



Quality Management Plan

Cooper Environmental Services

Version 1.0

Cooper Environmental Services

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APPENDICES

- A. Standard Operating Procedures
- B. Key QA Staff Resumes

History of Revision

Revision	Date	Description of Change
1.0	3/10/99	New Document

General Terms, Abbreviations, and Acronyms

Accuracy	The agreement between an experimentally determined value and the accepted reference value.
Calibration	The process of comparing a standard or instrument with one of greater accuracy (smaller uncertainty) for the purpose of obtaining quantitative estimates of the actual values of the standard being calibrated, the deviation of the actual value from a nominal value, or the difference between the value indicated by an instrument and the actual value.
CES	Cooper Environmental Services
CES Management	President and QAM
CoC	Chain-of-Custody
DOS	Disk Operating System
GALP	Good Automated Laboratory Practices
IO-3.3	Inorganic Compendium Method 3.3 <i>Determination of Metals in Ambient Particulate Matter Using X-ray Fluorescence (XRF) Spectroscopy</i>
Laboratory Technician	Individual designated for conducted analytical procedures and following quality systems as outlined in the QMP and project specific QAPP.
LIMS	Laboratory Information Management System. A MS Access data base which includes chain-of-custody and analysis results for laboratory samples.
Management System Review	The qualitative assessment of data collection operation and/or organization (s) to evaluate the adequacy of the prevailing quality management structure, policies, practices, and procedures for obtaining the type and quality of data needed.
NIST	National Institute of Standards and Technology.
Precision.	The degree of mutual agreement between individual measurements, namely repeatability and reproducibility.
President	CES sole proprietor
QA	Quality Assurance
QAM	Quality Assurance Manager; Individual responsible for implementing the CES quality system as discussed in the QMP.
QAPP	Quality Assurance Project Plan as developed using

QAU	Quality Assurance Unit
QC	Quality Control
QMP	Quality Management Plan
Records	All books, papers, maps , photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics.
RMS	Records Management System
Standard	A concept that has been established by authority, custom, or agreement to serve as a model or rule in the measurement of quantity or the establishment of a practice or procedure.
Standard Operating Procedures	Procedures describing routine verification activities including sample collection, analytical testing, and associated verification processes.
Uncertainty	An allowance assigned to a measured value to take into account two major components of error (1) the systematic error, and (2) the random error attributed to the imprecision of the measurement process.
XRF	X-ray fluorescence

1.0 MANAGEMENT AND ORGANIZATION

1.1 INTRODUCTION

This plan describes the quality system management approach for Cooper Environmental Services (CES). This document includes organizational structure, functional responsibilities, and required interfaces for planning, implementing, and assessing CES analytical activities.

1.2 QUALITY POLICY

The highest quality data is needed to make informed regulatory and scientific decisions. Therefore, it is our mission to provide scientifically sound data of known and documentable quality. This mission will be realized by: (1) clearly defined objectives and structures (2) well documented QA/QC and analytical procedures (3) information management control (4) a comprehensive audit system and (5) management support. Acceptable measurement data includes characterization of precision, accuracy, completeness, and comparability. The fulfillment of this mission will result in reliable, legally defensible analytical data.

CES is committed to continued development and improvement of the analytical program as technologies advance and protocols are improved upon. Sufficient funding is available for necessary training and technical support to meet program needs. Quality control (QC) checks have been provided throughout the program to minimize impacts on data quality and integrity and to identify problems that could influence results. Any situation that compromises data quality will be identified and addressed immediately. The President or QAM have the authority to stop work for safety and quality considerations.

1.3 QA STAFF RESPONSIBILITIES AND AUTHORITY

Executing an effective Quality Assurance program demands the commitment and attention of both management and staff. The President and Quality Assurance Manager (QAM) are responsible for QA efforts at CES. The QAM reports directly to President and has the responsibility for overseeing and regulating all laboratory functions. The QAM operates independently of all areas generating analytical data to ensure complete objectivity in the evaluation of laboratory operations.

The QAM is the final authority on all issues dealing with data quality and has the authority to require that procedures are amended or discontinued and analyses suspended or repeated. Also, the QAM has the responsibility to notify the President of any need to suspend or terminate an employee on the grounds of dishonesty, incompetence, or repeated noncompliance with QA procedures. The authority of the QAM comes directly from the President.

President's responsibilities:

- Provides overall program direction.
- Serves in program leadership role with stakeholders.

- Approves and implements annual budgets and resource allocations.
- Allocates laboratory personnel and other resources to accomplish CES goals.
- Reviews and approves Quality Management Plan (QMP), Standard Operating Procedures (SOPs), Quality Assurance Project Plans (QAPP)

Quality Assurance Manager responsibilities:

- Implementing Quality Assurance policies.
- Developing and ensuring adherence to Chain of Custody requirements.
- Ensuring limited access to analytical software data in accordance with the Good Automated Laboratory Practices (GALP).
- Conducting Level I and II validation on data to ensure reasonable inter-relationships and expectations relative to the physical environment.
- Monitoring the implementation of the Quality Management Plan within the laboratory to ensure complete compliance with Quality Assurance objectives
- Conducting in-house audits to identify potential problems.
- Performing statistical analyses of QC data and establishing data bases that accurately reflect the performance of the laboratory
- Prescribing and monitoring corrective actions.
- Serving as the in-house client representative on all project inquiries involving data quality issues.
- Monitoring the preparation and verification of analytical standards.
- Reporting the status of the laboratory Quality Assurance program to the President with formal and informal communications.
- Maintaining records and archives of all QC data, Performance Evaluation results, audit comments, and customer inquires concerning data quality.
- Monitoring laboratory performance in the areas of holding times, turnaround times, and meeting contractual obligations.
- Conducting explanations of Quality Assurance issues for clients and laboratory staff .
- Preparing Quality Assurance Project Plans when needed .
- Writing of Quality Assurance policies and procedures.

