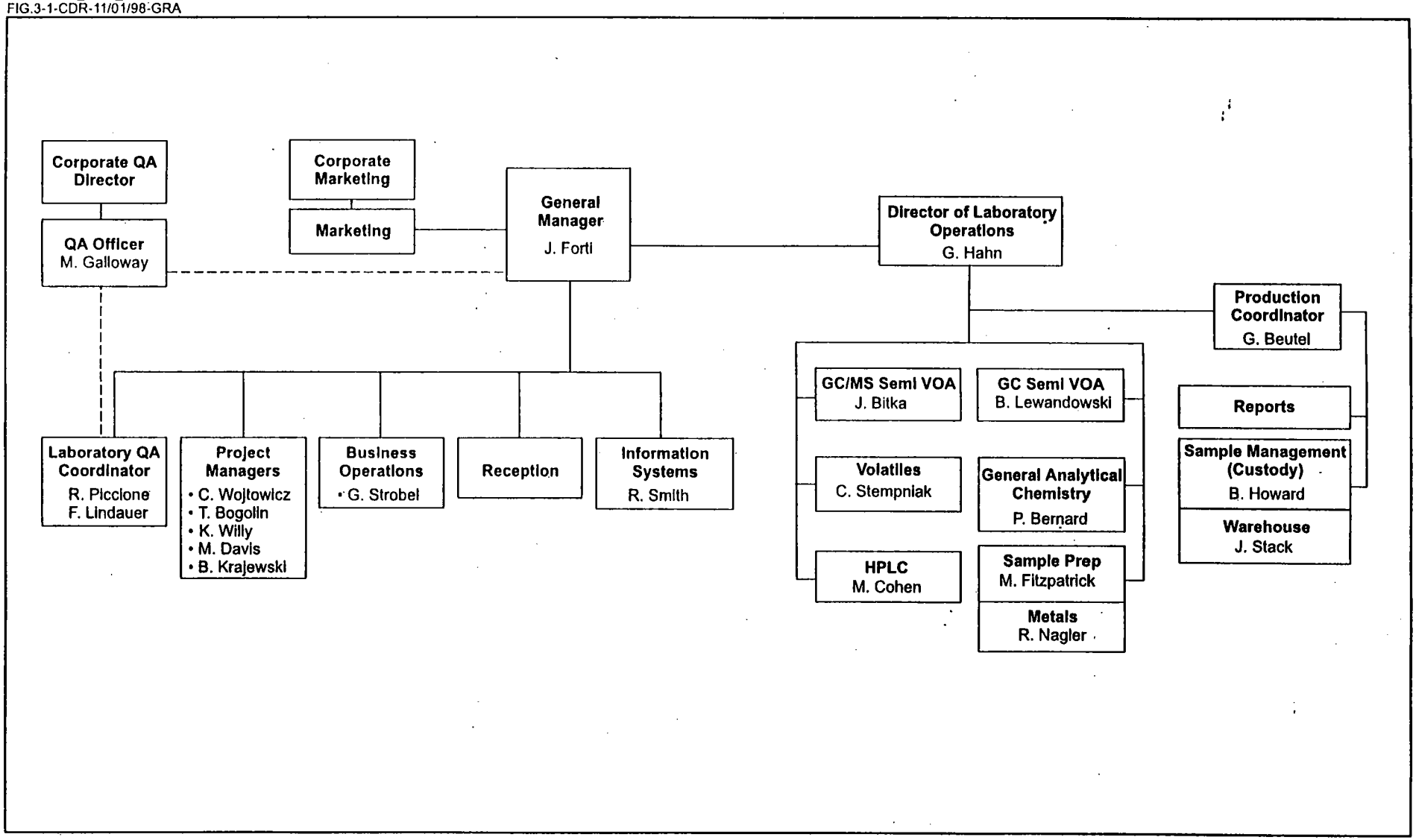


Figure 3-1 ASC ORGANIZATIONAL PLAN

Responsibilities and authority of key personnel are summarized in this section. Resumes of key ASC personnel are found in the company's training record files.

3.2.1 Responsibility and Authority

All personnel are responsible for establishing, implementing, maintaining, and enforcing procedures for data quality management and control as defined in the QAM and related documentation. Each person is responsible for the day-to-day quality of data and the services performed. The overall responsibilities of the ASC staff are defined below. Additional specific job functions and duties are listed in the job descriptions for the following positions. Job descriptions are maintained in the QA files.

General Manager

- Reports to E & E Executive Vice President for Technical Services.
- Designates the Quality Assurance Coordinator.
- Ensures adequate resources are available to all staff to meet the objectives of the QA program.

Laboratory Director

- Reports to the General Manager and is responsible for all technical operations.
- Designates Section Supervisors.
- Responsible for:
  - implementing the QA program and technical operations at ASC;
  - overseeing of the supervision of personnel employed by the laboratory;
  - overseeing that criteria for accepting client samples are met and logged into the tracking system;
  - understanding client and market needs, requirements, or standards;
  - ensuring that data reported meet the method or client-specific requirements;
  - overseeing data quality issues that affect the client; and
  - participating in quality decisions affecting any client.
- Conducts an annual management review of all quality systems in conjunction with the General Manager.

- Names, in the event of a temporary absence, a chief-level project manager to fulfill all duties.

QA Coordinator

- Reports to the General Manager. May report directly to t he Corporate QA Director any QA concerns.
- Implements and reviews all QA/QC practices, including corrective actions, internal audits, training, and other activities as defined in Section 4.3 and throughout the QAM.
- Monitors and reports to the Laboratory Director and General Manager on the status of all QA/QC related matters.
- Maintains the QAM, the QA files, and other version-controlled documents as current documents.
- Retrieves all laboratory records as defined for archiving in the document control procedure.
- Is independent of all production responsibilities.

~~The function of the laboratory QA Coordinator is currently performed by two chemists. The Senior Laboratory QA Coordinator has management responsibilities for the QA Unit. One of the QA Coordinators will be on site at any time.~~

Section Supervisors

- Report to the Laboratory Director for all technical and production matters.
- Coordinate with the Laboratory Director and Production Coordinator to evaluate the resources available for daily work production.
- Review data and evaluate the QC elements for recurring or continuing nonconformances.
- Work with the Laboratory Director and General Manager to resolve process and system nonconformances.

Project Managers

- Reports to the General Manager for all matters related to client services.
- Implements and reviews all QA and QC practices as defined in the project- or client-specific requirements.
- Maintains all project files and client QA/QC documentation.
- Communicates relevant information to the appropriate staff.

~~Production Coordinator~~

- ~~Reports to the Laboratory Director.~~
- ~~Responsible for workflow scheduling and ensuring that production meets all QA and QC objectives.~~
- ~~Responsible for improving throughput, implementing system improvements, and reviewing the effectiveness of the improvement.~~

Technical Staff

- Reports to the Section Supervisor for work assignments and scheduling of samples to be analyzed.
- Responsible for performing work according to the SOP, meeting agreed-upon time scale, and achieving the QC criteria defined in the SOP.
- Records information on a corrective action form when QC criteria are not within defined limits, or when procedures deviate from the SOP or client requirements.
- Performs all necessary administrative operations according to the documented SOP, including corrective action, document control, data review, traceability, and sample management.
- Performs all necessary ancillary technical operations according to the documented SOP or good laboratory practice, including routine preventative maintenance, standard preparation and inventory, and calibration of instruments and equipment.

Sample Custody Staff

- Reports to the ~~Production Coordinator~~ Laboratory Director for all matters related to sample receipt, handling, and disposal.
- Responsible for performing work according the sample management SOP(s) and performing all operations within agreed-upon time scale.
- Records information on a corrective action form when samples or materials are received that do not conform with the SOP or client requirements.
- Performs all necessary administrative operations according to the documented SOP, including corrective action, document control, data review, and traceability.

Quality Assurance Staff

- Reports to the QA Coordinator for the job duties assigned.
- Responsible for performing work according the assigned SOP and performing all operations within agreed-upon time scale.
- Records information on a corrective action form when data or other information is received that does not conform with the SOP or client requirements.
- Performs all necessary administrative operations and record keeping according to the documented SOP, including corrective action, document control, data review, reporting, and traceability.

Administrative Staff

- Reports to the General Manager for the work area assigned.
- Responsible for performing work according to the assigned SOP and performing all operations within agreed-upon time scale.
- Records information on a corrective action form when data or other information is received that does not conform with the SOP or client requirements.
- Performs all necessary administrative operations and record keeping according to the documented SOP, including corrective action, document control, data review, and reporting.

Corporate Quality Assurance Director

The corporate QA Director ensures compliance with the Corporate QA Program. The QA Director remains independent of day-to-day, direct project activities, but is responsible for ensuring that all QA/QC requirements are met. The parent company assists with QA oversight at the laboratory and utilizes staff with appropriate training and expertise to evaluate those operations.

Quality Assurance Officer

The corporate QA Officer reports to the QA Director. The corporate QA Officer is responsible for the independent oversight of the laboratory QA/QC activities. The QA Officer reviews and approves the QAM and client-specific QA project plans (QAPP); provides input on the development and implementation of SOPs, and reviews specific QA/QC concerns generated from independent data review or client reports.

The QA Officer provides ongoing assessment of the effectiveness of the QA/QC operations by reviewing QA reports, documentation, and project data deliverables, attending QA staff meetings, and conducting independent audits as necessary.

3.2.2 Verification

Verification activities include inspection and monitoring of process and data quality, and auditing the quality system, processes, and data. Effective verification is achieved by providing personnel with adequate resources, including adequate training, supplies, and equipment; time for verification activities; knowledge of requirements and documented procedures; and access to quality records.

Technical personnel, under the direct supervision of the Section Supervisors, are responsible for the inspection and monitoring of in-process and final data. Audits of the quality system and process are performed by personnel who do not have direct responsibility for the work being performed. Quality system audits are carried out by the QA Coordinator. Process audits are scheduled by the QA Coordinator and carried out by designated personnel and trained internal auditors (see Section 4.4).

3.2.3 Management Review

The QA Coordinator reports directly to the General Manger, functions independently of production, and has the authority to implement and maintain the quality system. The QA Coordinator meets at least monthly with the Section Supervisors to determine the status of quality systems in their laboratory section. The QA Coordinator attends the biweekly management meetings and reports on the status of all QA activities, including open and closed corrective actions, internal audit results, external audit results, status of certifications and approvals, client complaints, and major quality issues. The QA Coordinator interacts frequently with personnel at all levels throughout the organization.

A management review of the quality system is conducted annually by the Laboratory Director, General Manager, and corporate QA. The management review must ensure that the quality system remains effective, meets quality objectives and policies, and satisfies the requirements of state and federal certifications or approvals held by ASC. Management review includes review of the annual QA systems audit and changes in laboratory operations, staff activities, and client concerns. The management review includes areas for improvement in relation to quality systems.

4

Quality System

4.1 Objective

The objective of the staff at ASC is to provide data and services that are legally defensible, scientifically valid, timely, and to the satisfaction of clients' expectations.

4.2 Policies

The management of ASC supports the following policies in order to achieve the objective and promote the overall QA program:

- Laboratory procedures, including client requirements, are documented in SOPs that clearly communicate these procedures to laboratory personnel.
- Management emphasizes quality improvement through commitment and leadership.
- A comprehensive QC system has been established and is maintained to verify and assure continued precision and accuracy of analytical results.
- Adequate training on laboratory operations is provided for all employees whose decisions affect the quality of laboratory data and services.
- A comprehensive program of documentation has been implemented and is maintained to ensure accountability and traceability throughout the analytical process.
- Measures are taken to ensure that sample integrity is protected.
- Studies are performed to demonstrate the capabilities for each analytical method.
- The instrumentation, equipment, and materials used in the production process are controlled to ensure that required quality standards are within specifications.

- A comprehensive program for data reduction, review, reporting, and archiving is maintained.
- Preventive and corrective actions are taken, as necessary, to eliminate the causes of potential or actual nonconformance.
- Measures are taken to fulfill the requirements of agencies from whom certifications and accreditations have been granted.
- Client-specific requirements are incorporated in the overall QA program by addendum to appropriate SOPs.

4.3 Quality Assurance

Through a formal QA system, ASC provides testing services that meet specific quality standards. These quality standards are defined to meet the needs and requirements of clients, the analytical methods used, government agencies, and E & E's senior management.

Quality control: A system of activities applied at each stage of the data production process designed to ensure that data meet defined quality standards. This system includes the following: system, operational, and performance audits; reference materials; statistical evaluations; re-analysis; and measurement bias investigation (when measurements may be operator-, instrument-, or methodology-dependent).

Quality Assurance is composed of **quality control** and **quality assessment**.

Quality assessment: A system of activities designed to ensure that quality control takes place at each stage of the production process. This system includes the following: employee education, training, and experience; documentation (e.g., instructions, document control, records); instrument calibration and maintenance; traceability of samples, data, and methods; laboratory facilities; and inspection.

ASC management is accountable for the quality of the services provided, and each employee is an integral part of achieving the system objectives. This section is limited to a discussion of the major activities performed and administered by the QA unit; policy details are discussed throughout this manual.

The QA program at ASC is affected by the requirements of certification agencies. The QA Coordinator is directly responsible for coordination of the following external quality assessment activities:

- On-site audits by outside agencies;
- Analysis of performance evaluation (PE) samples;
- Corrective action responses to deficiencies cited in external audit reports and external PE results; and
- Dissemination of requirements and status of certifications to relevant laboratory personnel and project managers.

4.3.1 Quality Assurance Unit

At ASC, the QA unit monitors the QA system and reports the results of its observations to the Laboratory Director, General Manager, and QA Officer. The QA Coordinator has no direct responsibility for production, scheduling, or workflow in the laboratory. The objective of this independence is to eliminate all conflicts of interest in the performance of QA duties. Major activities performed and administered by the QA unit are summarized below. Each activity is discussed in greater detail elsewhere in the QAM.

- Performance of internal audits and coordination of external audits (Section 4.4);
- Administration of laboratory certification/accreditation programs (Section 4.7);
- Administration of a system for formal corrective action reports (Section 4.5);
- Administration of the document control system, including the publication of the QAM (Section 11) and other documents that describe ASC's QA system; and
- Administration of the in-house training program (Section 5.5).

4.4 Audits

ASC conducts internal audits in which the laboratory reviews and examines itself, and undergoes external audits in which the laboratory is audited by outside organizations. Internal system audits are defined in the internal audit SOP QA.19 as operational and system audits.

4.4.1 Internal Audits

The internal audit is a review of the quality system as it is employed in the laboratory. Auditors verify that adequate written instructions are available for use; that analytical practices performed in the laboratory are consistent with SOPs; that the QC practices are applied during production; that corrective actions are applied as necessary; that deviations from approved protocols occur only with proper authorization and documentation; and that SOPs, quality records, analytical records, and magnetic tape are properly maintained.

System Audit

Internal system audits are implemented by the QA Coordinator at least once per year. The system audit is a review of the overall system of operations and is used to verify that corrective actions are being implemented effectively. The system audit is a sampling of all operations and must include sample tracking from receipt to disposal, a data audit of a completed report, and audits of ancillary operations as necessary to support the data audit. Data audits ensure that data comply with method and SOP requirements, deliverable specifications and standard traceability. The internal system audit report is provided to laboratory management and forms the basis for management review of the quality systems described in Section 3.2.3.

Operational Audit

The QA Coordinator schedules internal operational audits for all sections at least once per year. The operational audits are a more detailed review of laboratory (procedure) operations. They are performed by analysts, Section Supervisors, or supervisors from sections other than those being audited. This manner of conducting operational audits allows for the exchange of practices, improving production flow and operations.

Prior to a scheduled audit, checklists or the SOP specific to the area are reviewed by the assigned auditor. The checklist or notes from the audit are returned to the QA Coordinator as part of the audit report. The specific contents and process for conducting and reporting on the audit are detailed in the internal audit SOP QA.19. Any deficiencies or nonconformances found during the audit are recorded on a corrective action form. The corrective action procedure is followed to ensure the nonconformance is corrected.

4.4.2 External System Audits

Representatives sent by clients, government, or accrediting agencies often perform system audits at ASC. These audits are usually announced inspections, but sometimes are conducted without announcement. The QA Coordinator usually accompanies the external audit team through the laboratory. The auditors receive a brief overview of company objectives, activities, and facilities. Interviews with essential supervisory and technical staff are arranged and any documentation pertinent to the audit is retrieved. Auditors typically provide a report on their findings shortly after the audit. This account is evaluated by the QA Coordinator and reported to management, along with a corrective action form responding to any cited deficiencies.

4.4.3 Performance Evaluation Samples

A PE sample is the analysis of a fortified blank sample or real world sample for the purpose of evaluating laboratory or analyst performance. PE samples are submitted by external organizations and have analyte concentrations unknown to ASC. PEs may be analyzed as part of inter-laboratory round-robin studies, in conjunction with accreditation programs, or as blind check samples submitted by clients.

Internal performance audits are fortified blanks with known analyte concentrations. Each analyst, whether aware of the value of the concentration or not, must successfully complete a blind performance standard on a method as described in the training SOP QA.5. On a continuing basis, analyst must demonstrate performance in the method as described in the SOP on Continuing Staff Proficiency A.29. Performance requirements may be from either external or in-

ternal PE samples or as described in the SOP: Internal performance audits may be used to provide information to an accrediting agency on correction of past performance on an external performance audit.

As the sole laboratory for E & E, the ASC does not participate in its own interlaboratory comparisons except through external PE programs or client split samples.

4.5 Corrective Action

ASC takes the necessary actions to prevent or correct nonconformances in data and services. When corrective actions result in permanent procedural changes, pertinent documentation (e.g., SOPs) is modified to reflect these changes. A formal corrective action reporting system, administered by the QA unit, is in place at ASC. The process is described in the corrective action SOP QA.1 and is applicable to all nonconformances or client concerns.

Routine corrective actions are made by the analysts, technicians, or other personnel who detect problems or nonconformances during analysis of samples. SOPs for testing procedures contain instructions for implementing and documenting corrective actions for typical problems. These actions are typically noted in the laboratory section documentation. Any data reported outside SOPs or project requirements must be described on a corrective action form submitted with the results for project manager approval.

Sample handling concerns, such as problems during cooler receipt or holding time violations, are reported immediately on a corrective action form to the project manager for resolution. Deviations from the SOP and other activities that require approval or actions by others also may be recorded on the corrective action form (see Appendix B).

All non-routine problems, deficiencies, or irregularities are reported to management as part of the corrective action process. The corrective action process is used to report all audit findings from both external and internal audits as well as any client comments or complaints from the review of analytical data.

The QA unit monitors the progress of corrective actions, maintains completed documentation, and provides reports to the Laboratory Director on the status of the corrective action activities. Corrective action forms may be originated by any ASC personnel. A completed form is sent to the person responsible for completing the corrective action. This person is responsible for recording the corrective action plans, implementations, and follow-up actions to be completed. During the corrective action process, several measures may be taken, including: determination of the root cause through careful analysis

of processes, specifications, quality records, customer complaints, and use of statistical process control; implementation of process controls to ensure that effective corrective action is taken; application of remedial actions to reports or data affected by the identified problem; and revision of documentation for procedures that changed as a result of the corrective action. The goal of the corrective action process is to complete all corrective action forms before data are reported to the client.

4.6 Quality Control

QC is applied at every stage of the testing process at ASC. Its purpose is to assure that the data reported to clients are within defined acceptance and performance criteria. QC activities are described in many sections of this manual; this section presents those QC activities that are quantified with defined acceptance and performance criteria.

The criteria are derived from several sources, including requirements of the analytical methods, needs stated by clients, and standards established within ASC. During the generation of data, verification activities evaluate the performance of the measurement to the specified criteria. These verification activities include data review by a second analyst, proofreading of all data entry, project-specific review, and a data review by the QA Coordinator on a random selection of the final reports (see Section 12.2).

When defined quality standards have not been met (a nonconformance), the corrective action process is initiated to document and track the nonconformance and the corrective actions taken. The QA Coordinator and Laboratory Director or their designees review the information to determine the effectiveness of the QC system.

4.6.1 Data Quality Objectives

The data quality objectives (DQOs) are developed by the client during the design of a given study and typically presented to the laboratory as a QAPP or contract statement of work (SOW). The DQOs are qualitative and quantitative indicators used to define the quality of the data needed to support specific project decisions. DQOs specify critical data points or acceptance criteria to be achieved to make the proper decision. The qualitative and quantitative indicators are often expressed as precision, accuracy, representativeness, completeness, and comparability (PARCC). Achievement of these quality indicators helps to demonstrate that the data are scientifically valid, legally defensible, and adequately meet client requirements as stated by the DQOs. The laboratory reviews all project-specific DQOs and identifies any areas in which internal QC criteria indicate project DQOs may not be achievable (see Section 13).

Precision

Precision measures the reproducibility of measurements under a defined set of conditions. It is a quantitative measure of the variability of a group of measurements compared to their average value. Precision is usually stated in terms of standard deviation, coefficient of variation, or relative percent difference (RPD) between two values. Precision is determined in the laboratory by evaluating laboratory duplicates, matrix spike duplicates, or replicate measurements of the sample or standard. Precision measurements for overall sampling and analytical testing are evaluated through field duplicates or split samples.

Accuracy

Accuracy is a quantitative measure of the relationship of reported data compared to the true or expected values and includes a combination of random and systematic error. Accuracy is determined in the laboratory by evaluating the recoveries of analytes spiked into samples, through the use of surrogate spikes, matrix spikes (MS), and laboratory control samples (LCS), and stated in terms of percent recovery or the average (arithmetic mean) of the percent recovery. Accuracy measures for overall sampling and analytical testing are evaluated through blank samples, background samples, or external PE samples.

Representativeness

Representativeness expresses the degree to which data represent a characteristic of a population, a parameter variation at a sampling point, or an environmental condition. Representativeness is a qualitative parameter that is most concerned with proper design of the measurement program. Sample measurement locations may be biased (judgmental) or unbiased (random or systematic). For unbiased schemes, the sampling must be designed not only to collect samples that represent conditions at a sample location, but also to select sample locations that represent the total area to be sampled.

Representativeness is usually dependent upon sampling techniques not controlled by the laboratory; however, there is representativeness of sub-samples prepared within the laboratory from collected samples. Parent samples must be subjected to thorough homogenization prior to sub-sampling to ensure unbiased measurements within the laboratory. Sample duplicates prepared in the laboratory are a measure of the representativeness.

Completeness

Completeness is defined as the percentage of measurements performed that are judged to be valid. A quantitative goal defines how

much valid data must be generated to make a decision regarding completeness. Critical samples typically have higher completeness goals than noncritical samples and require additional measures of QC. In the laboratory, the quantitative measure of the amount of valid data is obtained from the analytical process and compared to the amount that was expected to be obtained. Valid data are data that are not rejected for failure to meet project DQOs.