Laboratory Technician responsibilities:

- Enter all field sampler and Chain of Custody data into the Laboratory Information Management System.
- Validating software manipulation of analytical hardware data output.

- Maintaining Chain of Custody protocols.
- Level 0 validation of data performed and entered.
- Deletion of data that is incomplete or incorrect due to hardware or operator errors.
- Marking data outside of QC limits with qualifier flags.
- Corroborating data entries against laboratory bench sheets.

1.4 QA ORGANIZATIONAL CHART

CES is organized along clear lines of authority to provide clients with service that is efficient and reliable. The leaders have full management control over their staff allowing for an organized chain of authority. Key personnel meet at least weekly to discuss laboratory QA/QC activities. The following are the key personnel and their responsibilities. Resumes of key personnel can be found in Appendix B.

Dr. John A. Cooper	President
Bruce Johnsen	Quality Assurance Manager

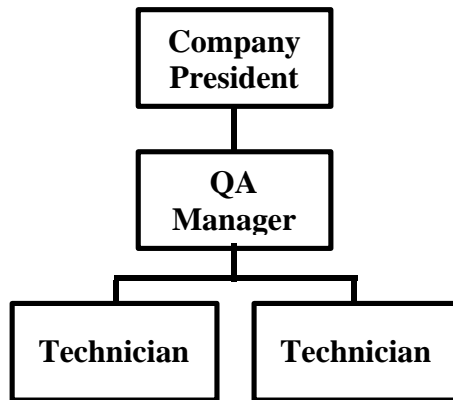


Figure 1. CES Organizational Chart

1.5 PROGRAMS REQUIRING QA SUPPORT

CES analytical program focuses on high quality air filter analyses. QA support is required to:

- Ensure document control.
- Ensure conformity to analytical SOPs (Appendix A),
- Oversee Chain-of-Custody compliance.
- Initiate QA/QC training sessions and opportunities.

- Develop and validate calibration and QA/QC routines.
- Ensure that analytical hardware is within tolerance limits.
- Conduct QA audits.
- Maintain Good Automated Laboratory Practices (GALP).

1.6 IMPLEMENTATION OF QUALITY SYSTEM

The CES Quality System is integrated into all phases of the CES analytical process. Written copies of the corporate QMP and applicable QAPPs and SOPs are distributed to new employees during initial training and after major revisions. At a minimum, an annual review is conducted to revise the quality documents and ensure continued use of the Quality System. Adherence to the Quality System is included during the laboratory technicians' job review process and are reflected in salary adjustments. The Quality Assurance Manager is responsible for conducting periodic audits to certify procedural compliance.

2.0 QUALITY SYSTEM AND DESCRIPTION

The CES quality system has been developed and endorsed by CES management under the guidelines presented in the final drafts of *EPA Requirements for Quality Management Plans (QA/R-2)* and *EPA Requirements for Quality Assurance Project Plans (QA/R-5)*. Table 1 outlines the roles for various components in the CES Quality System.

Quality Management Plan (QMP)

The QMP is a "living document" which presents a blueprint of the organizational quality system. The QAM is responsible for initiating an annual review of the QMP which includes input from all end-users of the QMP. The QAM is also responsible for ensuring compliance with the QMP and communicating compliance efforts to the President. Laboratory technicians are required to follow QMP goals, outlines, and strategies; and are encouraged to actively participate in QMP revisions.

Management Assessments

Multiple QA and QC checks are performed at all phases of program implementation, as addressed in each section of this QMP, to prevent and/or detect quality problems. Since most activities are monitored by at least two hierarchical levels of supervision, problems are identified quickly and corrective action is employed promptly. CES management is constantly informed of the quality process and has made a commitment to quality improvement activities. It is further understood that peer review is an essential component of this program, which leads to the development of better products and services.

Systematic Planning Processes

The President and QAM are responsible for initiating development of data quality objectives (DQO's) using the *EPA's Guidance For the Data Quality Objectives Process (EPA/600/R-96/055)* as a guide. DQO's include specific decision rules and limits on decision errors for each significant analytical program.

Quality Assurance Project Plan (QAPP)

The QAPP provides project specific planning, implementation, and assessment methodology for obtaining quality environmental data. Quality assurance (QA) and quality control (QC) are applied to achieve defensible products and decisions. The President is responsible for initiating, evaluating, and reviewing the QAPP. The President is also responsible for revision approval. The QAM is responsible for implementing the QAPP, verification of QA/QC protocols and ensuring adherence to appropriate measurement methods, data handling, and data analysis. The QAM is also responsible for data validation and ensuring proper training in quality related matters. Laboratory technicians are responsible for maintaining document control, following SOPs, and conducting Level 1 quality assurance.

Standard Operating Procedures (SOPs)

Analytical SOPs (Appendix A) follow strict document control and revision requirements. XRF SOPs are a modified version of Inorganic Compendium Method IO-3.3 *Determination of Metals in Ambient Particulate Matter Using X-Ray Fluorescence Spectroscopy*. IO-3.3 has been modified to match the CES QuanX ed-XRF analyzer while maintaining required detection limits and QA/QC. The QAM is responsible for ensuring that SOPs are followed, while laboratory technicians are responsible for adhering to SOPs and communicating questions and/or revision suggestions to the QAM. The President is responsible for reviewing and confirming any significant SOP variation.

Technical Assessments (Self And Independent)

Periodically, a thorough, systematic audit is conducted of facilities, equipment, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of the CES program. These audits are conducted by the QAM or independent organization (Section 9.0) and given as a written report to the President. Audit results are used in evaluating QAM and Laboratory Technician performance and are included in the annual Quality System review. Independent assessments are encouraged by contracting agencies. CES management has a history of innovative Technical Assessment programs including organizing the first and second XRF aerosol analysis interlaboratory comparisons (see resume for John Cooper). CES continues to encourage and initiate interlaboratory comparisons to ensure independent Quality Control.

Data Quality Assessments (DQA)

Statistical evaluations are conducted on all data sets to determine the validity and adequacy of the data set. QA/QC tests are included with each test run and must pass statistically assigned standard level parameters. The QAM is responsible for conducting statistical analyses of the test runs and has the authority to retest analytical samples in order to meet DQO's. The laboratory technician is responsible for including QA/QC samples in test runs by following SOPs.

TABLE 1. Description of Components of the CES Quality System

Component	Description	Application	Roles and Responsibilities
Quality Management Plan (QMP)	Document describing the quality system including organizational structure, responsibilities and QA assessment.	XRF analysis and Instrument calibration	The QAM is responsible for developing, revising and carrying out the QMP.
Management Assessments	An evaluation of the integrated quality assurance program implementation. Results are used to improve quality and management efficiency.	Quality Management System	The President is responsible for initiating evaluations of the QAM effectiveness. QAM and technicians are responsible for promptly and completely participating in the assessment.
Systematic Planning Processes	Planning process (e.g. DQO) which uses graded approach to ensure details in planning commensurate with intended work.	XRF analysis and Instrument calibration	President responsible for assigning project manager (PM). PM responsible for schedule, data type and quantity. PM and QAM develop QA/QC activities.
Quality Assurance Project Plan (QAPP)	Comprehensive document detailing QA and QC activities necessary to meet stated performance criteria for a project.	Laboratory operation	President and QAM develop and implement the QAPP. QAM and technician are responsible for carrying out QAPP.
XRF Standard Operating Procedures	A modified version of Inorganic Compendium method IO-3.3 designed for the CES XRF instrument	XRF analysis and Instrument calibration	President and QAM develop and implement the SOP. Laboratory technician is responsible for carrying out SOP.
Technical Assessments (Self And Independent)	Self and independent assessments verify compliance with regulatory and technical drivers	Laboratory operation	The President and QAM are responsible for developing and implementing self assessment plans and either a) hiring technically competent contractors or b) developing lab round robins to conduct independent
Data Quality Assessments (DQA)	Statistical evaluation of data set to determine validity of analytical design and determine adequacy of data set.	XRF analysis and Instrument calibration	President and QAM responsible for developing assessment methods and conducting DQAs

3.0 PERSONNEL QUALIFICATIONS AND TRAINING

3.1 PERSONNEL TRAINING

Although no regulatory requirements exist for operating an XRF analyzer, the QAM and laboratory technicians are required to have an educational background which includes a relevant bachelors degree from an accredited university and required training as discussed in the XRF SOP. The President, QAM and technicians are encouraged to continue to develop professionally through attendance at conferences, membership in professional organizations, and classes. Resources are made available for tuition reimbursement, conference costs, and time for attendance at professional meetings.

The QAM is responsible for identifying statutory, regulatory, and professional certifications for each member of CES on a project specific basis. The QAM shall also initiate required training sessions and document completion of training.

3.2 MAINTENANCE OF STAFF PROFICIENCY

All key CES employees maintain professional associations with the Air and Waste Management Association (AWMA) and American Society for Testing and Materials (ASTM). In addition, Dr. Cooper is a member of the Source Evaluation Society (SES) and EPA's Speciation PM_{2.5} Committee. Personnel are required to stay current in the scientific literature and are encouraged to seek additional scientific/academic training.

Appendix B includes position descriptions and qualifications of key CES personnel.

3.3 TECHNICAL, QUALITY, AND PROJECT MANAGEMENT TRAINING

The QAM is responsible for designating and documenting required training. All personnel who conduct routine laboratory procedures attend an annual Laboratory Methods meeting where personnel review standard laboratory practices related to updated XRF analysis techniques, QA/QC, and review of XRF theory and data handling. The QAM identifies academic trainers and appropriately certified instructors. The QAM is responsible for ensuring that all instructors and materials are current for any particular training. Training is verified by assessment and/or instructor certification at the conclusion of the course. The course will be evaluated by participants and comments will be provided to training personnel as part of the quality improvement process. Records of the training session and copies of applicable course certificates will be maintained in the employee file. The need for additional retraining is evaluated on an annual basis by the QAM.