Comparability

Comparability is a qualitative measure of the confidence with which one set of data can be compared to another. Sample data should be comparable with other measurement data for similar samples and sample conditions. Characteristics that make comparison possible include method performance samples as defined in Section 4.6.2; QC samples as defined Section 4.6.3; standardized report format; consistency of units (e.g., milligrams per liter [mg/L], parts per million [ppm]); and standardized sample collection, preparation, and analysis procedures. PE samples also help establish comparability of results between laboratories.

4.6.2 Method Performance

For any given analytical method, ASC initially demonstrates its ability to successfully perform the analytical method, and continues to demonstrate this ability as long as the method is used. Initially, the laboratory demonstrates the ability to meet the precision and accuracy criteria stated in the method and defined in the initial demonstration of capability SOP A.23. The demonstration normally requires analysis of four replicate samples. Each individual analyst also demonstrates the ability to perform the method in accordance with the training SOP QA.5 and method requirements. On an ongoing basis, the laboratory analyzes calibration standards as defined in Section 8, QC samples as defined in Section 4.6.3, and PE samples as defined in Section 4.4.3 to demonstrate method capability.

Method sensitivity is defined as the concentration of an analyte in a given matrix necessary to produce a detectable response. The sensitivity is measured for each analytical method as defined below.

Method Detection Limits

The method detection limit (MDL) for all quantitative analyses is determined based on the reference procedure found in 40 CFR Part 136, Appendix B and is verified annually per the MDL SOP A.18. The MDL SOP details the calculations and iterative process for determining the MDL. An MDL is determined for each method and matrix during method start-up and whenever the basic chemistry of the procedures is changed.

Practical Quantitation Limits

The practical quantitation limit (PQL) is the reporting limit used by the laboratory. The PQL must be greater than the MDL and is typically three to 10 times the MDL, depending on the method. The PQL is often the lowest standard used for calibration. Where client-specific criteria require reporting of a PQL that is below the lowest standard in the calibration range, a low level check standard is performed at the end of the analysis to validate the lower reporting limit. These client-specific reporting limits and the acceptance criteria for performance are defined in the client documentation.

4.6.3 Quality Control Samples and Splits

Analytical performance is monitored through QC samples and spikes, such as laboratory method blanks, surrogate spikes, QC check samples, matrix spikes, matrix spike duplicates, duplicate samples, and duplicate injections. Many of the QC measures applied at ASC are summarized below. ~~For laboratory QC criteria, when insufficient data points are available, the limits specified in the reference method are utilized~~. Laboratory QC criteria are defined in the appropriate method SOP. A heirarchy is established in the application of QC criteria: project-specific, method then laboratory-derived requirements. ~~Project specific requirements are used in lieu of internal and reference method limits.~~

All QC samples are applied on the basis of a laboratory batch. The laboratory batch associates samples that are prepared or analyzed together as described in the batching SOP A.22. The laboratory defines two basic types of batches: the preparation batch and the run (i.e., analytical) batch. The preparation batch includes all samples processed as a unit during organic sample preparation, metals digestion, or GAC preparation. Preparation batches do not exceed 20 samples excluding associated QC samples. The QC samples associated with sample preparation include method blanks, LCS, matrix spikes, and duplicates. The run batch is all samples analyzed together in the run sequence. The run sequence is typically limited to 24 hours unless defined differently for the analytical method. For some analyses, such as volatile organics, the run batch is equivalent to the preparation batch. The QC samples associated with the run sequence include calibration standards, instrument blanks, and reference standards. The specific procedures for documenting the laboratory batch are defined in the batching SOP. Additional batches may be defined for unique steps of the analytical process, such as a clean-up batch or reporting batch, and these additional batches are defined in the laboratory case narrative.

Laboratory Method Blank

A laboratory method blank is an analyte-free material processed in the same manner and at the same time as a client sample. The blank is prepared using American Society for Testing and Materials (ASTM) Type II water when analyzing water samples, and where practical, pre-cleaned sand or other solid material, such as sodium sulfate, when analyzing solid samples. The laboratory method blank sample is prepared along with the client samples at a frequency of one laboratory method blank per batch of 20 (or fewer) of client samples for the given matrix type.

The laboratory method blanks serve to demonstrate a contamination-free environment in the laboratory. The goal is for method blanks to be free of contamination. Low level contamination may be present, but must be less than the level in the samples as defined by the method SOP or the client. If contamination is greater, the samples are reanalyzed. If contaminants are present in the method blank but not in client samples, no further action is required. All sources of contamination that are not common laboratory contaminants as defined in the method SOPs are investigated as part of the corrective action process. Sample results are not blank subtracted unless specifically required by the analytical method.

Surrogate Standards

For certain organic methods, all samples, including the laboratory method blank and standards, are spiked with a set of specific surrogate standards to monitor the accuracy of the analytical determination. Surrogate spikes are added at the start of the laboratory preparation process. Surrogate compounds are not typically found in environmental samples. QC criteria for surrogate recoveries are method-and matrix-specific. Laboratory QC criteria are established after a sufficient number of data points (30 or more) is performed and updated annually as defined in the Control Charting SOP QA.20.

Surrogate recoveries within QC criteria for method blanks and LCS samples demonstrate acceptable method performance. If surrogate recoveries are outside QC criteria for method blanks or LCS samples, corrective action is required as defined in the appropriate method SOP. Surrogate recoveries in the samples indicate the method performance on the particular sample matrix. Surrogate recoveries that are outside QC criteria for a sample indicate a potential matrix effect. Matrix effects are verified based on review of recoveries in the method blank or LCS, sample reanalysis, or evaluation of interfering compounds. Sample clean-up procedures may be appropriate to alleviate potential matrix problems. Standard procedures for evaluating surrogate recoveries in samples are listed in the ap-

The percent recovery (%R) is calculated as:

$$\%R = \frac{X_1 - X_2}{|\ TV\ |} \times 100$$

where:

- % R = the percent recovery
- X_1 = the measured concentration of the sample with the spike addition
- X_2 = the measured concentration of the sample
- TV = concentration of the spike added

propriate method SOPs. However, these procedures are often modified by project- or client-specific requirements.

Laboratory Control Sample

An LCS consists of ASTM Type II water, and where practical, precleaned sand or sodium sulfate for solid matrices, or a purchased performance evaluation sample. The LCS is spiked with the analytes of interest or a representative subset usually near the mid-point of the calibration range, followed by the same sample preparation, standard addition, and analysis as client samples. The LCS concentration may be specified in the reference method or project-specific requirements. LCSs are analyzed at the frequency of one per batch of every 20 samples or fewer. The recovery of target analytes in the LCS is an estimation of method accuracy.

LCS recoveries are monitored on control charts. Laboratory QC criteria are established for each method and matrix using a minimum of 30 points. QC criteria are updated annually. If all target analytes are not included in the LCS spike, then the spike mixture is rotated throughout the year to evaluate control limits for all parameters. When the LCS recovery is within the control limits, the method performance is considered acceptable.

If the LCS recoveries are outside QC criteria for the target analytes, corrective action is required. QC criteria and appropriate corrective actions are defined in the specific method SOPs. After corrective action is complete, sample re-analysis may be required for the failed parameters. If LCS recoveries exceed the QC criteria, and that parameter is not found in any of the samples, re-analysis is not necessary unless specifically required for the project.

Matrix Spike Sample

An MS sample consists of a client sample (often specified by the client) split into two parts and processed as two separate samples in a manner identical to that of the rest of the samples. In addition to the regular addition of monitoring standards (internal standards, surrogate), ~~the analyst adds a set of the target analytes~~ spiking analytes are added to an aliquot of the chosen sample before preparation. Generally, all method target analytes, if compatible are added. A subset, as indicated in the method SOP, is reported unless specified otherwise by the client. The spike concentration levels for the target analytes are defined by the analytical method or by project-specific requirements or are specified by the laboratory in the analytical SOP. An MS is prepared for every batch of 20 samples (or fewer) for a given matrix if sufficient sample allows. The sample chosen for matrix spike is random except that field and trip blanks are not cho-

sen for spiking. Clients may specify the sample(s) to be spiked. The client must provide ASC with extra sample amounts for samples requiring ~~MSs~~ matrix spikes.

~~MS recoveries are not monitored on control charts. , and laboratory QC criteria are established for each method and matrix as specified in the Control Chart SOP. QC criteria for the LCS may be used in lieu of specific MS QC limits.~~

Due to matrix effects, matrix spike recoveries are not a measure of the performance of the method on the sample being analyzed. In the absence of observable quantitative interferences, an MS sample recovery that exceeds QC limits indicates matrix effects. For these reasons, MS recoveries are not monitored on control charts. The results of the MS are evaluated, in conjunction with other QC information to determine the effect of the matrix on the bias of the analysis. ~~Matrix effects are specified to the client when the method blanks, calibration data, and LCS are within control limits. The suspected matrix effect is discussed in the case narrative. Matrix effects are corroborated when a matrix spike duplicate (MSD) is performed or samples are re-analyzed per the specific method SOP.~~

Matrix Spike Duplicate Sample

The MSD sample is commonly prepared in conjunction with the MS sample. The MSD is prepared from a separate portion of the client sample and processed with the same additions as the MS. The sample chosen for matrix spike duplicate is random except that field and trip blanks are not chosen for spiking. The MSD is prepared for methods that do not typically show concentrations of target analytes above MDLs, such as organic methods. The RPDs between the recoveries in the MS and MSD measure the precision of the analytical method on the actual client samples. Laboratory QC criteria for RPDs may be established as specified in the Control Chart SOP QA.20 or by method requirements. RPD values may be tabulated in the analytical reports and not plotted on control charts. For the MSD sample, the client must provide ASC with extra sample amounts. If insufficient sample is available, the laboratory may run an LCS duplicate to measure precision, depending on the method.

The relative percent difference (RPD) is calculated as:

$$RPD = \frac{|X_1 - X_2|}{\left(\frac{X_1 + X_2}{2}\right)} \times 100$$

where:

RPD = the relative percent difference

X_1 = the concentration or percent recovery of the sample

X_2 = the concentration or percent recovery of the duplicate sample

Duplicate Sample

A duplicate sample consists of a set of two samples obtained in an identical manner from the same client sample. The collection of duplicate samples from a heterogeneous matrix requires homogenization to ensure that representative portions are analyzed. One sample per batch of 20 samples or fewer per matrix is analyzed. The sample chosen for duplicate analysis is random except that field and trip blanks are not used. Clients may designate the sample for duplicate analysis. The client must provide sufficient sample to allow for duplicate testing.

The duplicate is prepared for methods that typically show concentrations of target analytes above MDLs, such as metals and GAC methods. The RPDs between the recoveries in the original and duplicate measure the precision of the analytical method on the actual client samples. Laboratory QC criteria for RPDs are established for each method and matrix as defined in the Control Chart SOP QA.20. RPD values also may be tabulated in the analytical reports and not plotted on control charts.

If all other QC criteria are met, matrix effects may be established by observing the sample to determine any visual heterogeneity. If visual observation does not indicate a potential problem, the sample may be reanalyzed. Potential matrix effects are reported in the case narrative.

Splits

Clients may request that samples be split and sent to another laboratory, or they may split the samples and submit them to a minimum of two laboratories. Splits are often performed to evaluate the comparability and reproducibility of the data for critical decision making, or when sample re-collection is not practical. These inter-laboratory studies are defined in the client documentation. Data resulting from splits are evaluated by the client. Sample splits must be representative of the sample submitted. Errors from sample splitting must be minimized by ensuring that the sample is adequately mixed prior to splitting.

Other Laboratory QC Samples

The laboratory performs analysis of other QC samples or standards, depending on the analytical method. Standard QC samples or standards are documented in the specific method SOP. Method-specific QC samples or standards include internal standard spikes for GC/MS methods; post-digestion spikes and serial dilutions for metals analysis; and interference check samples (ICSs) for inductively coupled plasma (ICP) analysis.

Field QC Samples

To evaluate the overall sampling and analytical data quality indicators, the client submits QC samples from the field. The field QC samples include trip blanks, field blanks (such as ambient condition blanks or equipment blanks), and field duplicates. Trip blanks may be prepared in the laboratory as described in Section 10. The project managers will normally track the field QC samples to ensure that the frequency of sampling and analysis is consistent with project requirements. In most cases, the analytical staff are typically not aware of which samples are the field QC samples. In cases when MS/MSD samples are not client-specific for water sample analysis, the analyst should review the client samples to ensure that MS/MSD analysis is not performed on field blanks.

4.6.4 Statistical Evaluation

Statistical evaluations are performed for the quality indicators, MDLs, surrogates, and LCSs. Control charts offer the most graphic representation of a statistical evaluation. Control charts identify potential problems, and the causes of these problems are promptly investigated and eliminated. Internal QC criteria are determined through historical trend analysis of data collected on QC charts. The control chart process is defined in the control chart SOP QA.20. The control chart procedure allows for identification of points outside QC criteria or potential QC problems by evaluation of trends.

Control charts are plotted for the percent recovery of surrogates, and LCS compounds, ~~and MS compounds~~ as determined by the individual method SOP or certifying agency requirement. ~~At a minimum, all surrogate and target analyte recoveries in the LCS are plotted.~~

4.7 Accreditations, Certifications, Licenses, and Registrations

ASC has received approval from various state, federal, and national agencies for performing analytical testing. The laboratory has been granted numerous certifications and accreditations, based upon compliance with standards set forth by the granting agencies. The certifications are summarized in Appendix C. The scope of approval is based on each agency's requirements with regard to regulatory requirements, methodologies, or matrix. Specific information on the parameters approved is maintained in the QA files. The scope of evaluation as presented in Table C-1 in Appendix C is the process used for granting the approval.

5 Personnel

5.1 Job Qualifications for Key Technical Personnel

The following are the minimum experience, education, and qualifications required for key personnel. Specific job descriptions for each laboratory function are maintained in the QA files.

Laboratory Director: Experience in environmental laboratory managing administrative, business, personnel, and production activities. Minimum qualifications:

- Education: B.S. or B.A. in a scientific field related to the testing being performed or equivalent.
- Experience: Five years in general management and five years in laboratory management. Additional bench experience of at least three years is recommended.

QA Coordinator: Experience in coordination and management of QA activities. Minimum qualifications:

- Education: B.S. in Chemistry or equivalent.
- Experience: Five years in scientific field. At least one year course or laboratory experience in QC statistics and QA practices.

Section Supervisor: Experience in management of production operations, including supervision of technical staff for sample preparation and instrumentation. Minimum qualifications:

- Education: B.S. in related science such as Physical Science, Chemistry, or Biology or minimum two years college level chemistry and equivalent experience.
- Experience: Five years in chemistry or in the field of study for the area being supervised; two years supervisory experience.

5.2 Recruitment Policy

ASC's recruitment policy is defined by the corporate program. Recruitment is the responsibility of the Laboratory Director and corporate human resources personnel. Orientation training of all new employees includes review of the QAM, Chemical Hygiene Plan, and all SOPs required for the job function.

5.3 Corporate Ethics Policy

Laboratory ethics and ASC's ethics policy are discussed during initial training for new employees. Any employee found to have knowingly reported data values that are not actual values obtained, or improperly manipulated or intentionally reported dates and times of data analyses that are not the actual dates and times of analyses, is immediately terminated. Any laboratory personnel identifying an accidental or suspected intentional reporting of non-authentic data must report the finding immediately to the Laboratory Director. The project manager immediately notifies the client if any data are reported. All new personnel receive ethics training and are required to sign an ethics agreement.

5.4 Corporate Confidentiality and Propriety Rights

All work is performed in the strictest confidence. During orientation training, new and contract employees are required to review the corporate policy and practices for protecting client confidentiality and proprietary rights. The policy and practices are designed to ensure that information from the laboratory is transmitted only to the appropriate and responsible parties.

5.5 Training

New employees receive all necessary training for their job function. Refresher training is provided for current employees as required for their current job function. Training is performed both on and off site by members of ASC staff, contractors, equipment manufacturers, academic institutions, or regulatory authorities. Training procedures are documented in the training SOP QA.5.

Off-site training takes place on an as-needed basis. Completed studies are documented and updated in the training files of each employee. Off-site training may include the following:

- Courses taken at local colleges and universities.
- Workshops and seminars conducted by instrument manufacturers, software companies, and national associations specializing in analytical chemistry or laboratory QA.

- Specific training classes for instruments or software purchased at the laboratory.

Personnel provide the Document Control Officer with any attendance information and copies of any certificates earned during such training.

On-site training takes place for all new personnel according to the training procedure SOP. Personnel must demonstrate proficiency in the analytical and/or administrative procedures before independent operation in the job function. On-site training includes the following:

- Formal training in the QAM for all employees when newly hired and at yearly refresher training.
- Formal training on appropriate SOPs and all major revisions to those SOPs, including QC requirements.
- Assistance for the trainee performing a procedure.
- Observation and oversight for the trainee performing a procedure.
- Verification that the trainee demonstrates proficiency in the procedure.

5.5.1 Training Records Maintenance

The Document Control Officer is responsible for maintaining the training record files and entering information into the tracking database. Reports from the database provide training summaries by individual, and by SOP. The Document Control Officer notifies appropriate personnel when a revision is finalized for the controlled versions of the documents that will require retraining of all appropriate personnel.

Resumes, job descriptions, and biographies are included in the training record files. Biographies are put in a uniform format by the corporate human resources department and are updated with additional education and experience as needed.

5.6 Safety and Health Policies

All personnel receive a one-day orientation training session upon initial employment as well as on-the-job training concerning health and safety issues related to the operations being performed. In compliance with the Occupational Safety and Health Administration (OSHA), ASC conducts safety and health training annually, with a careful introduction to new principles. Personnel have access to the master Chemical Hygiene Plan and are trained in reading and locating the Material Safety Data Sheets (MSDS).

6

Laboratory Facilities

6.1 Facility

The laboratory facility has an area of 25,000 square feet with over 800 linear feet of laboratory benching and over 120 linear feet of fume hood space. The ASC floor plan is provided on Figure 6-1. The laboratory is divided into the following areas: administration and offices; GAC; metals sample preparation; organic sample preparation; metals analysis; HPLC; GC and GC/MS analysis for volatile and semivolatile compounds; and other laboratory support functions. The sample management office is approximately 1,500 square feet and has a 390-square-foot walk-in cooler. A separate ventilated room is used to store laboratory waste prior to pickup by a licensed waste hauler.

Off-site facilities are used for material storage and file archiving. The warehouse is located behind the laboratory facility and the corporate headquarters is located within four miles of the laboratory facility.

Deionized water from a recirculating reverse osmosis/ion exchange system is piped to all laboratory benches. Gases for laboratory instruments and operations are distributed from a central source to the required areas through piping and manifolds. Laboratory benches have chemical resistant work tops and surface bench-level exhaust grills to remove vapors.

6.2 Security Systems and Environmental Controls

ASC provides a secure environment for our employees, guests, clients, samples, and analytical data.

6.2.1 Access

To ensure security, all exterior doors remain locked unless directly monitored by personnel. Access to the laboratory is limited to employees and contractors. Visitors not under signed contract to E & E are required to sign the Visitor Log and must be accompanied by an E & E employee.

The sample management area is the defined high security area. Entry into this area is controlled by identification card activated locks on the internal and external entry doors. Personnel not assigned to the high security area must be accompanied by an employee assigned to the area.

The sample reports storage area is defined as a limited access area. Individuals requiring access must get a key from a designated staff member.

6.2.2 Security

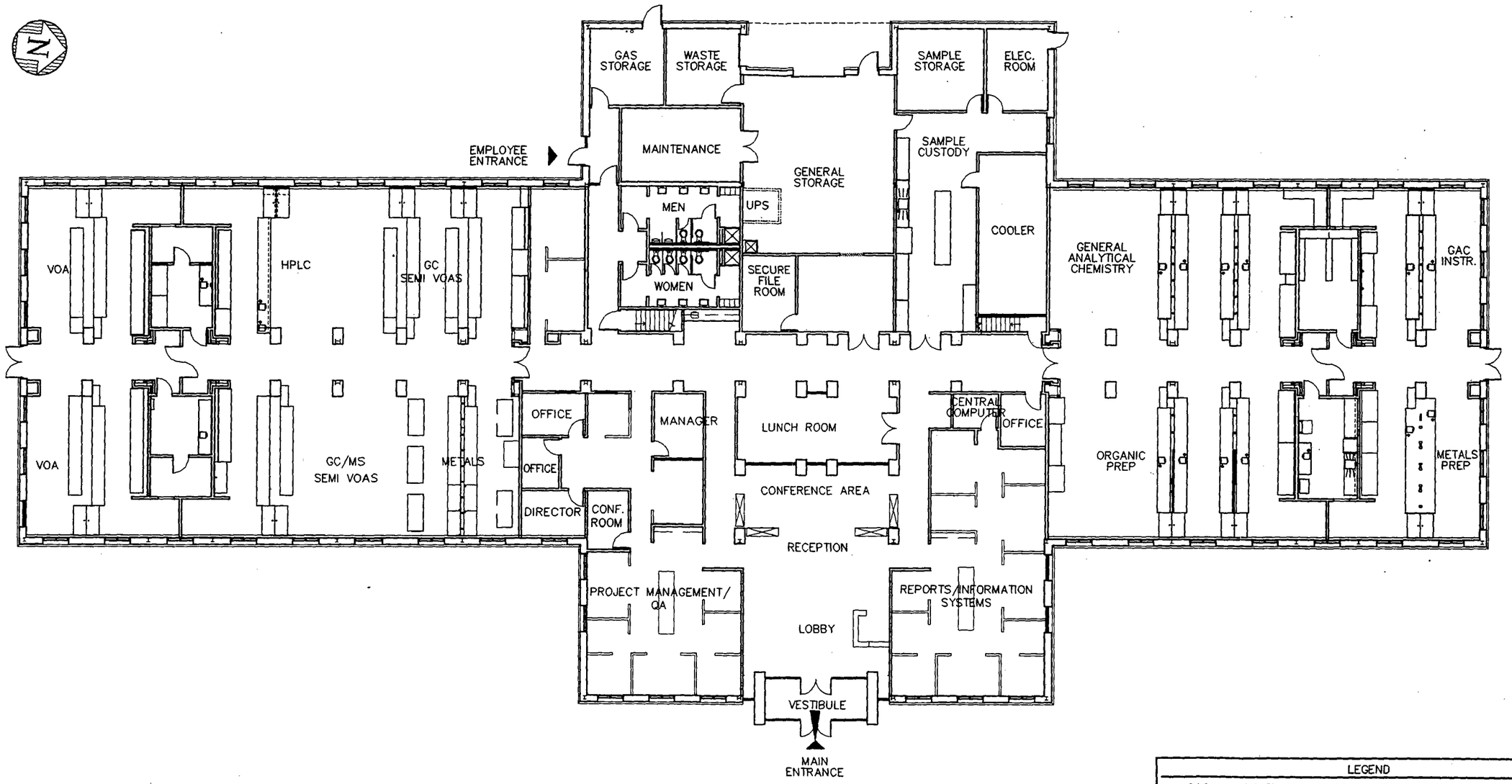
All doors are locked after normal business hours and require a card for entry. The security alarm at ASC continuously monitors for smoke, extreme fire-related heat, cold room temperatures, motion, and door contacts. When the alarm is activated, the appropriate emergency response offices are notified. An emergency contact list is provided to the local emergency offices for contact in case of an emergency.

6.2.3 Archives

Access to the archive facilities is limited to the QA Coordinator, Document Control Officer, or personnel designated by them. The archives include all ASC copies of analytical reports, raw data, inactive logbooks, and other data which facilitate traceability of analytical results that are typically older than one year. Materials housed in the archives are labeled with identification numbers to ensure retrievability. Electronic storage tapes and disks are maintained by the individual section supervisor in the laboratory.

6.2.4 Environmental Control

Lighting, noise, and other environmental factors at ASC are maintained at appropriate levels. Heating, ventilation, and air-conditioning systems satisfy the needs of the testing being performed. The laboratory building is designed to ensure constant temperature control for analytical equipment. The building has three completely separate air-handling systems to minimize airborne contaminants that may jeopardize sample integrity. Laboratory activities that involve use of large quantities of organic solvents or inorganic acids are conducted in the northern end of the building, well away from instrument areas.



LEGEND	
GAC	GENERAL ANALYTICAL CHEMISTRY
GC	GAS CHROMATOGRAPHY
HPLC	HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY
MS	MASS SPECTROSCOPY
QA	QUALITY ASSURANCE
VOA	VOLATILE ORGANIC ANALYSIS
SEMI VOA	SEMI VOLATILE ORGANIC ANALYSIS

Figure 6-1 LABORATORY FLOOR PLAN
ECOLOGY AND ENVIRONMENT, INC.
ANALYTICAL SERVICE CENTER
WALDEN AVE. AT RANSOM RD.
LANCASTER, NEW YORK

The working and storage environments are maintained in a safe and appropriate manner. Sample and standard storage areas are monitored and temperature controlled. Separate storage areas are designated for samples, standards, and other identified sources of potential cross-contamination. Sample storage areas for volatiles are separated from other storage areas and monitored for any cross-contamination effects.

Safety measures and equipment which protect personnel and property from injury or illness include: fume hoods, fire extinguishers, fire blankets, alarm systems, safety training, protective clothing, emergency showers, eyewashes, and spill control kits.

6.3 Chemical Storage

All chemicals are stored in appropriate cabinets and are properly disposed of when necessary. All flammable solvents are kept in OSHA and National Fire Protection Association (NFPA) approved cabinets. Acids are stored in OSHA approved acid cabinets.

All chemicals, samples, and wastes are accumulated in satellite areas in the laboratory as specified in the waste disposal SOP A.10 and Chemical Hygiene Plan. The samples and wastes are then transferred to the waste storage area. This area is specially designed and separately ventilated to accommodate waste storage prior to proper disposal.

An authorized waste carrier is contracted to pick up waste as needed and dispose of it, in accordance with all regulatory requirements. Post-analysis disposition of samples is dependent upon project-specific requests. Remaining sample material may be returned to the client, safely discarded, or archived for a specific period of time prior to disposal. Section 10.5 defines the specific requirements for sample disposal and other waste disposal operations.

7

Equipment and Materials

Accurate analysis consists of setting up proper instrument operating conditions, calibrating instruments, monitoring instrument performance tests, analyzing prepared samples, and collecting data from the analyses. Instrumental analysis procedures, frequencies, and acceptance criteria are described in the test method SOP. The basis for performance criteria, instrument conditions, and the steps of each procedure are derived from EPA or client-specified reference methods.

7.1 Instruments

Analytical instrumentation at ASC includes:

- Gas chromatographs (GC);
- Gas chromatographs/mass spectrometers (GC/MS);
- High performance liquid chromatographs (HPLC);
- Ion chromatographs (IC);
- ICP-atomic emission spectrophotometers;
- Atomic absorption spectrophotometers (AA);
- UV/visible and infrared spectrophotometers; and
- Flow injection analyzers.

ASC's major equipment is summarized in Table D-1 in Appendix D. All instrumentation is uniquely identified by an instrument code and serial number.

Regular maintenance procedures and frequency for all equipment ~~is~~ are defined in the test method SOP. A stock of spare parts and consumables are maintained for all analytical equipment. Backup instrumentation for most analytical equipment is available in the event of major equipment failure. The laboratory has a large uninterruptible power source (UPS) capable of sustaining power to the instruments and computers for up to three hours in the event of a power

The laboratory has a large uninterruptible power source (UPS) capable of sustaining power to the instruments and computers for up to three hours in the event of a power failure. The UPS prevents problems caused by fluctuations in the power source.

failure. The UPS prevents problems caused by fluctuations in the power source.

Service contracts are maintained for major instrumentation. Service technicians may be called for on-site service of major equipment if routine maintenance operations do not eliminate any problems. Procedures and schedules for preventive maintenance are available in the test method SOPs. All preventative and corrective instrument maintenance is recorded in the maintenance logbook assigned to the equipment. Records of external service are stored in files by the Section Supervisor. Instruments will be tagged as out-of-service until maintenance procedures are completed.

After instrument maintenance or repair, the instruments must be successfully recalibrated following the method SOP. Laboratory personnel must demonstrate acceptable QC performance on the instrument before sample analysis is conducted with it.

7.2 Instrument Operating Conditions

The reference methods for a given analysis define the instrument operating conditions. In many of the reference methods, a range or general guidance for the operating conditions is defined. The operating conditions may be modified to clarify the reference methods or improve the quality of the results. In all cases where the method is modified, the performance criteria from the reference method must be within the defined acceptance limits. Acceptable modifications to the operating conditions are stated in the method SOP. Any change in the operating conditions not stated in the SOP is documented on a corrective action form. When a change in the operating condition is proven to improve performance for all matrices, the method SOP is revised.

7.3 Computer Systems

E & E maintains an extensive network of computer systems centralized in the corporate headquarters building. ASC's domain includes an integrated network of standalone instrument computers, instrument data systems, servers, personal computers, a central VAX, and VAX terminals.

The GC/MS data system is a UNIX-based Hewlett Packard (HP) 9000/735 system running Target Chromatographic Analysis software by Thru-put. The central server (i.e., PA-RISC, 208 megabyte (MB) random access memory (RAM) and 8 gigabytes (GB) disk space) is supported with eight PC stations and three HP1000 minicomputers. In addition, the UNIX data system is networked to two HPLC PC stations running HP Chemstation software. The GC data system is the newest version of the Perkin Elmer Turbochrom Cli-

ent-server Chromatographic Analysis software running on an HP Netserver LH Pro/200 with 64 MB RAM and 4.2 GB of disk space. The GC data system supports seven PC stations. The PE Optima ICP stand-alone Winlab data system runs on a Windows 95 PC station. All other instruments operate standalone data systems.

The ASC is currently upgrading their laboratory information management system (LIMS). Developed by E & E in FOCUS for in-house use, the current system (LABMIS) is a menu-driven, multiuser database management system operating on a VAX 3100. LABMIS provides full-feature, flexible laboratory information management including sample management, work assignment, sample tracking, data reporting, QA, financial planning, and resource allocation. LABMIS is supported by Laboratory Report System (LRS) developed for generating custom reports and electronic deliverables. LRS was developed in-house as a multi-user client-server application. LRS, developed in Powerbuilder running a Microsoft SQL central database, runs on a Windows NT Pentium PC server. For Contract Laboratory Program (CLP) reporting, ASC runs Formmaster software for organics analysis and Ward software for inorganic reporting on stand-alone PC stations. The existing system also uses a VAX 4100 as a network and e-mail server. The new LIMS will replace all existing functions of LABMIS and LRS.

In addition to the LIMS, all ASC support software has been upgraded to Microsoft Office 97 running in Windows 95. All the systems are linked to over 45 PCs and 20 printers.

E & E's Corporate Computer Support Center, publications network, graphics, and computer-aided design (CAD) departments also support ASC. Through these groups, ASC has complete access to the latest programming and office support software required by clients.

7.4 Sampling Materials

While ASC does not routinely perform sampling, ASC does provide clients with materials needed for sampling upon request. Materials are assembled to meet project-specific requests. The materials provided may include the bottles, blanks, custody form(s), preservatives, and cooler(s) to be used during sample collection. Tables 7-1 and 7-2 list standard containers provided by ASC. The sample containers or bottles for sample collection are purchased either precleaned, with a certificate of the test results, or precleaned but without a certificate for which ASC then tests lots for contamination. The certificates of analysis are maintained by shipping personnel. The lot numbers, expiration date, and amount of reagent used for sample preservation are recorded and tracked by shipment. Field and trip blanks are preserved with the same reagents as the samples and are tracked by lot number.

Table 7-1 Sample Containers and Volumes for Soil Samples

Type of Analysis	Type and Size of Container	Number of Containers and Sample Volume (per sample)	Minimum Volume per Test (grams)
Purgeable (volatile) organics	40-ml glass VOA vial with teflon-backed septum or 4-oz. VOA glass jar with teflon-lined cap	One; fill completely, minimal air space	Fill container
Extractable organics	8-oz. glass jar with teflon-lined cap	One; fill completely	50
Metals	8-oz. glass jar with teflon-lined cap	One; fill completely	25
General analytical tests	8-oz. glass jar with teflon-lined cap	One; fill completely	15

Notes:

All sample bottles are prepared in accordance with generally accepted bottle-washing procedures.

Several types of analyses may be performed on samples from the same container, depending on the sample density and minimum volume requirements.

When project-specific laboratory QC samples are required, a double volume of the sample should be collected and labeled as MS/MSD, or duplicate, etc. Minimum volumes do not include QC samples.

Sample preservation requirements and holding times are presented in Appendix E.

Key:

VOA = Volatile organic analysis.

Table 7-2 Sample Containers and Volumes for Water Samples

Type of Analysis	Type and Size of Container	Number of Containers and Sample Volume (per sample)	Minimum Volume per Test (mL)
Purgeable (volatile) organics	40-ml glass vial with teflon-backed septums	Two; fill completely; no air space	40
Extractable organics	0.5-gallon or 1-liter amber glass bottle with teflon-lined caps	One 0.5-gallon or two per test; fill 7/8 full	1,000
Metals	1-liter polyethylene bottle with polyethylene-lined cap	One; fill 7/8 full	600
Cyanide	1-liter polyethylene bottle with polyethylene-lined cap	One; fill 7/8 full	50
TOC	125-mil polyethylene bottle	One; fill completely	50
Sulfide	1-liter polyethylene bottle	One; fill completely, no air space	200
Acidity, alkalinity, pH, dissolved solids, suspended solids	1-liter polyethylene bottle with polyethylene-lined cap (multiple analyses) all from one bottle)	One; fill completely	1,000
Hardness	1-liter polyethylene bottle with polyethylene-lined cap	Can take out of metals analysis bottles	100
Chloride	1-liter polyethylene bottle with polyethylene-lined cap	One; fill completely	100
Sulfate	1-liter polyethylene bottle with polyethylene-lined cap	One; fill completely	100
Nitrate	1-liter polyethylene bottle	One; fill completely	100
Nitrite	1-liter polyethylene bottle	One; fill completely	100
Total phenol	1-liter amber glass bottle	One; fill completely	500
Dissolved oxygen	BOD bottle	Two; fill completely	Fill/container
TOX	1-liter amber glass bottle	One; fill completely, no air space	200
Ammonia-nitrogen	1-liter polyethylene bottle with polyethylene-lined cap	One; fill completely	500
BOD_5	1-liter polyethylene bottle with polyethylene-lined cap	One; fill completely	100
COD	1 125-ml polyethylene bottle with polyethylene-lined cap	One; fill completely	100
Color	1-liter polyethylene bottle with polyethylene-lined cap	One; fill completely	100
Fluoride	1-liter polyethylene bottle with polyethylene-lined cap	One; fill completely	100
TKN	1-liter polyethylene bottle with polyethylene-lined cap	One; fill completely	200
Hexavalent chromium	One 125-ml polyethylene bottle with polyethylene-lined cap	One; fill completely	200
Oil and Grease	1-liter amber glass bottle	One; fill completely	1,000

Table 7-2 Sample Containers and Volumes for Water Samples

Type of Analysis	Type and Size of Container	Number of Containers and Sample Volume (per sample)	Minimum Volume per Test (mL)
TRPH	1-liter amber glass bottle	One; fill completely	1,000
Orthophosphate	1-liter polyethylene bottle with polyethylene-lined cap	One; fill completely	50

Notes:

All sample bottles are prepared in accordance with generally acceptable bottle-washing procedures.

Several types of analyses may be performed on samples from the same container depending on the minimum sample volume and preservation requirements.

When project-specific laboratory quality control samples are required, a double volume of the sample should be collected and labeled as a matrix spike/matrix spike duplicate, duplicate, etc. Minimum volumes do not include QC samples.

Sample preservation requirements and holding times are presented in Appendix E.

Key:

BOC_5 = Five-day biochemical oxygen demand.
BOD = Biochemical oxygen demand.
COD = Chemical oxygen demand.
TKN = Total Kjeldahl nitrogen.
TOC = Total organic carbon.
TOX = Total organic halogen.
TRPH = Total recoverable petroleum hydrocarbons.

Materials used for sampling are stored in the warehouse building adjacent to the laboratory building. Reagents for preservation are stored in designated areas to avoid contamination during storage. Trip blanks are prepared as needed in the laboratory volatiles area. All glass containers are packaged to prevent breakage. The containers are placed in plastic coolers, filled with additional packing material, and sealed with tape for shipping.

Sample containers are purchased from vendors using EPA-approved glass cleaning procedures. Vendors are qualified approximately every one to two years. The vendor selection process includes a preselection review of qualifications, preparation of a request for quotation, and receipt and review of proposals. Competitive bidders are required to send a series of bottles for testing. ASC tests a subset by batch of containers to ensure product quality prior to awarding contracts. Once a vendor is awarded the contract, the vendor secures large lots of bottles required by the laboratory. Bottles are shipped to ASC or directly to sampling sites from the lots allocated to E & E. ASC retests the bottles every time the lot is expended.

7.5 Glassware and Glassware Cleaning

Glassware subjected to heat or chemicals are of borosilicate glass. The laboratory also possesses Teflon™ ware for certain tests. Volumetric glassware is Class A.

All glassware used for the preparation of samples is cleaned as described in the ~~SOPs~~ SOP for glassware cleaning, A.31, defined for each laboratory preparation area. These procedures include pre-rinses and soapy water washes. The pre-rinse may be solvent, water, or acid solution, depending on the analysis. Glassware is washed with laboratory grade detergents, followed by multiple ASTM Type II water rinses. Cleaning procedures required by specific methods may include solvent, acid, or other rinses. The clean glassware is air dried unless other drying is recommended by the reference test method. The clean glassware is stored in the laboratory area as specified in the reference method or on designated shelves.

Cleaning areas and materials are segregated to avoid cross-contamination. Glassware used for high concentration analyses is kept segregated from glassware used for low concentration analyses. Dedicated glassware is used for volatiles, extractable organic compounds, GAC, and metals analyses.

8 Standards and Calibration

During the analytical process, a variety of measurements are required including volume, weight, concentration, pH, and temperature measurements. ASC follows established practices as documented in SOPs that ensure the calibration and verification of all equipment and the traceability of standards to national standards of measurement (where available).

8.1 Chemical Standards

The procurement, preparation, handling, storage, and documentation of chemical standards is critical to the analytical process. It is through these chemical standards that reported analyte measurements in samples are traceable to reference values. ASC uses only the highest quality chemicals as reference materials. Whenever possible, standard solutions must be traceable to national standards, such as National Institute of Standards and Technology (NIST) or EPA-certified reference materials.

Preparation of the chemical standards is documented in the method SOP. The documentation requirements for ensuring traceability are defined in the reagent and standard traceability SOP A.28. The procedures describe the management of these analytical standards and the reagents used in preparing the standards. All analysts are trained in the reagent and traceability SOP and are responsible for implementing the procedures.

8.1.1 Sources of Standards, Traceability, and Verification

ASC purchases chemical standards from approved suppliers. Information about the standards along with any client requirements are recorded in the pertinent standards logbook. The analyst receiving a chemical standard shipment verifies that the information on the standard label is consistent with that on the supplier's certificate or other paperwork. Information about the standard is recorded in a standards logbook. Codes that unambiguously identify the supplier materials and all derived preparations are also used to trace standard

solutions. Non-certified materials are verified against certified reference standards, when certified reference materials are available.

Primary Standard - A neat or concentrated standard received from a supplier. A primary standard is traceable to NIST or verified as equivalent to a certified reference material.

Secondary Standard - A neat or concentrated standard received from a supplier or prepared at a laboratory. The solution's concentration is determined against a primary standard.

Stock Standard - A solution of a standard at a high concentration, used to prepare working standards. These may be prepared in-house or received from a supplier. This standard may be a primary or secondary standard.

Working Standard - A solution of one or more standards or stock standards containing the analyte(s) of interest. The standard is prepared at the concentration defined in the appropriate method SOPs. The working standard is used to directly prepare instrument calibration or sample fortification. These may be prepared in-house from primary or stock standards, or purchased from a supplier.

8.1.2 Types of Standards

Analytical methodologies define a variety of QC standards which are used by the laboratory and include: surrogate spikes, MS, internal standards, QC check standards, and calibration standards. The composition and concentration of these standards must conform to method specifications. Standards used to prepare QC standards are categorized at ASC according to primary standard, secondary standard, stock standard, and working standard.

8.1.3 Preparation of Standards

Standard solutions are prepared by experienced analysts and documented in the appropriate standards logbooks. How a standard solution is prepared depends upon the amount required, the concentration required, and the solution's intended application. New standards are prepared as needed.

All standards are assigned an expiration date. If provided, the supplier's assigned expiration date is used for standard or stock standards, otherwise, the expiration date is assigned based on the supplier's date of preparation and the known stability of the analyte. Analytes known to be highly volatile or subject to rapid degradation or reaction are assigned shorter expiration dates. A standard mixture is assigned an expiration date no later than that of the shortest-lived components.

The expiration date is a latest use date. Standards are examined for deterioration and evaluated for their contribution to analytical problems during each analytical sequence. The QC parameters for each analysis are designed to monitor the working standards. Standard solutions showing signs of deterioration or with uncertain integrity are replaced immediately prior to their expiration date.

Analyte or standard components common to calibration solutions and associated QC sample(s) may be from the same source or an independent source. QC samples such as the LCS or initial calibration verification (ICV) are typically prepared with reference material that is independent of the associated calibration standards. In cases where the working standard used for the calibration solutions and the QC samples are from the same supplier, different batch or lot numbers are used.

8.1.4 Inventory and Storage

Documentation for all standards is carefully kept in relevant standards logbooks. Certificates from the manufacturer are taped in

the bound logbook or placed in a ring binder. Each certificate includes the code number for the standard. The manner of storage for a standard is determined by its type, expiration date, shelf life, or manufacturer's specifications. All light sensitive standards are stored in amber vials or bottles in designated refrigerators, freezers, or chemical shelves. Analytical standards are never stored together with samples, extracts, or digestates.

8.2 Calibration Procedures and Frequencies

All equipment used for measurement and testing meets the specific requirements of pertinent analytical methods and applicable certification agencies. Calibration procedures and frequencies for specific types of equipment are briefly summarized below. Section 8.3 describes major instruments such as GC/MSs, GCs, HPLCs, and ICPs. Section 8.4 describes support equipment, such as thermometers, analytical balances, pH meters, autopipettors, and volumetric glassware. The specific calibration procedure and frequency are specified in separate SOPs for support equipment or the SOP for the test method using the instrument. Calibration criteria are listed in the method SOP. ASC does not report data for any samples unless the performance criteria for calibrations are satisfied.

Most instrumentation software indicates for the calibration curve the test method, date, analyte, and standard concentrations used and corresponding instrument responses. When prepared manually, the analyst records these. The software reports the equation of the calibration curve and the correlation coefficient. When the curve is recorded manually, the analyst records the equation of curve and the correlation coefficient.

The instrumental performance requirements of the published methods and/or manufacturer specifications are followed unless otherwise specified for a project. Other performance tests may also be executed to further demonstrate proper functioning of instrumentation. Any instrument not functioning properly will be tagged out-of-service until proper operation is restored. SOPs for the operation of measurement equipment on the test method contain the following information, as applicable:

- Equipment used in the procedure;
- Calibration procedure, including all formulas and calculations;
- Acceptance criteria for the calibrations, including the accuracy and precision required;
- Corrective action for failed acceptance criteria, including assessment of previous calibration results;

- List of calibration standards;
- Frequency with which the equipment is calibrated, adjusted, and checked; and
- Maintenance of the equipment and record keeping to track performance before and after maintenance.

8.3 Instrumentation

8.3.1 Gas Chromatography/Mass Spectrometry

The GC/MS is hardware tuned prior to performing the initial and continuing calibrations and all sample analyses. Results are required to meet the peak ratio specifications of the analytical methods. For volatiles analyses, bromofluorobenzene (BFB) is used, and for semivolatliles analyses, decafluorotriphenylphosphine (DFTPP) is used.

The GC/MS is calibrated using internal standard techniques by analyzing a set of five or more initial calibration solutions, using procedures specified in the method and SOP.

Calibration criteria are listed in the method SOP. The initial calibration is verified by analysis of a second source standard.

Each day the initial calibration is verified through the analysis of a continuing calibration standard at the start of each clock sequence. The concentration of the continuing calibration standard is dependent on the requirements of the specific method and SOP.

8.3.2 Gas Chromatography and High Performance Liquid Chromatography

External standard calibration is utilized for analysis by GC and HPLC. The method-specified number of calibration standards are used (e.g., generally 5 points) and specified in the SOP. For multiple response components (e.g., polychlorinated biphenyls, toxaphene) the quantitation consists of an average of the quantitated values for selected peaks. Calibration criteria are listed in the method SOP. The initial calibration is verified by analysis of a second source standard.