4.0 PROCUREMENT OF ITEMS AND SERVICES

CES's President and QAM have the responsibility of acquiring goods and services needed to fulfill all the obligations and requirements of the analytical program. Contracts and legally binding agreements are administered by the President.

The administrative staff (i.e. President and QAM) are expected to, at a minimum:

- 1) Review and track all significant paperwork related to contracts, including: scope of services; budget; request for contracts and amendments or proposals; purchase and change orders; invoices; payments; ensure dual sign-off where needed for technical and administrative review; and ensure all commitments/requests of any kind are in writing and by the appropriate persons.
- 2) Ensure that minority/disadvantaged business enterprises have the maximum opportunity to compete for and perform contracted services.
- 3) Personally inspect all purchases and deliverables and verify whether they are satisfactory and in keeping with the terms and conditions of the contract. Authorization or payment of invoices should not be processed until deliverables are in-hand or documented.
- 4) In the case of contracted facilities or laboratories, monitoring reports are provided by the contractor at the time of invoicing and reviewed by CES administrative staff for compliance. The CES staff complete a performance evaluation form at the end of the contract period and provide this to the administrative staff. The review of the contractor includes evaluating compliance with CES standards and the contract conditions and deliverables.
- 5) Obtain, review, approve, and maintain quality system documents of contracted facilities or laboratories.

5.0 DOCUMENTATION AND RECORDS

5.1 IDENTIFICATION OF QUALITY-RELATED DOCUMENTS

All quality-related documents and records are indexed, archived, and maintained for at least five years. Quality-related documents requiring control include:

- QMP, QAPP's, and SOPs.
- Raw or Transformed Data Sheets.
- Cooperative agreements, contracts.
- Internal and external audit results.
- Annual Quality System review meeting minutes.
- Correspondence relating to data analysis and QA/QC
- Chain -of-Custody forms.
- Laboratory notebooks and XRF Journals.
- Reported analytical results including concentrations, uncertainties and method protocols.
- QA Level 0, 1 and 2 checklists and reporting forms.

5.2 DOCUMENT HANDLING

Document and record management is critical to attaining the CES mission of providing defensible data. Standardized procedures ensure that any document (including all raw or transformed data or information not compiled into a finished report) or report is prepared in a timely fashion, reviewed, approved, used, revised, disseminated, and maintained.

Document Chain-of-Custody (CoC) protocols are followed using Standardized Operating Procedures (Appendix A). Sample information including labels, field data, and a unique lab ID number are entered into the Laboratory Information Management System (LIMS). The ID number is written on all forms, notebooks, and other documents related to laboratory analysis.

Data and record tracking is an important aspect of information control and utilization. The term tracking in this section refers to the compilation and organization of data and records in a format that identifies its contents and location in order to make the data and records easily accessible to users.

Proper data and record tracking entails collecting all information relative to a particular project and organizing this material to enable users to locate and utilize the findings. Management strategy includes a filing system for all records and gives directions as to where other information relating to the project can be found. The tracking system will allow the user to follow data from its raw form through spreadsheets, analysis, and reports.

Hard Copy

All data, documents, and records kept in the project files will be labeled upon entry into the file and tracked. Tracking codes will include project number, type of file, and document number. XRF journal entries must be initialized by laboratory technicians and reviewed by the QAM.

Electronic Copy

All sampling and CES reported concentration data are to be entered into MS Access Data Bases which are backed up at regular intervals based on the value of the program, potential for loss, and difficulty of restoration (graded approach) using a Seagate Tape Back-up system or an Iomega Zip drive. All data sets in spreadsheets will be identified by project number, the type of data, and dates and backed-up electronically. The file name will have a special code under which it will be saved for easy identification purposes. The MS Access Data Base, under the guidance of the QAM, will include a master file containing the names, codes, and locations of all data files maintained for the project.

Obsolete Records

Obsolete records should be clearly marked as such. These records may be retained in the workplace for historical reference, or they may be removed to archival storage. The current minimum requirement is that all records be kept for seven years after the final payment .

5.3 TECHNICAL GUIDANCE DOCUMENTS

Technical guidance documents are prepared and/or updated by the QAM. Before use, guidance documents are reviewed by the President for conformance with the quality system requirements. Significant revisions to technical guidance documents are noted in the guidance document and communicated to end-users of the document in writing.

5.4 QUALITY PLANNING DOCUMENTS

It is understood that the QMP is a "living" document that will evolve over time. Any changes to the QMP will be distributed to all individuals performing work under the QMP as the change occurs, and these changes will be reviewed during the annual training. If significant changes are made, a revised version will be published and distributed. Quality assurance training and evaluation will be conducted annually to assess the effectiveness of the Quality Management System, both organizationally and procedurally.