Each day the initial calibration is verified through the analysis of a continuing calibration standard at the beginning of the analytical sequence at least every 20 samples. The concentration of the continuing calibration standard is dependent on the requirements of the specific method and SOP.

Other standard checks may be required for a specified reference method. Instrument performance checks specified in the reference

method must be performed and within the acceptance limits stated in the reference method.

8.3.3 Atomic Absorption Spectrophotometry

An initial calibration is performed daily with standards as specified in the SOP. The initial calibration is verified at the beginning of the run sequence and every 10 samples. Continuing calibration blanks are run at the same frequency.

The continuing calibration must be within the range specified in the analytical method SOP utilized. Analysis of samples cannot begin until an initial calibration verification has been performed and is found to be within the specified range of the true value (generally 10% of the expected value).

8.3.4 Inductively Coupled Plasma Emission Spectrophotometry

Initial calibration is performed daily and continuing calibrations are performed every 10 samples. The number of initial calibration standards used depends on the method employed. Samples are not analyzed until an initial calibration verification has been performed and is found to be within specified range of the true value, depending on the method. Continuing calibration is required to meet the criteria of the analytical method.

8.4 Support Equipment

All equipment is calibrated according to the SOP used for the analysis. The most common support equipment used in the laboratory are thermometers, balances, pH meters, and conductivity meters. This section provides a general summary of the procedure used for calibration and measurement controls. Other equipment calibration is defined in the test method SOP.

8.4.1 Thermometers

Laboratory thermometers are routinely checked for accuracy against certified, NIST-traceable thermometers following the thermometer calibration procedure. These calibrations are performed annually. Correction factors derived from the annual calibrations are applied to temperature readings. NIST-traceable thermometers are professionally calibrated and recertified every five years. Records of thermometer calibrations are retained in one logbook in the general analytical chemistry laboratory area. All thermometers are tagged with the thermometer ID number, correction factor to be applied to the measurement, and the expiration date of the calibration check. Thermometers past the calibration expiration date or thermometers not reading properly are not used. Replacement thermometers are calibrated, and the maintenance logbook is updated when a change

in the thermometer is required due to breakage, damage, or expired calibration.

8.4.2 Balances

Calibration checks are performed for each day of use, for each balance. The calibration consists of a minimum of two weights which bracket the weight to be measured. The balance calibration procedure defines the acceptance criteria and performance criteria for the various balances used in the laboratory. Calibration weight measurements must meet the acceptance criteria listed in the SOP A.19 and balance calibration logbook. Each balance is serviced and calibrated by a certified professional at least annually. The accuracy of the calibration weights used by ASC is verified each year by an accredited calibration service. Balances are labeled with the balance number, date of service, and the expiration date for the annual service check. The balance number used for any measurements requiring traceability is recorded with the measurement data. Balances with expired calibrations or that fail the weight check are not used.

8.4.3 pH Meters

Each day pH meters are calibrated prior to use. The meter is calibrated following the procedure for pH analysis (SOP GAC.34). Records of the calibration are documented in an instrument logbook or in the raw data for the analysis being performed. At least two buffer solutions that bracket the measurement range of the analysis are used for calibration. A check standard is used at the end of the analysis run to verify meter stability.

8.4.4 Conductivity Meters

A five-point calibration curve using potassium chloride (KCl) solutions is analyzed annually. The calibration curve is used to determine the cell constant for the meter. The cell constant from the annual calibration curve is compared to the acceptance criteria defined by the manufacturer. If performance is unacceptable, the cell is cleaned and rechecked. The cell is not used until satisfactory performance is achieved.

A single KCl standard solution is used as a check standard each day the meter is used. The meter is labeled with the expiration date for the annual calibration.

9

Test Methods and SOPs

ASC is a full service analytical laboratory. Products include the preparation and analysis of a wide variety of sample matrices using standard, approved methods. In addition, ASC develops and validates non-routine analytical methods. ASC's standard products are listed in Table E-1 in Appendix E. ASC's procedures for validation of new methods are described below.

9.1 Routine Analytical Methods

ASC utilizes a variety of in-house analytical methods that are based on the most recent versions of EPA or other published methods. In some cases, minor modifications of the reference methodology may be employed. Such modifications are listed in the corresponding SOP and must be validated prior to implementation. Accuracy, precision, and sensitivity must be within the acceptance criteria of the reference method. Compounds, elements, or parameters to be measured are chosen from the reference methods. Additional compounds, elements, or parameters may be added based on client or project specific requests. Reference methods are utilized from the latest version of the following references:

- *Test Methods for Evaluating Solid Waste, Physical/Chemical Methods*, EPA SW-846;
- *Standard Methods for the Examination of Water and Wastewater* (American Public Health Association [APHA]/American Water Works Association [AWWA]);
- *Methods for Chemical Analysis of Water and Wastewater* (EPA);
- Wastewater testing references cited in 40 Code of Federal Regulations (CFR) Part 136;
- EPA Contract Laboratory Program Statements of Work for Organic and Inorganic Analyses;
- Drinking water testing references cited in 40 CFR Part 141;
- ASTM guidelines; and

- Specialty testing references cited by state regulatory programs.

The test methodologies are listed in Table E-1. An inventory of the ASC SOPs is provided in Appendix F.

SOPs are written for each analytical method as described in the SOP on SOPs. Analytical SOPs include a method summary; health and safety concerns; references; interferences; instrumentation and equipment; reagents and materials; preservation and container handling; a detailed description of the procedure including all calculations; data reduction and reporting; QA/QC procedures; and sample disposal. Any special client requirements are listed in a separate section. SOPs are developed, reviewed, and revised according to document control procedures described in Section 11. All SOPs must reflect actual laboratory practice and are used as a training tool for new and existing analysts. SOPs are reviewed annually or when the method is revised. All analysts receive training on the major revisions prior to the actual implementation date.

9.2 Target Compounds

Most of the organic analytical methods can be used to analyze multiple parameters that are either listed in the method or considered potentially detectable by the analytical technique. The target compounds for the method depend on the specific application or project. For each method, the laboratory maintains a standard target compound list as identified in the individual method SOPs. The standard compound list is made up of the compounds that are analyzed routinely, included in all standards, and used to generate internal control limits and method performance data. The laboratory may add or delete compounds from the method and will generate the QC data for the compound as required for the specific application or project. In some cases, the method SOPs list compounds that ASC has historical data demonstrating the use of the method for that compound.

9.3 Non-Routine Analytical Methods

~~ASC has over 20 years of experience in the development of non-routine analytical methods.~~ The process of development of non-routine analytical methods includes a literature search and review, development and approval of an experimental approach, testing of analytical techniques, and generation of method performance data such as an MDL or Initial Precision and Recovery (IPR) studies. Method development studies are conducted under Good Laboratory Practice procedures. Methods are documented in an SOP.

10 Sample Management

10.1 Sample Receipt and Chain-of-Custody

The sample custodian or designee receives all samples. A job number is assigned to each shipment of samples received from a client. In-house records for a new job are initiated with a cooler receipt form. Samples not received in coolers are received by the sample custodian with all documentation recorded on the custody form. The sample custody form is signed by the client and sample custodian when the samples are received at the laboratory. Samples received via overnight courier are signed on the bill of lading. The bill of lading, cooler receipt form, and the sample receipt log are completed for samples delivered by courier (see examples in Appendix B).

The shipping containers, their contents, and accompanying client documentation are examined by the sample custodian. Information about the presence and condition of custody seals, the state of preservation of the samples, and other required information is noted on the cooler receipt form and/or package receipt log. The cooler temperature, along with the presence or absence of ice, is recorded on the cooler receipt form and chain-of-custody (COC), if applicable. ASC recommends clients include a temperature blank in all coolers. Any discrepancies in documentation or problems with sample condition are noted and immediately brought to the attention of the client via the corrective action form. The project manager provides the sample custodian with instructions on the processing of samples that are incomplete or missing required information.

The sample custodian logs the samples into the LIMS, and a label for each container is printed. The custodian attaches each barcode label to the appropriate sample container. The following information is recorded for tracking samples: laboratory sample ID, client sample ID, sample matrix, and storage location. The sample receipt and handling SOPs describe procedures for sample receipt and log-in, COC, and handling of sample shipment containers provided by clients.

10.1.1 Sample Acceptance Policy

ASC will only accept samples that are appropriate for the requested tests, that are accompanied by sufficient documentation, that are representative of the media sampled, and that pose no abnormal health and safety threats to facilities or employees.

Samples are appropriate for the requested tests if:

- they are in the proper containers,
- the matrix is compatible with the test,
- there is sufficient volume,
- they are properly preserved, and
- they are within hold times.

Documentation is sufficient if:

- the sampler is identified correctly;
- the sample location, date, time of collection, and sampler's name are noted;
- preservatives added are noted;
- information is legible; and
- a COC form or equivalent documentation is used.

A sample is representative if:

- the proportion of multiple layers represents the source;
- multiple matrices are in separate containers; and
- the container contents match the documentation.

A sample is acceptable from a health and safety perspective if:

- it is not radioactive (≤2 x background);
- it contains no dioxin or furan compounds in concentrations which will cause health, safety, or disposal problems;
- it is not explosive, shock sensitive, air or water reactive; and

- the outside of the sample container is clean.

It is the responsibility of the sample management staff to note when samples are unacceptable. It is the responsibility of project managers to make final determinations regarding samples, to notify clients, and to make appropriate comments in laboratory reports.

10.2 Sample Preservation and Security

Samples are stored in a secure manner to ensure their integrity. Samples are stored at temperatures that meet the specifications of the methodology, regulatory agencies, and client. Refrigerator temperatures are maintained at required temperatures (2° - 6°C) and monitored regularly. Preservatives, temperatures, holding times, and container storage requirements are listed in Appendix E. QAPPs may list preservation requirements differing from the laboratory. This information is provided to the sample custodians for project-specific handling.

Chemical preservatives are normally added to sample containers in the field at the time of sampling. Chemical preservation and temperature preservation are checked upon receipt with the exception of preservation for volatile organic compounds, which is checked at analysis. Any differences from laboratory or client-specific requirements are recorded on corrective action forms, and the client is contacted by the project manager.

Sample storage facilities are located within the sample management area which is secured by locked doors. Internal procedures and documentation pertaining to sample possession, removal from storage, and transfer are outlined in the sample custody procedure. Samples are returned to the sample management area after the required sample portion is removed for analysis.

Precautions are taken to ensure that cross-contamination does not occur during sample storage. Refrigerator storage blanks are monitored weekly for volatile compounds. Storage blanks from the volatiles sample storage refrigerator are replaced weekly and the previous blanks removed. The storage blank information helps ASC personnel assess potential cross-contamination in the sample storage refrigerator. Additional project-specific storage blanks are used as required.

Temperatures of cold storage areas are monitored using NIST-traceable thermometers and recorded daily. Corrective action is taken as necessary when temperatures are not within the control criteria. All temperature records document which thermometer

was used to obtain the measurement. Walk-in coolers are monitored electronically 24 hours per day. Details regarding sample storage and preservation are provided in the sample log-in SOP SM.2 and SM.4, and in the SOP A.43.

10.3 Sample Preparation and Analysis

All sample preparation and analysis procedures employed at ASC are covered by appropriate SOPs. Samples are prepared and analyzed following the method specified by client requirements and the matrix to be analyzed. Most samples must be prepared and/or analyzed within a method-specified holding time after sampling (see Appendix E). Any exceptions to the specified holding times are subject to the corrective action process and noted in the case narrative.

Holding times listed in the applicable project-specific documents are followed as required. Samples are occasionally received after holding times have expired. A corrective action form is completed whenever holding times are exceeded. The project manager notifies the client, and the client decides to continue with the analysis or suspend the testing.

The LIMS tracks holding times and applicable analytical methods and helps ensure that all method and client requirements are met.

10.4 Sample, Extract, and Digestates Archiving

The sample custodian and other authorized personnel are responsible for archiving and disposing of raw samples, extracts, and digestates. Raw and prepared samples are not archived or disposed of until all of the designated analyses are complete and resultant analytical data is sent to clients. Samples in storage are retained for at least 30 days after reporting of the results; any samples requiring longer storage are archived. Longer retainage is available on a project-specific basis.

Archive samples are placed in boxes, labeled with the project numbers and disposal date, and retained in a sample archive area for any additional length of time specified by the client prior to disposal. The archive samples may be stored in the refrigerator or at ambient temperature, as specified by the client. Archived samples are disposed of at any time after the predetermined date in accordance with all applicable rules, regulations, and SOPs. Clients are informed of sample disposal and archiving procedures and given an opportunity to request exceptions to the routine practices as part of the contract or task order.

10.5 Sample Disposal

It is the policy of ASC to dispose of all samples and waste in accordance with all applicable rules and regulations. The following lists the primary regulations regarding disposal.

Resource Conservation and Recovery Act (RCRA): Regulations pertaining to the Resource Conservation and Recovery Act (RCRA) and its amending legislation are published in 40 CFR 260-299. The regulations pertaining to satellite accumulation are found in 40 CFR 262. Regulations for generators are found in 40 CFR 265. Solid and hazardous waste definitions are located in 40 CFR 260 and 261.

Hazardous Materials Transportation Act (HMTA): The U.S. Department of Transportation (DOT) promulgates regulations under the HMTA in 49 CFR. HMTA regulations cover all hazardous materials (including both hazardous substances and hazardous wastes) and all aspects of their packaging, preparation, identification, and segregation during transportation.

Occupational Safety and Health Act: The Occupational Safety and Health Act (OSH) authorizes OSHA to provide and enforce regulations governing worker safety. OSHA regulations are found in 29 CFR, with many of the sections pertaining to the laboratory found in part 1910 including 1910.120 *Hazardous Waste Operations and Emergency Response*, 1910.1200 *Hazard Communication*, and 1910.1450 *Occupational Exposure to Hazardous Chemicals in Laboratories*.

New York State Requirements: The State of New York has primacy in the area of environmental enforcement under RCRA. The regulations governing generators and storage of hazardous waste are found in Title 6, Conservation, of the State of New York Code of Rules and Regulations (NYCRR).

10.6 Sample Return to Clients

When a client has requested the return of samples, the sample custodian prepares and ships the samples according to the same custody procedures used to originally send the samples, and following any client-specified requirements. Special packaging procedures are implemented to protect the samples during delivery. Packages are delivered by a commercial carrier whose procedures for protecting the samples are beyond the control of ASC. Clients are informed that a commercial carrier will deliver their samples.

10.7 Sample Loss, Damage, or Unsuitability

Samples or sample containers can be lost, damaged, or deemed unsuitable, for whatever reason, after initial receipt at ASC. Whenever this happens, the event is recorded by the observer on the corrective action form. The problem is reported to the project manager who informs the client. Plans for disposition of the affected sample(s) or containers are agreed upon with the client, carried out, and recorded on a corrective action form.

11 Document Control and Records

11.1 Document Control

ASC controls all documents that directly impact data quality as specified in the document control SOP A.27. This includes, but is not limited to, the QAM, SOPs, checklists, and forms. Electronic copies of controlled documents are available to all laboratory personnel via the internal Web page. A hard copy of each document is stamped in green as the control copy and maintained by the Document Control Officer. The document control form (see Appendix B for example) provides a hard copy record of all review and approval signatures, and applicable training and implementation dates.

Uncontrolled copies may be made from the control copy for training and operational review or for external use. The procedure for version document control allows for the retention of a previous version for historical information purposes and includes the status of each active, inactive, or archived document. Inactive documents are procedures not currently requested that may be required in the future. Archived documents are old versions of procedures that have been revised. Each document and any subsequent revisions must be reviewed and approved by authorized personnel prior to issue.

Every document is assigned a unique identification number which is present on each page of the document and entered on a master list of documents. The revision number, approval date, and page number are also listed on each control copy. All version-controlled documents are assigned an implementation date to clearly indicate when a new version is applicable.

11.2 Records

The laboratory maintains an extensive series of records related to sample tracking, analytical results and support information. Records management encompasses document control, software management, analytical reports, and the LIMS. The types of records the laboratory manages include SOPs, forms and checklists, letters and memos, project files, analytical reports, electronic media, QA files, LIMS

data, accounting data, instrument maintenance and other logbooks, programs, spreadsheets, and electronic data deliverables. The general procedures for managing records are outlined in the document control SOP A.27, but additional records management information is presented in individual administrative, QA, reports, and computer SOPs. The following sections summarize policy and procedures on some of the major records retained at the laboratory. All records are required to unequivocally reproduce the analytical results reported and provide evidentiary COC. Records are maintained in retrieval format at the laboratory for at least five years.

11.2.1 Standard Operating Procedures

SOPs are documents detailing every repetitive or standard operation performed by the laboratory. The author of each SOP is generally the person most familiar with the topic being addressed. Each SOP is peer reviewed and authorized by management and the QA area prior to distribution and implementation.

SOPs are evaluated by laboratory supervisors and key technical personnel. The content of each SOP conforms with applicable requirements of analytical methods and certification agencies and is consistent with the good laboratory practice standards. Within these constraints, the content of an SOP may be customized to meet the needs of a particular area of the laboratory. The performance of laboratory operations is subject to audit for compliance with written SOPs. If an SOP is impractical, difficult to follow, or no longer meets laboratory needs, it is modified or replaced.

The process for developing new or revising existing SOPs is documented in the SOP on SOP Administration (QA.18). At a minimum, SOPs are reviewed annually to ensure they reflect current procedures. Revisions are made to SOPs as necessary to reflect changes in procedures. Interim changes may be made to operations based on the implementation of a corrective action, provided that the corrective action is authorized. Finally, all personnel involved in the process affected by the change must be trained in the SOP change and the revised SOP.

The QA Coordinator administers the SOP program, and the Document Control Officer is responsible for clerical preparation and distribution of new or revised SOPs, record keeping, and archiving of replaced and retired SOPs under his/her direction.

11.2.2 Quality Assurance Records

Quality records at ASC are maintained to prove that the QA system is being effectively applied. Specific procedures for the identification, collection, indexing, filing, storage, maintenance, and disposition of various quality records at ASC are described in the document control SOP A.27. All quality records are recorded in permanent (indelible) ink, legible, attributable to those personnel who created them, and protected so they are not adversely affected by an unsuitable environment. They are stored and maintained in a manner that facilitates rapid retrieval for a period of at least five years after completion. Project-specific quality records are available for evaluation by the client or a client representative during the five-year archive period.

11.2.3 Laboratory Data

Laboratory report records are maintained in a job file to prove that adequate QC procedures are being implemented, accountability of the data is maintained, and traceability of analytical results is completed. Accountability means that reported data reflect the sample as it was received, that sample mix-up was avoided, and that the sample was properly preserved after receipt. Traceability means that reported data may be reconstructed at a later date. Through proper documentation, the laboratory is able to demonstrate to clients or government agencies that the data quality is what the laboratory reports it to be. Records contain sufficient information to permit the reconstruction of calibrations, sample preparations, and sample analyses. Raw data information includes method identification, sample identification, instrument identification, and reference to operating conditions, date of analysis, example calculations, and analyst signature.

11.2.4 Project Files

Project managers maintain project files for all projects with specific requirements that deviate from routine SOPs. Project files may include an SOW, proposal or quotation, contract, client communications, or permit/regulatory requirements. The project documentation provided to specify analytical and QA requirements may be in the form of a QAPP.

QAPPs provide an overview of the way a project, group of projects, or specific analytical program is to be conducted. A copy of all client QAPPs to be used by the laboratory are available in the QA area. Historical copies of outdated QAPPs are retained in the archives by the Document Control Officer to aid historical interpretation of the data.

11.2.5 Archives

The archives are contained in a separate building, locked at all times, with access limited to the QA Coordinator, Document Control Officer, and their designees. The person retrieving the records must sign and date a logbook held by the Document Control Officer. All materials removed from and returned to the archive building must be signed, dated, and remain intact.

State and federal agencies and clients have access to applicable archived documentation.

All magnetic and hard copies of data, calibrations, equipment maintenance records, calculations, records of original observations, final test results, and any other miscellaneous quality records directly associated with sample analyses are stored in the archives for a minimum of five years after completion of a project.

11.3 Quality Assurance Manual

The QA Coordinator is responsible for the publication and distribution of the QAM. The QAM is submitted to management for review and authorization annually. As major changes are implemented in the QA system, the QAM is revised and submitted to management for authorization. The QAM is published and revised with the assistance of laboratory management.

The authorization signatures found on the authorization page signify management review and approval of the QAM. The authorization section is kept current to reflect any organizational changes affecting the authorizing positions. The revision number and date of each section is always the same as the revision number and date for the authorization section, indicating that all major revisions have passed through management review. Minor revisions are authorized by the QA Coordinator as specified in the revision table. The revision table is updated to reflect major or minor revisions to sections.

Distribution of the QAM is regulated through document control procedures. Controlled copies of the manual may be distributed to an individual, client, or certifying agency. Uncontrolled copies distinctly marked as "Uncontrolled Copies" may be issued to persons or organizations outside ASC. A distribution list is maintained for all controlled copies of the manual. Updates are provided to all parties listed on the distribution list. All other copies marked as "Uncontrolled Copies" are not subject to updates upon revision of the manual.

Appendices of the QAM are controlled separately from the major text of the document and are not subject to the same training requirements as the policies in the QAM.

11.4 Software Management

The goals of the software development methodology, existing system validations, and the change control system are to ensure that the software systems perform the required functions accurately, that the users understand how to use the system, and that auditors can assure themselves of the validity of the analytical methods. This in turn insures the delivery of accurate, timely analyses to the client.

The computer systems used at ASC are leased from E & E or purchased for a specific instrument system. ASC has a formal validation program for its computer systems that ensures that data transmitted, reported, or manipulated by electronic means are correct and free from errors. The validation and verification program is divided into three areas.

First, new software is developed according to the computer SOP Comp.9 for software validation. New software includes the development of macros for spreadsheets and other tools using commercial software packages.

Second, requests for changes to software are identified through flaws in existing documentation or the need to improve system processes. Final implementation of the change is documented with the software. This documentation provides a complete record of all software and electronic data reporting problems.

Finally, system integrity is verified through programs for routine maintenance, protection from unauthorized access, and electronic verification. Routine maintenance, including system backups, is performed on a scheduled basis. The backup process, password system, and access protection are defined in the computer area SOPs. Electronic verification programs may be used to assure that commercially purchased software is performing at its original specifications. This includes virus checking of all network operations at least once per day. Documentation of all verification and maintenance operations are retained in the equipment logbook for the computer network.

12 Reports

12.1 Data Collection and Reduction

Data collection is performed by the analyst, and data reduction is performed by the analyst and data reporting personnel. Data collection and reduction procedures for specific types of analytical methods are described in the Method SOPs. These procedures vary depending on whether data are acquired manually or electronically.

12.1.1 Manually Acquired Data

Manually acquired data may be recorded on data sheets, logbooks, or entered directly into the computer system. All data are immediately recorded in permanent ink by the analyst, and each page is signed and dated. Corrections are made by drawing one line through the error, dating, initialing, and, where appropriate, noting reasons for the correction in the margin. Unused portions of logbook page intentionally left blank are marked with a large "Z," then signed and dated on the "Z." All logbooks are signed by a peer or supervisory reviewer.

Data sheets are standardized, preprinted forms which are subject to document control and bound in a book. Notebooks are bound, consecutively numbered, and subject to document control.

Either the analyst or data entry personnel enter all manually acquired data directly into LIMS for reporting. Hand-entered data are checked for transcription errors as part of the data review process. Data processed in the LIMS may be corrected for dilution factor, percent solids, and the correct significant figures.

12.1.2 Electronically Produced Data

Electronically produced data may consist of chromatograms, spectra, data printouts, and raw quantitation reports. Raw data for each sample and calibration are signed and dated by the responsible analyst(s) and are fully traceable back to the actual sample. Any alterations to the raw data hard copies and computer files are fully documented and clearly attributable to the person making such alterations. All

manual integrations are hard-copied for inclusion in the raw data, with area changes fully documented on the data printouts. No ambiguity is allowed in data system printouts with regard to correspondence between peaks on a chromatogram and analytes of interest. Computer-collected data is reduced to hard copy as soon as possible. The signed and dated hard copies of the data files for all samples are maintained in the job file for a minimum of five years. The electronic files are safeguarded by a system of backup media to protect against loss of data and programs. Software used for data acquisition and quantitation reports is tested according to written procedures to assure that no data anomalies are present.

Electronically produced data are transferred directly to the LIMS through an instrument interface program, or the data may be hand entered from the instrument printout. All data are checked for accuracy and transcription errors as part of the data review process. Electronically produced data may be corrected for percent solids, dilutions, and significant figures in the LIMS.

12.2 Data Review

Data review is performed by the analyst, the peer analyst, project manager, and QA Coordinator as defined in the data review SOP A.25. At each stage of the analytical process, data are reviewed for completeness, adherence to protocol requirements and project-specific requirements, and documented on appropriate checklists. Results are fully validated; possible compromises of data quality are evaluated; and deviations from protocol requirements are documented. To the greatest extent possible, computer programs are utilized for data reduction. Where manual data manipulation procedures are required, data review includes additional steps to check for transcription errors. If any nonconformances are noted during data review, corrective actions are initiated at the earliest possible opportunity and documented according to the corrective action procedure.

12.2.1 QC Review

The main purpose of the QC review is to determine the extent to which the method and final data meet established requirements. Checklists for each test method and project requirements reference the QC criteria to be reviewed along with the acceptance criteria. The review is conducted by the analyst and peer review analyst. The data review includes a 100% review of all QC elements. All nonconformances are documented as defined in the corrective action procedure. After analyst and peer review, the project manager reviews the reported information for consistency with project requirements. All exceptions are noted in the case narrative for client review. The checklists are signed and dated to indicate that the QC review is complete.

12.2.2 QA Review

Data reviews are performed by the QA Coordinator on a random sampling of ASC data reports. The goal is to perform an evaluation of approximately 10% of sample reports. The actual number is dependent upon available resources and the apparent effectiveness of the operational audits. A data report is carefully evaluated for technical, clerical, and administrative accuracy. Primary emphasis is placed on the ability of the data report to meet current SOP requirements. Data audits are comprehensive assessments of the data review process as defined in Section 4.4. Data audits are conducted annually and allow upper level management to identify opportunities for process improvement, evaluate the efficiency of the system, detect inadequate execution of QC procedures, detect potential system deficiencies, and recommend corrective actions.

12.2.3 Data Qualification and Validation

As part of the data review process, ASC may qualify data prior to reporting. For CLP or CLP-equivalent reports, data qualifiers consistent with the CLP SOW are used. For routine reports, the laboratory uses the following qualifiers:

- "J" – Data are estimated, and typically reported below the practical quantitation limit (PQL).
- "B" – The compound also was detected in the associated method blanks.
- "D" – Dilution.
- "L" – Parameter spike diluted out.
- "M" – Matrix interference.
- "U" – Not detected above the reporting limit.
- "P" – Results from second column confirmation are > 25% D.
- "X" or "E" – Data are reported above the linear range of the calibration.
- "N" – The compound was present, but not confirmed on a second column.
- "C" – See an additional comment.
- "*" – Value outside a laboratory control limit.

After the laboratory releases the data, an E & E corporate or client data validation chemist may review the data package. The data validation chemist will evaluate the package for completeness, and the results against the project-specific DQOs and determine the usability of the results. The data validation chemist may add or remove qualifiers from the data as required for the project. All potential problems will be reported to the laboratory on a corrective action form to ensure appropriate follow-up and tracking.

12.3 Data Reporting

Data are reported by analytical method, target analytes identified, and the quantities present. The content of the final report is dependent on the project-specific requirements. At a minimum, all reports include a coversheet, a case narrative (if applicable to client), analytical results, signature of the responsible laboratory party, the test methods used, dates of sampling and analysis, data qualifiers, and any QC results associated with the samples.

Full data packages may be presented in the latest CLP format or equivalent. CLP format includes a case narrative, standard report forms, and all associated raw data. Customized data packages following RCRA program QC requirements are also prepared. The project-specific checklists for reporting are developed at the start of the project for full data packages if customized packages are substantially different than standard report forms.

Clients requiring electronic data deliverables (EDD) receive data in the electronic format standard developed by the ASC. If client requirements differ from the ASC standard formats, EDDs may be compiled based on the criteria defined at the start of the project. The project-specific acceptance criteria are placed in the electronic file and used to check the final reported data. All flags or data anomalies are presented in the case narrative. The data are retained through the laboratory network back-up process. Details regarding EDD generation are presented in the electronic reporting SOPs.

12.3.1 Data Package Delivery

Data packages are prepared for delivery by each laboratory and compiled in the reporting area according to the reporting SOP Rep.20 and related electronic reporting SOPs. Unless otherwise requested by the client, a copy of the data is shipped while the original is retained in the laboratory archive facility to guard against possible loss of original data. Reports are fully paginated prior to copying. The method of delivery of the data package is specified in the project or contract. Should the shipped data package be lost or damaged during delivery, a copy will be prepared from the original as a replacement. Results also may be faxed or e-

mailed per client requirements. Hard copy reports will be sent by regular mail the following day.

12.4 Corrections and Additions to Documentation

Additions or corrections to reports already issued are handled according to the following policy. The project manager can request an addition or correction in writing using a corrective action form. The form is given to the appropriate data reporting personnel. The requested change is made in a timely manner and may need to be internally verified with the analyst and peer reviewer and must be approved by the laboratory director. After the change is reviewed by the responsible parties, the reporting area issues the new report to the customer. These reports are marked "Amended." The case narrative is changed to record the amended report and the reason for the change from the original. The amended report is stored with the original data package for a minimum of five years.

13 Contracting

13.1 Contract Review

For all analytical services provided by ASC, contract review is accomplished through the generation of a written quote or contract. A written quote is utilized for short-term contracts, usually consisting of one analytical project. A written contract is utilized for long-term contracts consisting of multiple analytical projects.

Project managers are responsible for implementing and documenting contract review. Client requirements, including special needs that are not documented in the current SOPs, are defined and documented in the written quote or contract. Section Supervisors having expertise in specific analytical services are consulted to ensure that the laboratory can meet special requirements. If it is decided that the special requirements cannot be met, this is discussed with the client, and alternatives may be offered. Information about ASC's capacity and availability is made available to project managers by the production coordinator on a regular basis to enable them to make informed decisions regarding contracted delivery times.

Client or project requirements that are not included in the routine laboratory SOPs are communicated to all affected laboratory staff through the training program. Long term project requirements are added to the affected SOPs in the section "Client Specific Requirements." Short term project requirements such as one-time task order requirements or purchase orders are communicated by the project manager to the appropriate personnel by the use of a project memo or a data review checklist. This documentation contains the project-specific requirements used by the analyst, peer reviewer, and project reviewer to ensure that all the requirements are met. The training procedure is followed to document communication with the affected staff.

13.2 Subcontracted Analyses

ASC has established procedures for subcontracting any analyses they cannot perform. The client may be referred directly to another laboratory if no part of the work is to be performed by ASC, or work

may be subcontracted. Subcontracting follows corporate procedures and the laboratory SOP A.32 on subcontracting. All subcontracted laboratories must be approved by the QA Officer and Laboratory Director prior to submitting samples. The approval process ensures that the subcontracting laboratory meets all requirements of the contract including appropriate certifications. For areas that ASC routinely subcontracts, laboratories are audited either on-site or by a data audit at the beginning of the use of the laboratory. ASC subcontracts to laboratories that continue to meet quality objectives for the projects.

Subcontracting also may take place when ASC is able to perform only part of the requested analyses, testing capacity is exceeded, instrument failure occurs, analysis is not possible within the required hold times, or when a specific client request is made. Clients are notified in writing in advance of any work being subcontracted. Notification may be in the form of e-mail, fax memo, proposal, or contract. When the subcontracted analysis is one that ASC has been certified or approved to perform by the client or regulatory agency, the subcontracting lab must have an equivalent certification or approval.

Incoming samples which will be subcontracted are subjected to normal sample receipt procedures. The samples are prepared and shipped to the subcontracting laboratory following the appropriate COC procedures. Results are received at ASC and reviewed before the report is sent to the client.

14 Laboratory Procurement

14.1 Purchasing, Receiving, Inspection, Inventory, and Storage

The purchase, receipt, inspection, inventorying, and storage of laboratory materials are described in several SOPs. A completed purchase request form provides a clear description of the material to be ordered. The specification for the materials used in testing are listed in the test method SOP. This includes, where applicable, a precise identification and reference to any specifications that must be met. Purchase requisitions are prepared by section supervisors or designee and approved by the Laboratory Director. The corporate purchasing department orders the material from an approved supplier (see Section 14.3). Upon receipt of the goods, receiving personnel examine them for damage before signing the bill of lading. Materials and quantities in all shipments are compared with what was ordered, and this information is communicated to purchasing.

All stocked items are stored in the warehouse. Non-stocked inventory is forwarded to the requisitioning person. Reagent materials are recorded in a material receipt log, marked with the date received, and placed in storage so that the older materials will be used first.

14.2 Sample Container Purchase

Sample containers are purchased from vendors using generally accepted glass cleaning procedures. Vendors are qualified approximately every one to two years. The vendor selection process includes a pre-selection review of qualifications, preparation of a request for quotation, and receipt and review of proposals. The competitive bidders are required to send a series of bottles for testing. ASC tests a representative subset of containers to ensure product quality prior to awarding contracts. Once a vendor is awarded the contract, the vendor secures large lots of bottles required by the laboratory. Bottles are shipped to ASC or directly to sampling sites from the lots allocated to E & E. ASC retests the containers every time the lot is expended.

14.3 Vendor Qualification

ASC personnel select vendors for all materials and supplies impacting data quality. The corporate purchasing department selects vendors for office items and non-critical supplies. The vendor selection process is similar to that used for sample containers. Vendors are qualified for approximately one to two years based on historical quality and service. ASC develops a list of materials as part of a request for quotation, and vendors prepare a proposal based on these materials. The competitive bidders are selected for a long-term contract. Critical reagents and standards are pre-tested prior to award. For high use solvents and reagents, vendors are required to maintain large lots allocated for ASC's use. ASC will retest all new lots before the existing lot is expended.

The purchase of standards is somewhat different from the purchase of other supplies. In most cases, the laboratory has a reliable source of high quality standards and will continue to use that vendor for long periods. Many standards are ordered as custom mixes. All new lots of standards are tested against the existing lot to ensure consistent quality. All standards are traceable to NIST, EPA, or other approved certification.

15 Client Service

The Project Management Unit is the primary group responsible for providing client service. Other laboratory personnel may handle projects when they are uniquely qualified or technical experts in the area the concern for the project. Project managers are independent of laboratory production and function as the on-site representative for the customer. Project managers are responsible for all client interactions from the quotation or proposal to the final report and invoice. The project manager will represent the laboratory in all face-to-face meetings with the client. All project managers are experienced in laboratory analyses and possess the technical expertise to review, interpret, and report client-specific chemistry requirements. Project managers work closely with the production coordinator to maintain schedules and forecast sales. As a group, they are responsible for ensuring that ASC has adequate capacity for each project they manage and the analytical results are reported in a timely manner.

15.1 Project Documentation

The documentation used to specify client requirements may include the initial contract or SOW; project requirements from manuals, meeting notes, or other sources; the original laboratory proposal; contract negotiation notes; a QAPP developed by either the client or the laboratory; or a client audit report. Contracts from the client are reviewed as described in Section 13.1. A process similar to the contract review process is used to review other project documentation. The project manager is responsible for communicating project requirements to the appropriate staff and reviewing all final reports to ensure that the reports meet the client requirements.

Client requirements are communicated to the laboratory staff in many ways, depending on the type of project. Examples of incorporating project-specific requirements into the laboratory process are as follows:

- A project-specific QAPP is developed as an addendum to the QAM or provided by the client. The QAPP is distributed and the staff trained in its use.

- Client-specific requirements are added to administrative or method SOPs.

- Client-specific requirements are incorporated into method data review checklists.

- The project manager holds a kick-off meeting to review requirements of the project.

- The project manager reviews the laboratory job folders before distribution to the staff and inserts project-specific requirements.

- The project manager adds client- or project-specific tests to the LIMS.

15.2 Client Concern Resolution

All problems or non-conformance with client requirements are handled through the corrective action process described in Section 4.5. The corrective action process requires the project manager to be notified immediately of any non-conformance with the samples or data. The project manager is responsible for informing the client. Depending on the situation and the client, the project manager will document the problem in the case narrative, or notify the client immediately and document the problem in the narrative.

If the client raises concerns after receiving the analytical report, those concerns are addressed as part of the corrective action process. All client inquiries should be addressed within 48 hours of receipt. If follow-up reports or analysis is required, the laboratory will proceed to complete the tasks with the highest possible priority. Long-term client concerns will be tracked as part of the corrective action process. The status of client concerns will be reported to laboratory management at weekly project management meetings. A record of all inquiries and their resolution is maintained with the corrective action form in the QA files or in the project files. The QA department periodically submits questionnaires to clients to obtain an independent assessment of the client's interpretation of the quality of services.

16 References

40 CFR Part 136, Appendix A, paragraphs 8.1.1 and 8.2 and Appendix B.

American National Standards Specification and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (ANSI/ASQC E-4), 1994.

APHA/AWWA/WEF, 1992, *Standard Methods for the Examination of Water and Wastewater*, 18th ed.

International vocabulary of basic and general terms in metrology (VIM): 1984, issued by BIPM. IEC. ISO. and OIML.

ISO Guide 8402: 1986. Quality – Vocabulary.

ISO/IEC Guide 2: 1986. General terms and their definitions concerning standardization and related activities.

ISO/IEC Guide 25: 1990. General requirements for the competence of calibration and testing laboratories.

NELAC, July 2, 1998, *Quality Systems Manual*, Revision 9.

Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, SW-846 3rd ed., Update III, June 1997.

United States Environmental Protection Agency (EPA), August 1992, *Methods for the Determination of Organic Compounds in Drinking Water – Supplement II*, EPA-600/R-92/129.

_____, revised July 1991, *Methods for the Determination of Organic Compounds in Drinking Water*, EPA-600/4-88/039.

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_____, revised March 1983 and 1979, *Methods for the Chemical Analysis of Water and Wastes*, EMSL, Cincinnati, EPA-600/4-79-020.

_____, *Methods for Organic Chemical Analysis of Municipal and Industrial Wastewater*, Appendix A to Part 136.

_____, *Environmental Monitoring Systems Laboratory, Office of Research and Development*, Cincinnati, OH 45268.

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A

Definitions

The following definitions are used in the QAM or related SOPs. The following references were used: ISO 8402, ANSI/ASQC E-4, EPA's Quality Assurance Division Glossary of Terms, EPA SW-46, New York State Department of Health Environmental Laboratory Approval Program, definitions developed by NELAC and/or the ASC QA Unit. The source of each definition is noted.

Acceptable Criteria: specified limits placed on characteristics of an item, process, or service defined in requirement documents. (ASQC)

Accreditation: the process by which an agency or organization evaluates and recognizes a program of study or an institution as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory. (NELAC)

Accuracy: the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Batch: A group of samples which behave similarly with respect to the sampling or testing procedures being employed which are processed as a unit, using the same lot(s) of reagents. A **preparation batch** is composed of one to 20 of the same matrix which are prepared together. An **analytical batch** is composed of prepared samples (extracts, digestates or concentrates) which are analyzed together as a group. (EPA SW846, ASC)

Blank: a sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage, or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. (ASQC, Definitions of Environmental Quality Assurance Terms, 1996)

Blind Sample: a subsample for analysis with a composition known to the submitter. The analyst/laboratory may know the identity of the sample but not its concentration. It is used to test the analyst's or laboratory's proficiency in the execution of the measurement process. (NELAC)

Calibrate: to determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter or other device, or the correct value for each setting of a control knob. The levels of the applied calibration standard should bracket the range of planned or expected sample measurements. (NELAC)

Calibration: the set of operations which establishes, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a measurement. (VIM - 6.13)

Calibration Curve: the graphical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response. (NELAC)

Calibration Method: defined technical procedure for performing a calibration such as internal standard or external standard. Internal standard calibration is typically used for GCMS methods. External calibration is used for most other methods. (NELAC, ASC)

Calibration Standard: a solution prepared from the primary dilution standard solution or stock standard solutions and the internal standards and surrogate analytes. The calibration solutions are used to calibrate the instrument response with respect to analyte concentration. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Certified Reference Material (CRM): a reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body. (ISO Guide 30 - 2.2)

Chain of Custody: an unbroken trail of accountability that documents the physical security of samples, data, and records. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Confirmation: verification of the presence of a component through the use of an analytical technique that differs from the original method. These may include:

Second column confirmation,
Alternate wavelength,
Derivatization,
Mass spectral interpretation,
Alternative detectors, or
Additional cleanup procedures. (NELAC)

Continuing Calibration Verification: analysis of a calibration standard to verify the validity of the daily calibration during and at the end for each analytical batch or sequence. (ASC)

Corrective Action: action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence. (ISO 8402)

Data Audit: a qualitative and quantitative evaluation of the documentation and procedures associated with measurements to verify that the resulting data are of acceptable quality (i.e., that they meet specified acceptance criteria.) (NELAC)

Data Quality Objectives: A statement of the overall level of uncertainty that a decision-maker is willing to accept in results derived from environmental data. (EPA/QAMS)

Data Reduction: the process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, etc., and collating the data into a more useful form. (NELAC)

Data Validation: The process of evaluating the available data against the project DQOs to make sure that the objectives are met. (EPA SW-846)

Document Control: the act of ensuring that documents (and revisions thereto) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly, and controlled to ensure use of the correct version at the location where the prescribed activity is performed. (ASQC, Definitions of Environmental Quality Assurance Terms, 1996)

Double Blind Sample: a sample submitted to evaluate performance with concentration and identity unknown to the analyst. (NELAC)

Holding Times (Maximum Allowable Holding Times): the maximum times that samples may be held prior to preparation and analysis and still be considered valid. (40 CFR Part 136).

Initial Calibration Verification: analysis of an independent calibration standard to verify the validity of the initial calibration curve for each analytical batch. (ASC)

Initial Demonstration of Analytical Capability: procedure to establish the ability of the laboratory to generate acceptable accuracy and precision which is included in many of EPA's analytical methods. In general, the procedure includes the addition of a specified concentration of each analyte into each of four separate aliquots of laboratory pure water or analyte-free solid matrix. These are carried through the entire analytical procedure, and the percentage recovery and the standard deviation are determined and compared to specified limits. (40 CFR Part 136, EPA SW-846).

Initial Precision Recovery: Same as Initial Demonstration of Analytical Capability. (ASC)

Instrument Blank: a clean sample (e.g., distilled water) processed through the instrumental steps of the measurement process; used to determine instrument contamination. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Internal Standard: a known amount of standard added to a test portion of a sample and carried through the entire measurement process as a reference for evaluating and controlling the precision and bias of the applied analytical method. (NELAC)

Job File/Number: The number assigned to a batch of samples delivered on the same day for the same project, site, or client. Also referred to as **sample login**. The job file contains all data associated with the samples in the job. (ASC)

Laboratory Control Sample: an uncontaminated sample matrix spiked with known amounts of analytes from a source independent of the calibration standards. It is generally used to establish intralaboratory or analyst-specific precision and bias or to assess the performance of all or a portion of the measurement system. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Matrix: The component or substrate which contains the analyte of interest. For purposes of batch determination, the following matrix types shall be used:

- Aqueous: Any aqueous sample excluded from the definition of a drinking water matrix or Saline/Estuarine source. Includes surface water, groundwater and effluents.
- Drinking water: Any aqueous sample that has been designated a potable or potential potable water source.
- Saline/Estuarine: Any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.
- Non-aqueous liquid: Any organic liquid with <15% settleable solids.
- Biological Tissue: Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.
- Solids: Includes soils, sediments, sludges, and other matrices with >15% settleable solids.
- Chemical Waste: A product or by-product of a industrial process that results in a matrix not previously defined.
- Air Samples: Media used to retain the analyte of interest from an air sample such as sorbent tubes or summa canisters. Each medium shall be considered as a distinct matrix. (Quality Systems)

Matrix Duplicate: an intralaboratory split sample which is used to document the precision of a method in a given sample matrix. (EPA SW-846)

Matrix Spike (spiked sample, fortified sample): prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Matrix Spike Duplicate (spiked sample, fortified sample duplicate): a second replicate matrix spike is prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

May: permitted, but not required. (TRADE)

Method Blank: a clean sample processed simultaneously with and under the same conditions as samples containing an analyte of interest through all steps of the analytical procedures. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Method Detection Limit (Analytical Detection Limit): the minimum concentration of a substance (an analyte) that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte. (40 CFR Part 136 Appendix B).