In order to continually improve and adapt the QMP, an annual review of the CES QMP is conducted to reconfirm the suitability and effectiveness of the approved quality management practices. This review includes:

- Clarification of roles and responsibilities
- An examination of problem areas
- Acknowledgement of successes

Copies of the original CES QMP (Version 1.0) and all subsequent versions are kept on file at CES. Upon review and revision, all appropriate CES personnel are notified of the changes. When CES is acting under an extramural agreement with the EPA, a copy of the revisions made during the review is submitted to the EPA as a report. CES QMP versions are identified by their version number. The annual review changes the number before the decimal point while intra-year changes are displayed after the decimal point (e.g. the revised QMP after an annual review might be identified as version 3.0 while the first revision during the following year would be identified as version 3.1).

5.5 COMPLIANCE ASSURANCE

In order to ensure compliance with all statutory, contractual, and assistance agreement requirements, a records management system (RMS) is maintained. The RMS consists of requirements for records disposition, storage, and retrieval. The MS Access Data Base, as a part of the RMS, includes a master file containing the names, codes, and locations of all data files maintained for the project. The QAM, acting as a records coordinator is responsible for:

- Implementing RMS development, revisions, and review.
- Ensuring that key records are preserved.
- Reviewing documents for conformance to the quality system.

- RMS training on document entry, maintenance, retention, protection, preservation, traceability, and transmittal.
- Initiating, developing and reviewing Records Data Base revisions.
- Data Base audits.
- Ensure complete documentation and filing of all significant procurement documents, correspondence, and other information.
- Coordinate, develop, or initiate correspondence, written alternatives, recommendations, responses, and preventative actions to project concerns/problems.
- Prepare post-assignment reports on all projects and contracts when completed.
- Inquire and arrange for orderly transfer of project/contract management responsibilities.

6.0 COMPUTER HARDWARE AND SOFTWARE

Computer software and computer hardware/software configurations covered by this QMP include configurations designed to evaluate and reduce environmental data, report environmental data, and data base storage of environmental data.

6.1 COMPUTER HARDWARE

CES XRF analyses are conducted using a 1999 Spectrace QuanX energy dispersive XRF analyzer. This analyzer relays spectra and counting rates to a Dell personal computer using TXCONFIG software. XRF hardware undergoes daily calibration according to the XRF Data Analysis SOP (Appendix A). If the XRF unit falls out of control limits, it is recalibrated using the XRF Calibration SOP (Appendix A). The Dell computer is equipped with a tape-back up system and port for a zip drive to back-up data. The computer is not connected via modem or network to other CES computers or the internet so that a firewall exists for system security. Password limitations for user access is also employed. Data can be printed directly from the computer to a HP LazerJet printer. Access to the computer is limited to approved CES employees or individuals authorized by CES management.

Each employee at CES has access to their own Dell or Micron personal computers. These computers operate using MS Windows software and are connected to the internet via modems and a dedicated internet phone line.

6.2 COMPUTER SOFTWARE

The Spectrace QuanX data is compiled and deconvoluted using proprietary DOS based Spectrace software and prepared MS Excel data processing worksheets. Sample identification and count rate information is imported into Excel spreadsheets for conversion to concentrations and are then imported to a MS Access database for final product delivery. Project specific Laboratory Information Management Systems (LIMS)

are developed using MS Access or MS Excel. The LIMS system follows Good Automated Laboratory Practices (GALP). The QAM is responsible for ensuring that data generated for the project deliverables are valid and secure. All data calculation and data validation methods are documented in the XRF Data Analysis SOP.

The current XRF software manual is *QuanX Software Manual Version 1.35*. Changes in the software are required to be noted in this user guide and, if significant, are noted by appropriate version number changes. Data and software are backed-up based on the value of the program, potential for loss, and difficulty of restoration (graded approach) using an Iomega zip drive or tape back-ups system. Back-up disks containing the original source code are maintained.

All personnel who conduct data processing and analysis attend in-house training sessions on the use of relevant software packages. QA audits include examination of data from the original count rates to the final listed concentrations ensuring software reliability.

CES operates a website (www.ces-info.com) which provides information on CES capabilities and analytical services. The website was developed using MS FrontPage and is revised internally.

7.0 PLANNING

7.1 SYSTEMATIC PLANNING

Environmental data operations are designed using a systematic planning approach based on *EPA QA/G-4 Guidance for the Data Quality Objectives Process*. Key decisions are identified, study boundaries are determined, and a decision rule and acceptable decision error is determined. Systematic planning documents include the QMP, QAPP, and analytical SOPs.

Systematic planning processes established for CES is conducted as follows:

1. Identification of internal and external customers. Appointment of appropriate personnel from CES to manage project responsibilities.
2. Establishment of technical and data quality objectives.
3. Assessment of contractual time and budgetary constraints.
4. A graded approach to identification of priorities, and requirements. Determination of data quantity and restraints.
5. Development of QA/QC processes, SOPs, and QAPP.
6. Analysis, Evaluation, and Assessment of Data following quality system protocols.

These elements are discussed in greater detail below.

Customer and Supplier Identification.

CES customers includes both external customers and CES management which have responsibility for the execution of the analytical program and expect conformance with management and quality policies. External customers are individuals not directly employed by CES. CES suppliers and customers include,

- Public and private sector buyers of analytical services
- Sponsoring organization and responsible official
- End users of analytical services
- Developers and vendors of technology
- Public and private sector decision makers using the analytical data
- Members of the public and scientific communities using data results
- Federal, state, and local government permitting/regulatory agencies.

A qualified CES manager is appointed by the President to manage the project and work with external customers and suppliers. The CES manager identifies necessary vendors, suppliers, subcontractors, and external customers involved with the project.

Technical and Quality Goals Description.

CES customers require reliable, defensible analytical data. This data must have:

- A justifiable approach to selecting analytical procedures and detection limits.
- Adequate detection limits and uncertainties.
- Well documented QA/QC and analytical procedures.
- Document control and accountability.
- Adherence to standard protocols and procedures.
- Cost-effective testing which provides efficient, and timely results.

Technical and quality goals are determined by CES management using a project specific graded approach to the desired level of detection limits and analysis required. Increased detection limits, decreased interferences, QA/QC capabilities, and complex protocols are ranked and evaluated relative to boundary limitations in order to provide the highest level of overall technical quality.

Cost and Schedule Requirements.

Improved detection limits and decreased turn around times are reflected in cost and schedule requirements. CES management is committed to meeting regulatory and contractual requirements by anticipating budgetary and timeline limitations and setting reasonable milestones and detection limits. Specifically, the CES manager, in coordination with the customer, has the responsibility of determining cost and schedule requirements relative to technical goals and communicating their findings to the external customer and CES management.

Data Specifications.

Data specifications are met when data objectives, quantity, and collection restraints are satisfied.

Data Objectives. Data should be accurate and precise. Uncertainties associated with the analytical process are included in the determination of detection limits and final reporting process.

Data Quantity. Data should be of sufficient quantity to give reliable statistical validity to the customer and quality objectives. Data quantity includes adequate numbers of samples and adequate sampling times (e.g. XRF count rates).

Data Collection Restraints. Potential interferences and method limitations are identified and communicated to the customer prior to analysis.

Before conducting analyses, the technical goals graded approach is modified to include quantity and quality goals needed to fulfill a customer's program objectives. Limitations such as filter type and availability are included in the graded approach. Acceptable accuracy and precision limitations are determined and potential inadequacies of the analytical approach are resolved. The CES manager is responsible for determining decision rules and acceptable uncertainties with the customer.

QA and QC Activities.

Required numbers and types of QA/QC samples are determined following SOPs so that data quality objectives can be met. QA and QC parameters are stated explicitly in the QAPP for each project and follow QMP guidelines. QA and QC applied to a project are required to be commensurate with:

- The purpose of the environmental data collection.
- The type of work to be done, and
- The intended use of the results.

Analysis, Evaluation, and Assessment of Data.

Laboratory analysis is conducted following SOP and QAPP protocols. QA/QC data is evaluated to determine if parameters are met and Level 1 and 2 quality assurance is performed by CES management. If data quality parameters are not met, the QAM has the authority to order reanalysis.

7.2 QUALITY ASSURANCE PROJECT PLANS

Planning results for each project are documented in a QAPP. QAPP's are developed following *EPA Requirements for Quality Assurance Project Plans (QA/R-5)*. The QAPP is developed by CES management and is authorized by the contracting agency (e.g. an authorized EPA reviewer) unless written delegation of authority by the contracting agency exists. Environmental work addressed by the QAPP is not begun until approval by the contracting agency is granted. A proposed QAPP is reviewed and approved by CES's President and is sent to the agency auditor. Once approved, it is the responsibility

of the CES project manager that all personnel involved in the work will have copies of the approved QAPP documents.

The process for developing the QAPP includes:

1. Identify individuals and organizations participating in the project and discuss their roles, responsibilities, and organization.
2. Determination of problem to be solved. Identification of the decision makers and principal customers.
3. Develop hypothesis test, expected measurements, standards, assessment tools, work schedule, and required reports.
4. Determine population parameters of interest action levels, and acceptable limits on decisions.
5. Identify special training that personnel will need.
6. Itemize the information and records into a database package, including report format and requirements for storage.
7. Outline the experimental design, including sampling design and rationale, sampling frequencies, matrices, and measurement parameters of interest.
8. Develop sample analytical approach.
9. Determine provisions for sample labeling, shipment, chain-of-custody forms, procedures for transferring and maintaining custody of samples.
10. Identify analytical method(s) and equipment for the study, including method performance requirements.
11. Describe routine QC procedures that should be associated with each sampling and measurement technique.
12. Discuss how inspection and acceptance testing, including the use of QC samples must be performed to ensure their intended use.
13. Identify tools, gauges and instruments, and other sampling or measurement devices that need calibration. Describe how the calibration should be done.
14. Describe how and by whom the sampling supplies and other consumables will be accepted for use by the project.
15. Define the criteria for the use of non-measurement data such as data that comes from databases or literature.
16. Outline the data management scheme including the path and storage of the data and the data record-keeping system. Identify all data handling equipment and procedures that will be used to process, compile, and analyze the data.
17. Identify the assessment activities needed for the projet.
18. Identify the frequency, content and distribution of reports issued to keep management informed.