Must: denotes a requirement that must be met. (Random House College Dictionary)

NELAC: National Environmental Laboratory Accreditation Conference. A voluntary organization of state and federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories. A subset of NELAP. (NELAC)

NELAP: the overall National Environmental Laboratory Accreditation Program of which NELAC is a part. (NELAC)

Performance Audit: the routine comparison of independently obtained quantitative measurement system data with routinely obtained data in order to evaluate the proficiency of an analyst or laboratory. (NELAC)

Performance Based Measurement System (PBMS): a set of processes wherein the data quality needs, mandates, or limitations of a program or project are specified and serve as criteria for selecting appropriate methods to meet those needs in a cost-effective manner. (NELAC)

Practical Quantitation Limit (PQL): the limit typically reported for the method that is above the MDL. The ability to reach the PQL should be documented with each analytical batch, typically by using the lowest standard of a verified calibration curve at the PQL. (ASC)

Precision: the degree to which a set of observations or measurements of the same property, usually obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance, or range, in either absolute or relative terms. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Preservation: refrigeration and/or reagents added at the time of sample collection to maintain the chemical and/or biological integrity of the sample. (NELAC)

Proficiency Test Sample (PT): a sample, the composition of which is unknown to the analyst and is provided to test whether the analyst/laboratory can produce analytical results within specified performance limits. (Glossary of Quality Assurance Terms, QAMS, 8/31/92)

Proficiency Testing: Determination of the laboratory calibration or testing performance by means of interlaboratory comparisons. (ISO/IEC Guide 2 - 12.6, amended)

Pure Reagent Water: shall be ASTM Type I or Type II water in which no target analytes or interferences are detected as required by the analytical method.

Quality Assurance: an integrated system of activities involving planning, quality control, quality assessment, reporting, and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence. (Glossary of Quality Assurance Terms, QAMS, 8/31/92)

Quality Control: the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users. (Glossary of Quality Assurance Terms, QAMS, 8/31/92)

Quality Control Sample: an uncontaminated sample matrix spiked with known amounts of analytes from a source independent from the calibration standards. It is generally used to establish intra-laboratory or analyst-specific precision and bias or to assess the performance of all or a portion of the measurement system. (Glossary of Quality Assurance Terms, QAMS, 8/31/92)

Quality Manual: A document stating the quality policy, quality system and quality practices of an organization. This may also be called a Quality Assurance Plan or a Quality Plan. (NELAC)

Quality System: a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC. (ANSI/ASQC E-41994)

Range: the difference between the minimum and the maximum of a set of values. (NELAC)

Raw Data: any original factual information from a measurement activity or study recorded in a laboratory notebook, worksheets, records, memoranda, notes, or exact copies thereof that are necessary for the reconstruction and evaluation of the report of the activity or study. Raw data may include photography, microfilm or microfiche copies, computer printouts, magnetic media (including dictated observations), and recorded data from automated instruments. If exact copies of raw data have been prepared (e.g., tapes which have been transcribed verbatim, data, and verified accurate by signature), the exact copy or exact transcript may be submitted. (NELAC)

Reagent Blank (method reagent blank): a sample consisting of reagent(s), without the target analyte or sample matrix, introduced into the analytical procedure at the appropriate point and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps. (Glossary of Quality Assurance Terms, QAMS, 8/31/92)

Reagent Grade: Analytical reagent grade or related terms which conform to the specifications of the Committee on Analytical Reagents for the American Chemical Society. (EPA SW-846)

Reference Material: a material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or the assignment of values to materials. (ISO Guide 30 - 2.1)

Reference Sample: prepared by spiking a known amount of analyte into an appropriate solvent. The concentrate or quality control sample preferably should be obtained from an independent source. A sample prepared in-house may be used if it is prepared independently of the calibration standard. (NYSDOH ELAP)

Replicate Analyses: the measurements of the variable of interest performed identically on two or more subsamples of the same sample within a short time interval. (NELAC)

Sample Delivery Group (SDG): a group of samples received for the same project, site, and/or client within a maximum two-week period that are reported together in a single data package. An SDG typically consists of multiple jobs or sample logins and is often designated by the client. (ASC)

Sample Duplicate: two samples taken from and representative of the same population and carried through all steps of the sampling and analytical procedures in an identical manner. Duplicate samples are used to assess variance of the total method, including sampling and analysis. (Glossary of Quality Assurance Terms, QAMS, 8/31/92)

Secure Storage Area: an area of the laboratory with access limited to essential personnel, trained in the function of retrieving samples or information from the area. (ASC)

Selectivity: the capability of a method or instrument to respond to a target substance or constituent in the presence of nontarget substances. (Analytical chemistry)

Sensitivity: the capability of a method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest. (NELAC)

Shall: denotes a requirement that is mandatory whenever the criterion for conformance with the specification requires that there be no deviation. This does not prohibit the use of alternative approaches or methods for implementing the specification as long as the requirement is fulfilled. (Style Manual for Preparation of Proposed American National Standards, American National Standards Institute, eighth edition, March 1991)

Should: denotes a guideline or recommendation whenever noncompliance with the specification is permissible. (Style Manual for Preparation of Proposed American National Standards, American National Standards Institute, eighth edition, March 1991)

Standard Additions: The practice of adding a known amount of an analyte to a sample immediately prior to analysis. It is typically used to evaluate interferences. (EPA SW-846)

Standard Operating Procedures (SOPs): a written document which details the method of an operation, analysis, or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks. (Glossary of Quality Assurance Terms, QAMS, 8/31/92)

Spike: a known mass of target analyte added to a blank sample or subsample; used to determine recovery efficiency or for other quality control purposes. (NELAC)

Split Sample: aliquots of sample taken from the same container and analyzed independently. In cases where aliquots of samples are impossible to obtain, field duplicates samples should be taken for the matrix duplicate analysis. These are usually taken after mixing or compositing and are used to document intra- or interlaboratory precision. (EPA SW-846)

Standard Reference Material (SRM): a certified reference material produced by the U.S. National Institute of Standards and Technology and characterized for absolute content, independent of analytical method. (NELAC)

Surrogate: a substance with properties that mimic the analyte of interest. It is unlikely to be found in environment samples and is added to them for quality control purposes. (Glossary of Quality Assurance Terms, QAMS, 8/31/92)

Systems Audit: a thorough, systematic, on-site qualitative review of the facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a total measurement system. (NELAC)

Temperature Blank: usually a 40 mL VOA vial sent with a shipment that is clearly marked "Temp Blank." The temperature blank is used to establish the temperature of the samples when the cooler is open. The packaging and placement of the vial should be representative of the samples in the container. (ASC)

Test: a technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

NOTE: The result of a test is normally recorded in a document sometimes called a test report or a test certificate. (ISO/IEC Guide 2 - 12.1, amended)

Test Method: defined technical procedure for performing a test. (NELAC)

Testing Laboratory: laboratory that performs tests. (ISO/IEC Guide 2 - 12.4)

Traceability: the property of a result of a measurement whereby it can be related to appropriate standards (generally international or national), through an unbroken chain of comparisons. (VIM - 6.12)

Verified Time of Sample Receipt (VSTR): the time the cooler is delivered to the laboratory by the client or independent courier as recorded in the package receipt log. (ASC from EPA CLP)

B

ASC Commonly Used Forms

ANALYTICAL SERVICES CENTER DOCUMENT CONTROL FORM

Document Title:	SOP, Checklist, Form:	
Assigned Author(s):	SOP or D No.:	Current Revision No.:
QA Coordinator /Project Manager:	Method/Revision:	Final Revision No.:
Management Reviewers:	Notes:	
Peer Reviewers:		

REVIEW SCHEDULE

	Draft Reviewed	Date Reviewed	Final Approved	Date Final
Original Author				
QA Review				
Management Review				
Peer Review				

Filing Directions: ☐ Update Revision ☐ Archive ☐ Inactive ☐ Other

MINOR REVISION APPROVALS

Comment	QA Authorization/Date	Date Revision Issued	Comment	QA Authorization/Date	Date Revision Issued

PRODUCTION INFORMATION (To Be Completed by Document Control Officer)

Training Schedule:	Date Training Completed:
Assigned Implementation Date:	Next Annual Review Date:
Controlled Copy Distribution List: ☐ Yes ☐ No	Date of Data Entry in Document Control Database:
Archive Instructions:	Date Archive Completed:

Corrective Action Form

Tracking Number	Total Pages

SECTION 1 INITIATION

Originator	Start Date	SOP No.	Instrument
Job No.	Sample Nos.		
How Non-Conformance Found?	Client	Section	

Non-Conformance Description

Assigned Responsible Person: Assigned Reviewer:

Additional Routing: Projected Closure Date:

SECTION 2 CORRECTIVE ACTION

Corrective Action Description

Completed or Overseen by: Actual Closure Date:

SECTION 3 REVIEW

Additional Corrective Actions/Follow-up Comments

Reviewed & Approved by: Date: New Form Tracking Numbers:

SECTION 4 QA

Additional Corrective Actions/Follow-up Comments

Approved by: Date:

QA Classification

[ ] Hold Times	[ ] Surr. Recovery	[ ] Sample	[ ] Reporting	[ ] Calibration Checks
[ ] Equip/Materials	[ ] Spike Recovery	[ ] Personnel	[ ] Documentation	[ ] PE
[ ] Blank	[ ] LCS Recovery	[ ] Field	[ ] Audit	[ ] Other_____

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C

Laboratory Certifications and Accreditations

Laboratory Certifications and Accreditations					
Source	**Issuing Agency**	**Description of License, Registration or Certification**	**License, Registration, Certification Number**	**Scope of Evaluation**	**Renewal Date**
United States Army Corps of Engineers	HTRW Center of Expertise, Omaha District	Solid and hazardous waste and water for organics and inorganics by EPA RCRA methods.	N/A	PE Sample Audit QA Manual	1/30/2000
United States Army	Army Environmental Center	Soil and water for organics, and metals by validated methods.	Lab EL	PE Sample Audit QA Manual	Updated by project
United States Air Force	Air Force Center for Environmental Excellence (AFCEE)	Solid and hazardous waste for organics and inorganics based on AFCEE requirements.	N/A	Subcontract Audit	Updated by project
Alaska	Department of Environmental Conservation	Soil and water for organics, and inorganics for UST projects.	UST-024	PE Sample QA Manual	3/18/99 (pending)
California	Department of Health Services	Solid and hazardous waste for organics and inorganics; waste extraction test.	1766	PE Sample Audit	6/30/2000
Florida	Department of Health and Rehabilitative Services	Wastewater, and solid and hazardous waste for organics and inorganics.	E87037	PE Sample Audit	6/30/99
Florida	Department of Environmental Protection	Approved comprehensive QA plan pursuant to statewide environmental chemistry laboratory QA programs.	860165G	QA Manual	1/22/99

Laboratory Certifications and Accreditations					
Source	**Issuing Agency**	**Description of License, Registration or Certification**	**License, Registration, Certification Number**	**Scope of Evaluation**	**Renewal Date**
Kansas	Department of Health and Environment	Solid and hazardous waste for organics and inorganics	E-10157	PE Sample	1/31/2000
Kentucky	Natural Resources and Environmental Protection Cabinet	Drinking water for organics and inorganics.	90083	PE Sample	12/31/99
Maryland	Department of Health and Mental Hygiene	Drinking water for metals and volatile organics.	290	PE Sample	9/30/99
Massachusetts	Department of Environmental Protection	Potable water for select parameters and nonpotable water for organics and inorganics.	M-NY050	PE Sample	6/30/99
New Jersey	Department of Environmental Protection	Nonpotable water for organics and inorganics.	73792	PE Sample Audit	6/30/99 (pending)
New York	State Department of Health Environmental Laboratory Approval Program	CLP for organics and inorganics by NYSDEC Analytical Services Protocol. Potable/ nonpotable water, solid/ hazardous waste, and air and emissions for organics and inorganics.	10486	PE Sample Audit	7/15/99
North Carolina	Department of the Environment and Natural Resources	Wastewater and groundwater for select parameters.	382	PE Sample Audit	12/31/2000

Laboratory Certifications and Accreditations					
Source	**Issuing Agency**	**Description of License, Registration or Certification**	**License, Registration, Certification Number**	**Scope of Evaluation**	**Renewal Date**
Pennsylvania	Department of Environmental Protection	Drinking water for organics and inorganics.	68-519	PE Sample Audit QA Manual	7/11/99
South Carolina	Department of Health and Environmental Control	Wastewater and solid and hazardous waste for organics and inorganics.	91001002	PE Sample	6/30/99
Tennessee	Department of Environment and Conservation	Underground storage tank approved.	N/A	Application Review	7/1/99
Virginia	Department of General Services	Drinking water for organics and inorganics.	00124	PE Sample	6/30/99
West Virginia	Division of Environmental Protection	Solid and hazardous waste for organics and inorganics.	266	PE Sample Audit	10/31/99

Notes:

PE Sample = Successful analysis of a performance evaluation sample.
Audit = Successful completion of on-site audit and response to audit report.
QA Manual = Review of Quality Assurance Manual and related documentation by off-site agency.

Key:

HTRW = Hazardous, toxic, and radioactive waste.
UST = Underground storage tank.
QA = Quality assurance.
PE = Performance evaluation.
CLP = Contract Laboratory Program (EPA).
NYSDEC = New York State Department of Environmental Conservation.
N/A = Not applicable.

D

ASC Equipment List

MAJOR LABORATORY EQUIPMENT FOR ANALYTICAL SERVICES CENTER			
Make/Model #	**Description**	**Year**	**Total**
Gas Chromatography Mass Spectrometry (GC/MS) Sections			
Hewlett Packard (HP) 5995C	GC/MS, Capillary Column	1985	1
HP 5972	GC/MS, Capillary Column	1994, 1997 [2]	3
HP 5971	GC/MS, Capillary Column	1993	1
HP 5970	GC/MS, Capillary Column	1985, 1986, 1987 [2], 1989	5
HP 5973	GC/MS, Capillary Column	1998	1
HP 9000/735	UNIX Operating Systems for GC/MS	1994	1
HP Vectra	Chemstation Operating Systems for GC/MS	1991[2], 1994[2]	4
HP 1000 RTE-A	Mini-Computer Operating Systems for GC/MS	1987, 1990, 1991	3
Tekmar LSC-2000	Liquid Sample Concentrators for volatile organic compounds (VOCs)	1989, 1990, 1991, 1997	4
Tekmar ALS-2032	Sampler for VOCs in Water	1993	1
Tekmar ALS-2016	Samplers for VOCs in Water and Soil	1989, 1990, 1991	3
OI Analytical Model 4560/4551	Purge-and-Trap Unit with Closed System Vial Autosampler and SIM/Spiker for VOCs in Water	1994	1
HP 7673A	Single Tower Automatic Samplers	1987[2], 1993, 1994, 1998	5
Nutech	Autosampler for Air Canisters	1994	
Nutech Model 3550A	Air System for Automated Method TO14 Analysis	1994	1
Dynatech Dynatrap	Automated Closed Loop Purge-and-Trap Unit for VOCs in Water and Soil	1993	1
	SUMMA® Canister Cleaning Apparatus	1992	1
Dynatech Precision PTA 30	Purge-and-Trap Closed Loop Autosampler for VOCs in Water	1992	1
Varian Archon	Purge-and-Trap Autosampler 5100, 4552	1998	2

MAJOR LABORATORY EQUIPMENT FOR ANALYTICAL SERVICES CENTER			
Make/Model #	**Description**	**Year**	**Total**
Gas Chromatography (GC) Sections			
HP 6890	GC with Dual Tandem Photoionization Detector/Electron Capture Detector (PID/ECD)	1998	1
HP 6890	GC Capillary Column with Dual ECD and HP7673B Twin Autoinjector Towers	1997	1
HP 6890	GC Capillary Column with Dual ECD and HP7673B Twin Autoinjector Towers	1997; 1998 upgrade	1
HP 5890 II	GC Capillary Column with Flame Photometric Detector (FPD), Nitrogen-Phosphorus Detector (NPD) and Antek Model 705E Chemiluminescent Nitrogen Detector (CLND) and HP7673A Single Autoinjector Tower	1994, 1997[CLND]	1
HP 5890 II	GC Capillary Column with Dual ECD and HP7673A Single Autoinjector Tower	1991, 1993	2
Varian 3600	GC Capillary Column with Photoionization Detector (PID)/Hall Detectors	1991, 1994	2
Varian 3400	GC Capillary Column; three with dual ECD and each with LEAP A200SE Autosampler; one with PID/FID; and one with FID	1989[4] 1990[1]	5
HP 5890 II	GC Capillary Column with Dual FID Detectors and HP7673A Twin Autoinjector Towers	1989	1
Varian Vista 6000	GC Capillary Column with PID/Hall Detectors	1986	2
Perkin Elmer (PE) Turbochrom Client Server	Chromatographic Analysis Data System running on HP Netserver LH Pro 200 with seven HP Vectra Pentium 133 PC Stations	1997	1 server, 7 work stations
Tekmar LSC-2000	Liquid Sample Concentrators for VOCs	1989[1], 1990[2], 1991[2]	5
Tekmar ALS-2016	Samplers for VOCs in Water & Soil	1989[1], 1990[2], 1991[2]	5
Varian 8200	Autosampler	1994	1
Whatman Model 75-34NA	Hydrogen Generators	1994 [1], 1996 [1]	2

MAJOR LABORATORY EQUIPMENT FOR ANALYTICAL SERVICES CENTER			
Make/Model #	**Description**	**Year**	**Total**
High Performance Liquid Chromatography (HPLC) Section			
HP Series 1050	HPLCs with Variable Ultra-violet Detectors and one Fluorescence Detector	1990[2], 1992, 1995	4
Dionex ED-40	Electrochemical/Anion Conductivity Detector	1996	1
Dionex 2000i	Ion Chromatograh w/Anion Conductivity Detector	1987	1
DEC Pentium II	Chemstation Operating Systems with Windows 95	1998	2
Organic Sample Preparation Section			
Organomation ROT-X-TRACT-HP	8-Position Extractor with Soxhlet Extractor Glassware	1994	1
National Model NLW-66	Glassware Washer	1994	1
ABC AS 2000	Gel Permeation/Autoevaporation Concentrator	1992	1
Zymark Benchmate	Gel Permeation/Autoevaporation Concentrator	1991	1
Turbovap II	Concentration Work Station	1997, 1998	2
Metals Analysis Section			
PE Optima 3000 XL	Inductively Coupled Argon Plasma (ICP) Spectrometer with standalone data system	1994	1
Jobin Yvon 50P	ICP Spectrometer with standalone data system	1990	1
PE 4100ZL	Zeeman Atomic Absorption Spectrophotometer (AAS) with Graphite Atomizer, Background Correction System, and Autosampler	1993	1
PE 5100	Zeeman AAS with Graphite Atomizers, Background Correction System, and Autosampler	1991	1
Leman PS 200	Mercury Analyzer	1998	1
PE 2380	AAS for Cold Vapor Mercury	1989	1
General Analytical Chemistry (GAC) Section			
Milton Roy Spectronic Geosys 5	Spectrophotometer	1994	1
Milton Roy Spectronic 601	Spectrophotometer	1990	1

MAJOR LABORATORY EQUIPMENT FOR ANALYTICAL SERVICES CENTER			
Make/Model #	**Description**	**Year**	**Total**
PE Model 1650	FT-IR Spectrophotometer (helium laser)	1990	1
Petrolab	Sulfur Analyzer	1993	1
Lachat QuickChem AE	Automated Analyzer with Flow InjectionRandom Sampler, Optical Dilution, and Heat Block	1990	1
Shimadzu SSM 5000/5050A	Total Organic Carbon Analyzer and Solid Sample Module	1997	1
MCI (COSA) TOX-10	Total Organic Halogen Analyzer	1985	1
Spectrace 9000	X-Ray Fluorescence (XRF) Energy Dispersive Analyzer	1996	1
YSI Model 35	Conductance Meter	1995	1
HF Scientific	Turbidity Meter	1992	1
Midi Model 110-1012	Cyanide Distillation System	1994	1
Bürchi 316	Distillation Unit	1994	1
Cahn Model 4100	Electrobalance	1992	1
Parr Model 1241	Adiabatic Oxygen Bomb Calorimeter	1985	1