19. State the criteria used to accept or reject the data base on quality.
20. Describe the process to be used for validating and verifying data, including the chain-of-custody for data throughout the lifetime of the project.
21. Describe how results will be evaluated to determine performance criteria have been satisfied.

Revision to the QAPP follows the document control guidelines established in this QMP and, if significant, is subject to approval by the same authorities that performed the original review. Only after the revision has been approved and received by project personnel, shall the change be implemented.

All CES analytical results are obtained under the direction of the CES QAPP and QMP. When performing work relevant to the EPA, use of outside sources without EPA approved QAPPs is not allowed. Outside sources are required to obtain EPA approval or follow strict CES QAPP parameters after receiving EPA approval. CES will cross-check adequate sample numbers of the outside source to determine statistical equivalence.

8.0 IMPLEMENTATION OF WORK PROCESSES

CES management has responsibility for development and enforcement of analytical work plans. The planning for and implementation protocols of CES management and quality work processes is contained in section 7.0. Work is performed according to approved planning and technical documents as discussed in this section. During the work phase, modifications to plans and procedures shall be documented, and the modifications shall be incorporated into the final protocols and test/QA plans. The authors, reviewers, and approvers of changes to these documents are the same as for the original documents.

Routine, standardized, or special/critical operations require standard operating procedures (SOPs). Examples of processes include:

- Chain-of-custody sample and document control (SOP 001).
- Sample handling, labeling, tracking, and preservation (SOP 001).
- Laboratory XRF analytical processes and instrument operation (SOP 002).
- XRF Analytical results reporting and record keeping (SOP 002).
- QA/QC of XRF analytical processes (SOP 002).
- Quality System audits, revisions, and annual review (QMP and QAPP)
- Procurement and reimbursement (SOP 003)
- Performance Evaluations (SOP 004)

Procedures are developed to meet the CES mission of reliable, defensible data and are modeled after *EPA QA/G-6 Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality Related Documents*. CES project-specific work processes are planned, discussed and implemented through Quality Assurance Project Plans (QAPP) developed using *EPA/QA G-5, Guidance for Quality Assurance Project Plans*.

9.0 ASSESSMENT AND RESPONSE

Assessments are planned, scheduled, and conducted to measure the effectiveness of the implemented management and quality systems. Assessors shall be technically knowledgeable with no real or perceived conflict of interest. Assessors from within the organization must have no direct involvement or responsibility for the work being assessed, except for self-assessments.

A variety of tools are employed in assessing the quality system and analytical results (Table 2). Data assessments evaluate reported data quality. Management assessments evaluate the effectiveness of the management systems, performance and technical evaluations determine performance of the technical operations. All reports generated using assessment tools are evaluated by the President and QAM and retained as discussed in section 5.0.

The QAM has responsibility for implementing data quality assessments and audits. Management and technical reviews are initiated by the President and carried out by CES management annually. If the QAM or external auditors identify a severe quality problems or a situation where the health and safety of personnel are in danger, they have the responsibility to bring it to the immediate attention of appropriate CES management. The QAM has the authority to halt work until the identified problem is resolved.

Peer review and external auditors are organizationally independent of the analytical program that they are auditing. CES management determines and documents the level of competence, experience, and training of the audit personnel during hiring and periodic performance reviews. Auditors have access to the appropriate management personnel and documents relevant to the audit. They have the responsibility and authority to:

- Identify and document problems that affect quality of analytical results
- Propose recommendations for resolving problems that affect quality of analytical work processes or results.
- Independently confirm implementation and effectiveness of solutions.

Problems identified during the assessment process are followed-up in a timely manner with a written action plan from management. Upon completion of the action plan , follow-up assessments by CES management shall be made to ensure that the response was effective. Significant revisions to quality related documents are documented and reviewed by all affected personnel as part of the training process.

When the recommendations and conclusions from the findings of assessment are adverse, response from the auditee detailing the corrective action shall be expected within 10 working days of receiving the audit report. Auditors shall follow up with appropriate documentation to confirm the implementation and effectiveness of the response. The President has final authority on all responses to audits and assessments.

TABLE 2. Assessment Tools and Criteria

Assessment Tool	Assessors	Document Reference	Reason for Assessment	Minimum Frequency
Data Quality Assessments	QAM, Lab Technicians	Lab SOPs and QAPP	Assess instrument accuracy and precision.	QC tests equal to 10% of samples.
Audits of Data Quality	QAM	Lab SOPs and QAPP	Assess data calculations and reporting.	QA on 10% of analytical data.
Management System Review	President, QAM	QMP	Assess quality management practices.	Annual
Technical Systems Audit	President, QAM	QMP	Assess quality of technical verification tests.	Annual
Performance Evaluations	President, QAM, self	Management SOPs, QAPP	Assess measurements performance	Annual
Peer Reviews	Contracted or independent org.	QMP	Assess technical performance, methodology.	Variable

10.0 QUALITY IMPROVEMENT

The President and QAM are responsible for identifying, planning, implementing, and evaluating the effectiveness of all quality improvement activities associated with sample handling practices, calibration, data collection and storage, statistical analyses, quality control criteria, data interpretation, and report generation. Assessments of activities will be conducted through audits, performance evaluations, peer reviews, and technical reviews. If necessary, the QAM will develop a corrective action program in a timely manner to ensure that adverse quality conditions are promptly identified and corrected. The QAM has the responsibility for communicating the assessment process and any corrective action program to the CES President and Contract Managers. Areas of evaluation for the QAM include:

- Adequacy of the CES quality system.
- Consistency of the quality system.
- Implementation of the quality system.
- Correction of quality system procedures.
- Completeness of documented information.
- Quality of data.