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ASC Product List

ASC Product List

Section	Product Code	Matrix	Description	Analysis/Prep Method	Anal SOP	Prep SOP	Container/Preservative	HT-Prep	HT-Anal
GAC	ALKALINITY	W	Alkalinity	2320B	GAC.17		1-L Poly/Cool		14
GAC	NH3	W	Ammonia Nitrogen (Nesslerization)	4500 NH3 B,C	GAC.2		1-L Poly/H2SO4		28
GAC	NH3 - TITR	S	Ammonia Nitrogen (Titrimetric)	4500 NH3 B,E-M	GAC.2		8-oz Glass TFC/Cool		28
GAC	NH3 - TITR	W	Ammonia Nitrogen (Titrimetric)	4500 NH3 B,E	GAC.2		1-L Poly/H2SO4		28
GAC	ASH	S	Ash	D482	GAC.53		8-oz Glass/None		14
GAC	BOD	W	Biochemical Oxygen Demand (5 day, 20-C)	5210B	GAC.11		1-L Poly/Cool		2
GAC	BOD:C	W	BOD, Carbonaceous (5 day, 20-C)	5210B	GAC.11		1-L Poly/Cool		2
GAC	COD	W	Chemical Oxygen Demand (Titrimetric)	5220 C	GAC.12		125-mL Poly/H2SO4		28
GAC	CR VI Color	S	Chromium VI, (Alkaline Digestion, Colormetric)	7196A/3060A	GAC.91	GAC.91	8-oz Glass TFC/Cool		1
GAC	CR VI Color	W	Chromium VI, (Colormetric)	7196A	GAC.121		125-mL Poly/Cool		1
GAC	CR VI Color - SM	W	Chromium VI, (Colormetric)	3500-Cr(VI) D	GAC.82		125-mL Poly/Cool		1
GAC	CN 335.3 AMENABLE	W	CN, Amenable (UV/VIS, Automated)	335.3	GAC.65	GAC.118	1-L Poly/NAOH		14
GAC	CN WASTE AMENABLE	S	CN, Amenable in Waste, (Total Reflux)	9012A	GAC.65	GAC.120	8-oz Glass TFC/Cool		14
GAC	CN WASTE AMENABLE	W	CN, Amenable in Waste, (Total Reflux)	9012A	GAC.65	GAC.120	1-L Poly/NAOH		14
GAC	CN 9012A AMENABLE	S	CN, Amenable, (Midi Automated Colormetric)	9012A/9012AM	GAC.65	GAC.106	8-oz Glass TFC/Cool		14
GAC	CN 9012A AMENABLE	W	CN, Amenable, (Midi Automated Colormetric)	9012A/9012AM	GAC.65	GAC.106	1-L Poly/NAOH		14
GAC	CLP CN 4.0	S	CN, CLP Distillation & Spectroscopy	ILM04.0	GAC.65	GAC.119	8-oz Glass TFC/Cool		12
GAC	CLP CN LOW	W	CN, CLP Distillation & Spectroscopy	ILC03.1	GAC.65	GAC.118	1-L Poly/NAOH		12
GAC	CLP CN 4.0	W	CN, CLP Distillation & Spectroscopy	ILM04.0	GAC.65	GAC.118	1-L Poly/NAOH		12
GAC	CN 9013	L	CN, Extraction for Solids and Waste	9012A/9013	GAC.65	GAC.122,120	8-oz Glass TFC/Cool		14
GAC	CN 9013	S	CN, Extraction for Solids and Waste	9012A/9013	GAC.65	GAC.122,120	8-oz Glass TFC/Cool		14
GAC	CN WASTE	S	CN, Total in Waste (Total Reflux)	9012A	GAC.65	GAC.120	8-oz Glass TFC/Cool		14
GAC	CN WASTE	W	CN, Total in Waste (Total Reflux)	9012A	GAC.65	GAC.120	1-L Poly/NAOH		14
GAC	CN 335.4	PW	CN, Total, (Midi Automated Colormetric)	335.3	GAC.65	GAC.118	1-L Poly/NAOH		14
GAC	CN 9012A	S	CN, Total, (Midi Automated Colormetric)	9012A/9012AM	GAC.65	GAC.106	8-oz Glass TFC/Cool		14
GAC	CN 9012A	W	CN, Total, (Midi Automated Colormetric)	9012A/9012AM	GAC.65	GAC.106	1-L Poly/NAOH		14
GAC	CN 335.3	W	CN, Total, (UV/VIS Spec., Automated)	335.3	GAC.65	GAC.118	1-L Poly/NAOH		14
GAC	HARDNESS	W	Hardness, Total (Titrimetric, EDTA)	130.2	GAC.27		1-L Poly/H2SO4		180
GAC	IGNITABILITY 1010	L	Ignitability (Pensky-Martens Method)	1010	GAC.72		1-L Poly/None		
GAC	IGNITABILITY 1030	S	Ignitability, Solids	1030	GAC.72		1-L Poly/None		
GAC	TKN	S	Kjeldahl Nitrogen, Total	351.3 M	GAC.4		8-oz Glass TFC/Cool		28
GAC	TKN	W	Kjeldahl Nitrogen, Total	351.3	GAC.4		1-L Poly/H2SO4		28
GAC	NO3	W	Nitrate (UV/VIS, Cadmium Reduction)	353.2	GAC.66		1-L Poly/Cool		2
GAC	NO3/NO2	W	Nitrate/Nitrite (UV/VIS, Cadmium Reduction)	353.2	GAC.66		1-L Poly/H2SO4		28
GAC	NO2	W	Nitrite (UV/VIS, Cadmium Reduction)	353.2	GAC.66		1-L Poly/Cool		2
GAC	NO2 4500-NO2 B	W	Manual Spectrophotometric	SM4500-NO2 B (354.1)	GAC.137		1-L Poly/Cool		2
GAC	TSS	W	Non-filterable Residue TSS (Gravimetric)	160.2	GAC.38		1-L Poly/Cool		7
GAC	O&G 413.1	W	Oil and Grease (Gravimetric)	413.1	GAC.48		1-L Amber/H2SO4, HCl		28

ASC Product List

Section	Product Code	Matrix	Description	Analysis/Prep Method	Anal SOP	Prep SOP	Container/Preservative	HT-Prep	HT-Anal
GAC	ORTHOPH 365.2	W	Orthophosphate	365.2	GAC.35		1-L Poly/Cool		2
GAC	PAINT FILTER	L	Paint Filter Liquids Test	9095	GAC.92		1-L Poly/None		
GAC	PER SOLID	S	Percent Solids	3550B	GAC.14		8-oz Glass TFC/Cool		28
GAC	PH 9045C	L	pH (Electrometric)	9045C	GAC.100		1-L Poly/Cool		1
GAC	PH 150.1	PW	pH (Electrometric)	150.1	GAC.34		1-L Poly/None		1
GAC	PH 9045C	S	pH (Electrometric)	9045C	GAC.100		8-oz Glass TFC/Cool		ASAP
GAC	PH 150.1	W	pH (Electrometric)	150.1	GAC.34		1-L Poly/None		1
GAC	PHENOLS 420.1 M	S	Phenolics, (UV/VIS)	420.1M	GAC.13		8-oz Glass TFC/Cool		28
GAC	PHENOLS 420.1	W	Phenolics, (UV/VIS)	420.1	GAC.13		1-L Amber/H2SO4		28
GAC	PHENOLS 9065	W	Phenolics, (UV/VIS)	9065	GAC.13		1-L Amber/H2SO4		28
GAC	PO4	S	Phosphorous (UV/VIS)	365.2M	GAC.36		8-oz Glass TFC/Cool		28
GAC	PO4	W	Phosphorous (UV/VIS)	365.2	GAC.36		1-L Poly/H2SO4		28
GAC	CN 7.3.3 & 9012A	S	Reactivity, Cyanide	Ch. 7 Sect. 7.3.3, 9010A	GAC.85		8-oz Glass TFC/Cool		ASAP
GAC	S 7.3.4 & 9034	S	Reactivity, Sulfide	Ch. 7 Sect. 7.3.4, 9034	GAC.130		8-oz Glass TFC/Cool		ASAP
GAC	TDS 2540C	PW	Residue, Filterable TDS (Gravimetric)	2540C	GAC.37		1-L Poly/Cool		7
GAC	TDS 160.1	W	Residue, Filterable TDS (Gravimetric)	160.1	GAC.37		1-L Poly/Cool		7
GAC	SETTLEABLE SOLIDS	W	Residue, Settleable Solids(Volumetric-Imhoff)	160.5	GAC.39		1-L Poly/Cool		7
GAC	TS	W	Residue, Total (Gravimetric)	160.3	GAC.126		1-L Poly/Cool		7
GAC	SIO2 370.1	W	Silica: Dissolved (UV/VIS)	370.1	GAC.124		1-L Poly/Cool		28
GAC	CONDUCTIVITY 120.1	W	Specific Conductance	120.1	GAC.15		1-L Poly/Cool		28
GAC	CONDUCTIVITY 9050A	W	Specific Conductance	9050A	GAC.15		1-L Poly/Cool		28
GAC	SPEC GRAV	W	Specific Gravity	2710F	GAC.41		1-L Poly/None		
GAC	SULFIDE 376.1	W	Sulfide (Titrimetric Iodine)	376.1	GAC.43		1-L Poly/NAOH		7
GAC	SURFACTANTS 425.1	W	Surfactants, MBAS (UV/VIS)	425.1	GAC.29		1-L Poly/Cool		2
GAC	TOC 9060	W	Total Organic Carbon	9060	GAC.103		125-mL Poly/H2SO4		28
GAC	TOC	S	Total Organic Carbon Lloyd Kahn	Lloyd Kahn	GAC.76		8-oz Glass TFC/Cool		28
GAC	TOC 5310C	W	Total Organic Carbon, Water	5310C	GAC.20		125-mL Poly/H2SO4		28
GAC	TOX 9020B	W	Total Organic Halides (TOX)	9020B	GAC.49		125-mL Poly/H2SO4		28
GAC	TRPH 418.1	W	TRPH by IR	418.1	GAC.79	GAC.8	1-L Amber/H2SO4, HCl		28
GAC	TRPH 418.1 M	S	TRPH by IR	418.1 M	GAC.79	GAC.83	8-oz Glass TFC/Cool		28
GAC	TRPH SOXHLET	S	TRPH by Soxhlet Extraction IR	418.1/9071A	GAC.79	GAC.87	8-oz Glass TFC/Cool		28
GAC	CORROSIVITY	W	Corrosivity Toward Steel	1110	GAC.133		8-oz Glass/None		
GCS	8151A/8151A	S	Chlorinated Herbicides By GC/ECD	8151A/8151A	GC.60	Ext.7	8-oz Glass TFC/Cool	14	40
GCS	8151A/8151A	W	Chlorinated Herbicides By GC/ECD	8151A/8151A	GC.60	Ext.8	80 oz Amber/Cool	7	40
GCS	515.1	PW	Chlorinated Herbicides By GC/ECD, Low	515.1	GC.13	Ext.61	80 oz Amber/Cool	17	28
GCS	8151A/1311/3510C	TCLP	Chlorinated Herbicides By GC/ECD, TCLP	8151A/3510C	GC.21	Ext.8	80 oz Amber/Cool	7	40
GCS	ADEC AK102	S	Diesel Range Organics (DRO)	ADEC AK102	GC.45	Ext.48	8-oz Glass TFC/Cool	14	40
GCS	8015B/3550B	S	Diesel Range Organics (DRO)	8015B/3550B	GC.37	Ext.30	8-oz Glass TFC/Cool	14	40

ASC Product List

Section	Product Code	Matrix	Description	Analysis/Prep Method	Anal SOP	Prep SOP	Container/Preservative	HT-Prep	HT-Anal
GCS	ADEC AK102	W	Diesel Range Organics (DRO)	ADEC AK102	GC.45	Ext.48	1-L Amber/H2SO4, HCl	7	40
GCS	8015B/3520C	W	Diesel Range Organics (DRO)	8015B/3520C	GC.37	Ext.30	1-L Amber/Cool	7	40
GCS	8015B/3510C	W	Diesel Range Organics (DRO)	8015B/3510C	GC.37	Ext.30	1-L Amber/Cool	7	40
GCS	504.1	PW	EDB & DBCP by Microextraction/ GC/ECD	504.1	GC.49		1-L Amber/Cool		14
GCS	8011	W	EDB & DBCP by Microextraction/ GC/ECD	8011	GC.49		1-L Amber/Cool		14
GCS	FL-PRO	L	Florida Petroleum Products	FL-PRO	GC.76	GC.30	8-oz Glass TFC/None	14	40
GCS	FL-PRO	S	Florida Petroleum Products	FL-PRO	GC.76	Ext.65	8-oz Glass TFC/Cool	14	40
GCS	FL-PRO	W	Florida Petroleum Products	FL-PRO	GC.76	Ext.64	1-L Amber/Cool	7	40
GCS	NON POLAR NITROSAMINES	S	Non-polar Nitrosamines by GC/CLND	Proprietary	GC.70		8-oz Glass/None	28	28
GCS	NON POLAR NITROSAMINES	W	Non-polar Nitrosamines by GC/CLND	Proprietary	GC.70		8-oz Glass/None	28	28
GCS	8141A/3550B	S	Organophosph Pesticides: GC/FPD/NPD	8141A/3550B	GC.22	Ext.16	8-oz Glass TFC/Cool	14	40
GCS	8141A/3510C	W	Organophosph Pesticides: GC/FPD/NPD	8141A/3510C	GC.22	Ext.26	80 oz Amber/Cool	7	40
GCS	AGENT DEG PROD	S	Organosulfur Compounds by GC/FPD	US LL04	GC.68	Ext.49	8-oz Glass TFC/Cool	14	40
GCS	AGENT DEG PROD	W	Organosulfur Compounds by GC/FPD	US LL04	GC.67	Ext.17	1-L Amber/Cool	7	40
GCS	8082	S	PCBs by GC/ECD	8082/3550B	GC.73	Ext.19	8-oz Glass TFC/Cool	14	40
GCS	8082	W	PCBs by GC/ECD	8082/3510C	GC.73	Ext.4	80 oz Amber/Cool	7	40
GCS	PCB WIPES	P	PCBs in Wipes by GC/ECD	8082	GC.73	GC.74	8-oz Glass TFC/None		
GCS	PCB OIL	L	PCBs in Oil by GC/ECD	600/4-81-045	GC.14	GC.26	8-oz Glass TFC/None		
GCS	8081A/3550B	S	Pesticides & PCBs by GC/ECD	8081A/3550B	GC.14	Ext.19	8-oz Glass TFC/Cool	14	40
GCS	608	W	Pesticides & PCBs by GC/ECD	608	GC.64	Ext.4	80 oz Amber/Cool	7	40
GCS	8081A/3510C	W	Pesticides & PCBs by GC/ECD	8081A3510C	GC.14	Ext.4	80 oz Amber/Cool	7	40
GCS	8081A/PUFs	A	Pesticides & PCBs by GC/ECD, Air PUFs	8081A/TO-4	GC.14	Ext.40	PUF/Cool	7	40
GCS	CLP PEST PCB	S	Pesticides & PCBs by GC/ECD, CLP	OLM03.2	GC.31	Ext.36	8-oz Glass TFC/Cool	10	40
GCS	CLP PEST PCB LOW	W	Pesticides & PCBs by GC/ECD, CLP	OLC02.0	GC.31	Ext.36	80 oz Amber/Cool	5	40
GCS	CLP PEST PCB	W	Pesticides & PCBs by GC/ECD, CLP	OLM03.2	GC.31	Ext.35	80 oz Amber/Cool	5	40
GCS	8081A/3550B	S	Pesticides by GC/ECD	8081A/3550B	GC.72	Ext.19	8-oz Glass TFC/Cool	14	40
GCS	8081A/3510C	W	Pesticides by GC/ECD	8081A/3510C	GC.72	Ext.4	80 oz Amber/Cool	7	40
GCS	8081A/1311/3510C	TCLP	Pesticides by GC/ECD, TCLP	8081A/3510C	GC.66	Ext.58	8-oz Glass TFC/Cool	14/7	40
GCS	8015B/3585	L	Petroleum Products Fingerprint, GC/FID	8015B/3585	GC.37		8-oz Glass TFC/None	14	40
GCS	POLAR NITROSAMINES	S	Polar Nitrosamines by GC/CLND	Proprietary	GC.71		8-oz Glass/None	28	28
GCS	POLAR NITROSAMINES	W	Polar Nitrosamines by GC/CLND	Proprietary	GC.71		8-oz Glass/None	28	28
GCS	ADEC AK103	S	Residual Range Organics (RRO)	ADEC AK103	GC.57	Ext.66	8-oz Glass TFC/Cool	14	40
GCV	602	W	Aromatic Volatiles by GC/PID	602	GC.44		40-mL VOA/HCl		14
GCV	ADEC AK101	S	Gasoline Range Organics (GRO)	ADEC AK101	GC.46		40-mL VOA/Methanol		28
GCV	8015B MeOH	S	Gasoline Range Organics (GRO)	8015B	GC.27		40-mL VOA/Methanol		14
GCV	ADEC AK101	W	Gasoline Range Organics (GRO)	ADEC AK101	GC.46		40-mL VOA/HCl		14
GCV	8015B	W	Gasoline Range Organics (GRO)	8015B	GC.27		40-mL VOA/HCl		14
GCV	601	W	Halogenated Volatiles by GC/HECD	601	GC.16		40-mL VOA/Cool		14

ASC Product List

Section	Product Code	Matrix	Description	Analysis/Prep Method	Anal SOP	Prep SOP	Container/Preservative	HT-Prep	HT-Anal
GCV	8015B/5030A	S	Nonhalogenated Volatiles by GC/FID	8015B/5030A	NJ Man.	NJ Man.	40-mL VOA/Cool		14
GCV	8015B/5030B	W	Nonhalogenated Volatiles by GC/FID	8015B/5030B	NJ Man.	NJ Man.	40-mL VOA/HCl		14
GCV	8015B/3810	S	Headspace Gases	8015B/3810	GC.62	GC.62	40-mL VOA/Cool		14
GCV	8015B/3810	W	Headspace Gases	8015B/3810	GC.62	GC.62	40-mL VOA/Cool		14
GCV	8021B/3585	L	Volatiles By GC/PID/HECD	8021B/3585	GC.59	GC.65	40-mL VOA/None		14
GCV	502.2	PW	Volatiles By GC/PID/HECD	502.2	GC.78		40-mL VOA/HCl		14
GCV	8021B/5030A	S	Volatiles By GC/PID/HECD	8021B/5030A	GC.59	GC.59	40-mL VOA/Cool		14
GCV	8021B/5035	S	Volatiles By GC/PID/HECD	8021B/5035	GC.59	GC.59	40-mL VOA/Cool		14
GCV	8021B/5030B	W	Volatiles By GC/PID/HECD	8021B/5030B	GC.59	GC.59	40-mL VOA/HCl		14
GMS	1653	W	Chlorinated Phenolics	1653	GCMS.40	Ext.78	1-L Amber/H2SO4	30	30
GMS	525.2	PW	Semivolatile Organics by GC/MS	525.2	GCMS.10	Ext.57	1-L Amber/HCl	14	30
GMS	8270C/3550C	S	Semivolatile Organics by GC/MS	8270C/3550C	GCMS.19	Ext.46	8-oz Glass TFC/Cool	14	40
GMS	625	W	Semivolatile Organics by GC/MS	625	GCMS.20	Ext.79	80 oz Amber/Cool	7	40
GMS	8270C/3510C	W	Semivolatile Organics by GC/MS	8270C/3510C	GCMS.19	Ext.20	80 oz Amber/Cool	7	40
GMS	CLP BNA	S	Semivolatile Organics by GC/MS, CLP	OLM03.2	GCMS.23	Ext.33	8-oz Glass TFC/Cool	10	40
GMS	CLP BNA	W	Semivolatile Organics by GC/MS, CLP	OLM03.2	GCMS.23	Ext.32	80 oz Amber/Cool	5	40
GMS	CLP BNA LOW	W	Semivolatile Organics by GC/MS, CLP, Low	OLC02.1	GCMS.35	Ext.71	80 oz Amber/Cool	5	40
GMS	8270C/3550C High	S	Semivolatile Organics by GC/MS, High	8270C/3550C	GCMS.19	Ext.12	8-oz Glass TFC/Cool	14	40
GMS	8270C/1311/3510C	TCLP	Semivolatile Organics by GC/MS, TCLP	8270C/35110C	GCMS.19	Ext.31	8-oz Glass TFC/Cool	14/7	40
GMS	1625	W	Semivolatiles, Isotope dilution GC/MS	1625	GCMS.39	Ext.80	80 oz Amber/Cool	7	40
GMV	8260B/3585	L	Volatiles, GC/MS	8260B/3585	GCMS.17	GCMS.41	40-mL VOA/Cool		14
GMV	524.2	PW	Volatiles, GC/MS	524.2	GCMS.8		40-mL VOA/HCl		14
GMV	8260B/5030A	S	Volatiles, GC/MS	8260B/5030A	GCMS.17	GCMS.17	40-mL VOA/Cool		14
GMV	8260B/5035	S	Volatiles, GC/MS	8260B/5035	GCMS.17	GCMS.17	40-mL VOA/Cool		14
GMV	624	W	Volatiles, GC/MS	624	GCMS.11		40-mL VOA/HCl		14
GMV	8260B/5030B	W	Volatiles, GC/MS	8260B/5030B	GCMS.17	GCMS.17	40-mL VOA/HCl		14
GMV	CLP VOA LOW	W	Volatiles, GC/MS CLP, Low	OLC02.1	GCMS.36		40-mL VOA/HCl		10
GMV	8260B LOW	W	Volatiles, GC/MS Low	8260B/5030B	GCMS.17	GCMS.17	40-mL VOA/HCl		14
GMV	CLP VOA	S	Volatiles, GC/MS, CLP	OLM0 3.2	GCMS.24		40-mL VOA/HCl		10
GMV	CLP VOA	W	Volatiles, GC/MS, CLP	OLM0 3.2	GCMS.24		40-mL VOA/HCl		10
GMV	TO2, VC	A	Volatiles, GC/MS, Molecular Sieve	TO2	GCMS.9		Tube/Cool		ASAP
GMV	TO14, SUMMA	A	Volatiles, GC/MS, Summa Canisters	TO14	GCMS.29	GCMS.28	SUMMA/None		ASAP
GMV	8260B/1311/5030B	TCLP	Volatiles, GC/MS, TCLP	8260B/5030B	GCMS.17	GCMS.17	40-mL VOA/Cool	14	14
GMV	TO1, TENAX	A	Volatiles, GC/MS, Tenax Tubes	TO1	GCMS.6		Tube/Cool		ASAP
GMV	1624	W	Volatiles, Isotope dilution GC/MS	1624	GCMS.38		40-mL VOA/HCl		14
LC	8330	S	Explosives by HPLC	8330	LC.8	Ext.68	8-oz Glass TFC/Cool	14	40
LC	8330 - LOW	W	Explosives by HPLC, Low Level	8330	LC.8	Ext.67	80 oz Amber/Cool	7	40
LC	IC FLUORIDE	PW	Fluoride by IC	300	LC.24		1-L Poly/Cool		28

ASC Product List

Section	Product Code	Matrix	Description	Analysis/Prep Method	Anal SOP	Prep SOP	Container/Preservative	HT-Prep	HT- Anal
LC	IC ANIONS 9056	S	Inorganic Anions By IC	9056M	LC.23		8-oz Glass TFC/Cool		28
LC	IC ANIONS (F, SO4)	W	Inorganic Anions By IC	300	LC.24		1-L Poly/Cool		28
LC	IC ANIONS (NO2, PO4)	W	Inorganic Anions By IC	300	LC.24		1-L Poly/Cool		2
LC	IC ANIONS 9056	W	Inorganic Anions By IC	9056	LC.23		1-L Poly/Cool		28
LC	IC NITRATE	PW	Nitrate By IC	300	LC.24		1-L Poly/Cool		2
LC	IC NITRITE	PW	Nitrite By IC	300	LC.24		1-L Poly/Cool		2
LC	NITRO/PETN	S	Nitroglycerine by HPLC	Proprietary	LC.14	LC.14	8-oz Glass TFC/Cool	14	40
LC	NITRO/PETN	W	Nitroglycerine by HPLC	Proprietary	LC.13	LC.13	1-L Amber/Cool	7	40
LC	8310/3550B	S	PAHs by HPLC	8310/3550B	LC.7	Ext.25	8-oz Glass TFC/Cool	14	40
LC	610	W	PAHs by HPLC	610	LC.25	Ext.13	80 oz Amber/Cool	7	40
LC	8310/3510C	W	PAHs by HPLC	8310/3510C	LC.7	Ext.13	80 oz Amber/Cool	7	40
LC	8310/3510C Low	W	PAHs by HPLC Low Level Fluorescence	8310/3510C	LC.7		80 oz Amber/Cool	7	40
MTA	AG 200.9	PW	Ag by GFAA	200.9-M	Metals.63	Metals.63	1-L Poly/HNO3		180
MTA	AS 200.9	PW	As by GFAA	200.9-M	Metals.63	Metals.63	1-L Poly/HNO3		180
MTA	AS 7060A	W	As by GFAA	7060A/3020A	Metals.41	Metals.11	1-L Poly/HNO3		180
MTA	CLP AS GF 4.0	S	As Furnace AA CLP	ILM04.0	Metals.16	Metals.36	8-oz Glass TFC/Cool		180
MTA	CLP AS GF 4.0	W	As Furnace AA CLP	ILM04.0	Metals.16	Metals.37	1-L Poly/HNO3		180
MTA	6010B	L	ICP Metals	6010B/3010A	Metals.18	Metals.11	125-mL Poly/Cool		180
MTA	METALS 200.7	PW	ICP Metals	200.7	Metals.54	Metals.54	1-L Poly/HNO3		180
MTA	6010B	S	ICP Metals	6010B/3050B	Metals.18	Metals.10	8-oz Glass TFC/Cool		180
MTA	METALS 200.7	W	ICP Metals	200.7	Metals.54	Metals.54	1-L Poly/HNO3		180
MTA	6010B	W	ICP Metals	6010B/3010A	Metals.18	Metals.11	1-L Poly/HNO3		180
MTA	CLP METALS 4.0	S	ICP Metals - CLP	ILM04.0	Metals.30	Metals.36	8-oz Glass TFC/Cool		180
MTA	CLP METALS 4.0	W	ICP Metals - CLP	ILM04.0	Metals.30	Metals.37	1-L Poly/HNO3		180
MTA	CLP METALS LOW	W	ICP Metals - CLP Low	ILC03.1	Metals.61	Metals.37	1-L Poly/HNO3		180
MTA	6010B/1311	TCLP	ICP Metals - TCLP	6010B/3010A	Metals.18	Metals.11	8-oz Glass TFC/Cool		180
MTA	HG EPA 7470A	L	Mercury CVAA	7470A	Metals.57	Metals.57	125-mL Poly/Cool		28
MTA	HG EPA 7471A	S	Mercury CVAA	7471A	Metals.12	Metals.12	8-oz Glass TFC/Cool		28
MTA	HG, 245.1	W	Mercury CVAA	245.1	Metals.64	Metals.64	1-L Poly/HNO3		28
MTA	HG EPA 7470A	W	Mercury CVAA	7470A	Metals.57	Metals.57	1-L Poly/HNO3		28
MTA	HG, 245.1	PW	Mercury CVAA	245.1	Metals.64	Metals.64	1-L Poly/HNO3		28
MTA	CLP HG 4.0	S	Mercury CVAA - CLP	ILM04.0	Metals.60	Metals.60	8-oz Glass TFC/Cool		26
MTA	CLP HG 4.0	W	Mercury CVAA - CLP	ILM04.0	Metals.21	Metals.21	1-L Poly/HNO3		26
MTA	HG EPA 7470A	TCLP	Mercury CVAA - TCLP	7470A	Metals.41	Metals.8	8-oz Glass TFC/Cool		28
MTA	NIOSH 6009 Hg Air	A	Hg in Air	NIOSH 6009	Metals.66	Metals.66	Hopcalite		30
MTA	PB EPA 7421	L	Pb by GFAA	7421/3020A	Metals.41	Metals.11	125-mL Poly/Cool		180
MTA	PB 200.9 M	PW	Pb by GFAA	200.9-M	Metals.63	Metals.63	1-L Poly/HNO3		180
MTA	PB EPA 7421	W	Pb by GFAA	7421/3020A	Metals.41	Metals.11	1-L Poly/HNO3		180

ASC Product List

Section	Product Code	Matrix	Description	Analysis/Prep Method	Anal SOP	Prep SOP	Container/Preservative	HT-Prep	HT-Anal
MTA	SB 200.9	PW	Sb by GFAA	200.9-M	Metals.63	Metals.63	1-L Poly/HNO3		180
MTA	SE 200.9	PW	Se by GFAA	200.9-M	Metals.63	Metals.63	1-L Poly/HNO3		180
MTA	SE EPA 7740	W	Se by GFAA	7740/3020A	Metals.41	Metals.11	1-L Poly/HNO3		180
MTA	SPLP	S	Synthetic Precipitation Leaching Procedure	6010B/1312	Metals.18	Metals.65	8-oz. Glass/Cool		180
MTA	TL 200.9-M	PW	Tl by GFAA	200.9-M	Metals.63	Metals.63	1-L Poly/HNO3		180
MTA	TL EPA 7841	W	Tl Furnace AA	7841/3020A	Metals.41	Metals.11	1-L Poly/HNO3		180
MTA	TCLP	L	Toxicity Characteristic Leaching Proc.	1311	Metals.8		125-mL Poly/Cool		7
MTA	TCLP	S	Toxicity Characteristic Leaching Proc.	1311	Metals.8		8-oz Glass TFC/Cool		7
MTA	TCLP	W	Toxicity Characteristic Leaching Proc.	1311	Metals.8		1-L Poly/Cool		7
	Notes	1	Samples indicated as Cool must be 4 +/- 2°C						
			Samples indicated preserved with acid must be to pH<2						
			Samples indicated preserved with base must be to pH>9						
			All Samples are cooled unless noted as None						

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ASC SOP Inventory

SOP INVENTORY

SOP No.	SOP Name	Annual Review	Rev.
A.4	Sample Container, Blank Preparation, and Shipment Procedures	29-Jan-99	2
A.6	pH Control/Pump System Calibration Procedures	22-Apr-99	1
A.7	Security for the ASC	05-Dec-98	1
A.8	Purchasing and Storing Materials for the ASC	06-Feb-99	2
A.10	Waste Disposal	03-Apr-99	3
A.15	Quality Control Testing of Sample Containers	15-Nov-98	3
A.18	Determination of Method Detection Limits	21-Jan-99	4
A.19	Balance Check	20-Jul-99	4
A.21	Laboratory Water Quality	02-Feb-99	5
A.22	Batch Identification	16-Jan-99	1
A.23	Initial Demonstration of Capability	21-Jan-99	3
A.24	Micropipette Calibration	21-Jul-99	3
A.25	Data Review	05-Dec-98	3
A.27	Document Control	13-Oct-98	0
A.28	Reagent/Standard Traceability	20-Jul-99	2
A.29	Continuing Demonstration of Staff Proficiency	21-Jan-99	0
A.30	Oven Calibration	26-Jan-99	0
A.31	Glassware Cleaning	26-Jan-99	0
A.32	Subcontracting	14-Apr-99	0
A.33	Project Management	26-Jan-99	0
A.34	Confidentiality/Proprietery	14-Apr-99	0
A.36	Electrical Power Outage	03-Apr-99	0
A.37	Laboratory Notebooks	06-Feb-99	0
A.38	Thermometer Calibration	20-Jul-99	5
A.39	Sonic Disrupter Tuning	23-Jul-99	0
A.40	BCM Engineering/Hudson Chromate Project	13-Oct-99	0
Comp.1	VAX Log-in	26-Jan-99	1
Comp.2	General LABMIS Fields Entry	02-Dec-98	1
Comp.3	LABMIS Work Assignment	04-Dec-98	1
Comp.4	LABMIS Work Completion	02-Dec-98	0
Comp.5	COMP Data Management	11-Dec-98	4
Comp.6	PC Backup, Security and Recovery	11-Dec-98	3
Comp.7	Editing Date of Completion	21-Dec-98	0
Comp.8	Review Process for Jacobs EDD	17-Dec-98	1
Comp.9	Generation of URS EDDs	04-May-99	0
Ext.4	Pesticide/PCB Extraction/Concentration of Water Samples by Method 3510C	13-Jun-99	4
Ext.7	Herbicide Soil Extraction for GC	13-Jan-99	2
Ext.8	Herbicide Water Extraction for GC	09-Jan-99	2
Ext.12	High Level BNA Soil Extraction	22-Jul-99	1
Ext.13	Extraction of PAH in Water for HPLC Analysis	27-Oct-98	1

SOP INVENTORY

SOP No.	SOP Name	Annual Review	Rev.
Ext.16	Organophosphorus Soil Extraction/Concentration	08-Oct-98	2
Ext.19	Pest/PCB Extraction/ Concentration by Method 3550B	16-Jan-99	2
Ext.20	Extraction/Concentration of Water for Semivolatile Compounds (3510C)	28-Aug-99	5
Ext.25	Extraction of PAH from Solids for HPLC Analysis	27-Oct-98	1
Ext.26	Organophosphorus Water Extraction/Concentration	21-May-99	2
Ext.30	EPH Extraction and Concentration of Soil and Water Samples	01-Dec-98	1
Ext.31	TCLP BNA Extraction and Concentration	05-Jun-99	1
Ext.32	Semivolatile Extraction from Water – CLP	05-Jun-99	4
Ext.33	Semivolatile Extraction from Soil – CLP	05-Jun-99	5
Ext.35	Pesticide/PCB Extraction from Water – CLP	12-Jun-99	4
Ext.36	Pesticide/PCB Extraction from Soil – CLP	06-Dec-99	4
Ext.46	Extraction/Concentration of Soil for Semivolatile Compounds for 8270	27-Oct-98	2
Ext.48	DRO Extraction/Concentration of Soil – AK102.0	27-Oct-98	2
Ext.49	Extraction of Organosulfur Compounds from Soil	15-Dec-96	0
Ext.58	TCLP Pest Extraction and Concentration	21-Apr-99	1
Ext.61	Herbicide Water Samples Extraction and Concentration by Method 515.1	25-Jun-99	0
Ext.66	RRO Extraction/Concentration of Soil Samples	22-Oct-98	2
Ext.67	Prep.of Water for Nitroaromatics and Nitroamines – Low Level	20-Jan-99	2
Ext.68	Prep.of Soils for Nitroaromatics and Nitroamines	27-Oct-98	3
Ext.70	Extraction Procedure and Special Clean-up for Buffalo Color Samples	13-Aug-99	1
Ext.71	Semivolatile Extraction; Low Concentration; CLP	13-Aug-99	1
Ext.72	GPC Clean-up for Pesticide/PCB Soils	28-Sep-98	1
Ext.73	GPC Clean-up for BNA Soils	28-Sep-98	1
Ext.78	Extraction of Chlorinated Phenolics by Method 1653	New	0
Ext.79	Extraction of Semivolatile Organics in Waters by Method 625	22-Sep-99	0
Ext.80	Extraction of Semivolatile Organics in Waters by Method 1625 Isotope Dilution	New	0

SOP INVENTORY

SOP No.	SOP Name	Annual Review	Rev.
GAC.2	Ammonia-Nitrogen Method 350.2	18-May-99	1
GAC.4	Total Kjeldahl Nitrogen (TKN) By Method 351.3	18-May-99	2
GAC.8	Petroleum Hydrocarbons in Water – IR	01-Dec-98	3
GAC.11	Biochemical Oxygen Demand (BOD5) By Method 5210B	11-Jun-99	3
GAC.12	Chemical Oxygen Demand	18-May-99	2
GAC.13	Phenols (4AAP) By Method 420.1	06-Aug-99	1
GAC.14	Percent Solids	13-Oct-98	2
GAC.15	Specific Conductance	14-Apr-99	1
GAC.17	Alkalinity-Hydroxide, Carbonate, Bi-carbonate and Total By Method 2320B	05-May-99	2
GAC.20	Total Organic Carbon By Method 5310	30-Jun-99	4
GAC.24	Color, Platinum-Cobalt	11-Jun-99	2
GAC.27	Hardness, Total By Method 130.2	05-May-99	2
GAC.29	MBAS (Method 425.1)	25-Aug-99	1
GAC.34	pH (Method 150.1)	08-Oct-98	2
GAC.35	Orthphosphate By Method 365.2	25-Aug-99	2
GAC.36	Phosphorous – Total (Method 365.2)	30-Jun-99	3
GAC.37	Solids – Dissolved (Methods 2540C & 160.1)	13-Apr-99	3
GAC.38	Solids – Suspended Method 160.2	05-May-99	2
GAC.39	Solids – Settleable	15-Oct-98	1
GAC.40	Solids, Volatile by Method 160.4	25-Aug-99	1
GAC.41	Specific Gravity	25-Aug-99	1
GAC.43	Sulfide by Method 376.1	16-Apr-99	1
GAC.48	Oil and Grease Gravimetric- Water	12-Feb-99	2
GAC.49	Total Organic Halogens by Method 9020B	06-Mar-99	2
GAC.50	Gross Heat of Combustion (Btu)	08-Aug-99	1
GAC.53	Ash by ASTM Method D 482	25-Aug-99	2
GAC.64	Lachat General Start Up Procedure	16-Apr-99	2
GAC.65	Cyanide Analysis	18-Nov-99	10
GAC.66	Nitrate/Nitrite by Lachat	16-Apr-99	1
GAC.72	Ignitability (Flashpoint, Liquids by Method 1010)	01-Apr-99	2
GAC.73	Physical Appearance	08-Sep-99	0
GAC.75	Chloride by Water Flow injection (Merthod 325.2)	18-May-99	1
GAC.76	TOC in Sediment (Lloyd Kahn)	18-May-99	2
GAC.79	PE 1600 FT-IR Operation	01-Dec-98	1
GAC.82	Hexavalent Chromium, Colormetric	15-Oct-98	1
GAC.83	Petroleum Hydrocarbons in Soil – IR by Method 5520F	22-Jul-99	2
GAC.85	Reactivity; Releasable Cyanide	18-May-99	1
GAC.87	TRPH by Soxhlet, Soils for IR	02-Dec-98	2
GAC.91	Alkaline Dig.Of Soils and Cr+ 6 Color.Analysis	16-Oct-98	3

SOP INVENTORY

SOP No.	SOP Name	Annual Review	Rev.
GAC.92	Paint Filter Liquids Test	13-Feb-99	1
GAC.100	Soil pH	24-Oct-98	1
GAC.103	Total Organic Carbon, Method 9060 in waters	01-Apr-99	2
GAC.106	Total Cyanide Preparation 9012	29-Jul-99	4
GAC.118	Total Cyanide in Water Preparation, CLP	20-Jul-99	5
GAC.119	Total Cyanide in Soil Preparation, CLP	20-Jul-99	4
GAC.120	Total Cyanide in Waste	20-Jul-99	2
GAC.121	Hexavalent Chromium in Water, Colorimetric Analysis (7196A)	28-Oct-98	2
GAC.122	Cyanide soil extraction 9013	18-Nov-98	0
GAC.126	Total Residue (Gravimetric), Total Solids (Method 160.3)	14-Apr-99	0
GAC.130	Reactivity; Releasable Sulfide	12-May-99	0
GAC.131	Acid Soluble and Acid Insoluble Sulfides by Methods 9030B and 9034	11-Aug-99	0
GAC.132	Extractable Sulfides not amenable to distillation by Methods 9031 and 9034	13-Oct-99	1
GAC.133	Corrosivity Tward Steel (Method 1110)	18-May-99	0
GAC.134	Cation Exchange Capacity of Soils (Sodium Acetate) by Method 9081	New	0
GAC.136	TRPH Soil Extraction by Shaker or Soxhlet (NJDEP)	31-Jul-99	0
GAC.137	Nitrite, Nitrogen by Method 354.1 (Spectrophotometric)	New	0
GAC.138	Sulfide by Method 376.2 Photometric	New	0
GAC.139	Alkaline Digestion (New Jersey)	25-Sep-99	1
GAC.140	Ignitability of Solids	New	0
GAC.141	Ammonia by Nesslerization	New	0
GAC.142	Suspended Particulate Matter High Volume Method	New	0
GC.13	Herbicide Analysis of Drinking Water Samples by Method 515.1	23-Jun-99	1
GC.14	Pesticide of Pesticide/PCB Analysis by Method 8081	16-Jan-99	4
GC.16	Purgeable Halocarbon Analysis by Method 601	26-Jan-99	1
GC.21	Herbicide Analysis of TCLP Extracts by Method 8151A	20-Apr-99	2
GC.22	Organophosphorous Pesticides 8141A	23-Jun-99	1
GC.26	Sample Prep.For PCB Oil Samples	25-Aug-99	1
GC.27	TPH-Gasoline 8015B and California LUFT	26-Nov-98	4
GC.31	Pesticides/PCB by GC; CLP	03-Jun-99	7
GC.37	TPH – Diesel or Extractable Petroleum Hydrocarbons, Modified 8015B and California LUFT	01-Dec-98	3

SOP INVENTORY

SOP No.	SOP Name	Annual Review	Rev.
GC.44	Purgeable Halocarbon Analysis by Method 602	26-Jan-99	1
GC.45	DRO Analysis – AK102.0	31-Oct-98	3
GC.46	Gas Range Organics Analysis – AK101.0	11-Jun-99	1
GC.49	EDB and DBCP by Method 504.1/8011	14-Apr-99	1
GC.57	RRO Analysis for Soil Samples by Method AK103	27-Oct-98	2
GC.59	Volatile Organic Compound Analysis by Method 8021B	22-Feb-99	3
GC.60	Herbicide Analysis of Soil or Water Samples by Method 8151A	13-Jan-99	3
GC.62	Volatiles By GC/PID/HECD for Drinking Water by Method 8015B/3810	New	0
GC.64	Method 608 Analysis of Pesticides by GC/ECD	20-Apr-99	0
GC.66	Analysis of TCLP Pesticides by Method 8081A	20-Apr-99	0
GC.69	Manual Integration	28-Apr-99	0
GC.70	Non Polar Nitrosamines	New	0
GC.71	Polar Nitrosamines	New	0
GC.72	Pesticide Analysis by Method 8081A	03-Mar-99	0
GC.73	PCB Analysis by Method 8082	03-Mar-99	0
GC.74	Sample Prep.For PCB Wipe Samples	25-Aug-99	0
GC.75	Nonhalogenated Organics Using GC/FID	New	0
GC.76	FL Petroleum Range Organics	New	0
GC.77	Pest/PCB by GC; CLP 4.0	New	0
GC.78	VOC Analysis by 502.2	New	0
GCMS.8	VOC by Method 524.2	02-Jul-99	1
GCMS.11	Method 624 Volatile Analysis by Purge and Trap GCMS	07-Jul-99	0
GCMS.17	GCMS Analysis of VOAs by SW-846 Purge and Trap	21-Jul-99	7
GCMS.19	Method 8270 Semivolatile Analysis	21-Jul-99	10
GCMS.20	Semivolatile Analysis of Water Extracts by Method 625	New	0
GCMS.23	CLP Analysis for Semivolatile Samples	23-May-99	5
GCMS.24	CLP Volatile Analysis by Purge and Trap GC/MS	18-May-99	3
GCMS.25	Data Transfer of HP Results into Formaster	08-Sep-99	4
GCMS.28	SUMMA Air Canister Cleaning Procedure	15-Aug-94	0
GCMS.29	Analysis of VOAs in Air using SUMMA Canisters	15-May-94	0
GCMS.35	Analysis for Low Conc.CLP BNAs by GC/MS	25-Jun-99	1
GCMS.36	Analysis for Low Conc.CLP Volatile Organics by GC/MS	11-Aug-99	1

SOP INVENTORY

SOP No.	SOP Name	Annual Review	Rev.
GCMS.38	Method 1624 Analysis of Volatile Organics by GC/MS Isotope Dilution	New	0
GCMS.39	Method 1625 Analysis of Semivolatile Organics by GC/MS Isotope Dilution	New	0
GCMS.40	Method 1653 Analysis of Chlorinated Phenolics by GC/MS	New	0
GCMS.42	GCMS Analysis of TCLP Semivolatile by 8270	23-Jun-99	0
GCMS.43	CLP Analysis for Semivolatile Samples OLM04.1	New	0
LC.7	PAH Determination by HPLC	10-Oct-98	3
LC.8	Nitroaromatics and Nitroamines by HPLC	20-Mar-99	6
LC.13	Determination of PETN and Nitroglycerine in Water	01-Sep-93	1
LC.14	Determination of PETN and Nitroglycerine in Soil	10-Aug-93	1
LC.23	Anion Analysis of Water Samples	11-Nov-98	1
LC.24	Anions by Method 300.0	11-May-99	0
LC.25	PAH Determination by HPLC for Method 610	11-May-99	0
Metals.8	Toxicity Characteristic Leaching Procedure	16-Apr-99	2
Metals.10	Digestion ICP or GFAA by Method 3050A	20-Oct-98	4
Metals.11	ICP or GFAA Digestion of Waters by Methods 3010A or 3020A	20-Oct-98	3
Metals.12	Cold Vapor Soil Digestion Method 7471A	18-Nov-98	5
Metals.15	California WET	07-Jul-99	2
Metals.16	GFAA Metals – CLP	22-Jul-99	3
Metals.18	ICP Metals SW-846 Method 6010B	19-Nov-98	9
Metals.21	Cold Vapor Digestion and Analysis for Waters – CLP ILM04.0	18-May-99	6
Metals.30	ICP Metals – CLP ILM04.0	05-Jun-99	3
Metals.36	GFAA and ICP Digestion of Solids by CLP Procedure	18-May-99	5
Metals.37	GFAA and ICP Digestion of Waters by CLP Procedure	18-May-99	6
Metals.41	Metals Analysis by GFAA SW-846	29-Oct-98	5
Metals.54	ICP Metals by Method 200.7	05-Jun-99	1
Metals.55	ICP or GFAA Digestion of Water by 3005A+D152	28-Oct-98	0
Metals.57	Cold Vapor Digestion Method 7470A	18-Nov-98	4
Metals.59	Interelement Correction Factor Determination	23-Jun-99	1
Metals.60	Cold Vapor Digestion and Analysis for Soils - CLP	18-May-99	5

SOP INVENTORY

SOP No.	SOP Name	Annual Review	Rev.
Metals.61	ICP Metals, CLP 3.0	19-Nov-97	0
Metals.63	GFAA for Potable Waters, Low Level Method 200.9	24-Aug-99	1
Metals.64	Mercury Preparation and Analysis for Potable and Waste Waters by Method 245.1	New	0
Metals.65	Synthetic Precipitation Leaching Procedure (Method 1312)	New	0
Metals.66	Mercury in Air NIOSH Method 6000	17-Nov-99	0
QA.1	Corrective Action Process	13-Oct-98	4
QA.5	Training Program	08-Dec-98	6
QA.18	Standard Operating Procedure: Use and Administration	02-Nov-99	9
QA.19	Conducting Audits	01-Oct-98	5
QA.20	Control Charting	12-Feb-99	2
Rep.1	Data Reporting Procedures	13-Jan-99	1
Rep.6	CLP Data Deliverables for Organics Analysis	11-Feb-99	3
Rep.7	CLP Data Deliverables for Inorganics Analysis	03-Mar-99	2
Rep.8	Job Case Filing	20-Jan-99	2
SM.1	Package Receipt	04-Nov-98	2
SM.2	Sample Log-in	22-Oct-98	6
SM.4	Sample Transfer	23-Jun-99	4
SM.10	Sample Splitting	04-Feb-99	0