- Quality of planning documents.
- Implementation of the work process.

A corrective action plan shall include:

- Identification of root causes of the problem.
- Determination of the impact of the problem and its implications.
- A recommendation for procedures to prevent recurrence and manage any potential retroactive problems.

All staff members must seek out ways for improved quality analysis in order for CES to remain competitive. As such, CES encourages staff to identify and establish communications among customers and suppliers, identify process improvement opportunities, identify problems, and offer solutions to those problems. In addition to the annual Quality System review, CES encourages proactive improvement efforts through job review criteria, attendance at conferences, reimbursement for professional classes, and membership in professional associations.

11.0 GOOD AUTOMATED LABORATORY PRACTICES

11.1 Introduction

Cooper Environmental Services' (CES) mission is to produce reliable, legally defensible analytical data. Defensible data requires careful management of Laboratory Information Management Systems (LIMS) to ensure data accuracy and integrity. To this end, CES relies upon a series of Good Automated Laboratory Practices (GALP) to manage LIMS which have potential system security and verification issues. CES' GALP program has been developed in accordance with *EPA 2185: Good Automated Laboratory Practices*.

11.2 CES Analytical Processes Subject to GALP

X-ray fluorescence (XRF) analyzers produce count rates which are proportional to the concentration of elements on a filter. CES uses a Spectrace QuanX analyzer for all XRF analysis. This analyzer's output is manipulated on a personal computer by the technician to account for standards calibration, absorption corrections, and interferences. As such, CES' XRF analysis program is subject to the GALP program.

11.3 GALP Components

Laboratory Management

CES management, which includes the President and Quality Assurance Manager (QAM), is responsible for laboratory administration as outlined in the CES Quality Management Plan. As part of the GALP, management is responsible for:

1. Ensuring that all personnel clearly understand the functions that they are to perform on the LIMS. Specifically, laboratory technicians are thoroughly versed in the Chain-of-Custody, XRF, Procurement, and Performance Evaluation SOPs.

2. Ensuring that personnel, resources, and facilities are adequate and available as scheduled, and have a current summary of their training, experience, and job description maintained at the facility.
3. Developing and approving SOPs that ensure LIMS raw data integrity and prompt corrective actions in response to GALP deficiencies.
4. Ensuring that a Quality Assurance Unit (QAU) monitors LIMS activities. The default QAU is the Quality Assurance Manager (QAM) unless a real or apparent conflict with LIMS is present. If a conflict exists, the President shall designate another individual as the QAU. The QAU has access to the most recent XRF and LIMS Standard Operating Procedures (SOPs) and technical documentation. QAU responsibilities include:
 - Verifying electronically stored SOPs.
 - Inspect LIMS at intervals adequate to ensure system integrity. Inspection shall occur after any significant change to software or hardware.
 - Prepare inspection reports for CES management which include any problems that may affect data quality.
 - Determination that no deviations from approved SOPs are occurring without proper documentation and authorization.
 - Periodically audit the LIMS raw data to ensure its integrity.
 - Maintaining records of QAU responsibilities and procedures.

LIMS Raw Data

CES management is responsible for maintaining the integrity of the raw data. Specifically, the XRF SOP requires storage of all raw data in the "LIMS Raw Data" folder on the hard drive. This folder is backed-up onto an Iomega Zip Disk or Seagate Tape Drive to ensure data integrity. Frequency of backup is dependent upon the sensitivity of the data. Raw data is periodically reviewed, as outlined in the QMP and XRF SOP, by examining spectra, calibration results, and QA/QC checks. The raw data, which is a text file, is given a unique name which includes the project number, initials of the individual responsible for recording the data, and date of analysis (DDMMYY). For example, testing conducted for project 12345 by John Aaron Doe on Dec 1, 1999 would be labeled 12345JAD011299.txt.

Software

The QuanX analyzer uses a DOS based operating system for 1) procedural set-up and 2) reading of count rate intensity. Although procedures (e.g. exposure times and wattage) vary according to client needs and SOPs, modifications are not made to the count rate using the DOS program. Knowledge of which procedures were used in determining count rates is critical to accurate analysis. For this reason, procedures used during analysis are recorded in the hard copy *XRF Operations Journal*. Changes to the raw data are discussed in the XRF SOP and are carried out using prepared, standard MS Excel spreadsheets which automatically incorporate sensitivity factors, correction for

absorption, and background subtraction. The original data and subsequent calculations are shown in the spreadsheets making for easy verification with original raw data. Entries in the *XRF Operations Journal* are kept of individuals who performed changes to the raw data or standard spreadsheets, and any variance from SOP protocols.

Any change to the DOS based operating system in determining count rate intensity requires approval of the CES management and revision of the SOP. Changes in the Excel Spreadsheets also require CES management approval and are listed in the revision history for the MS Excel spreadsheet. Significant revisions will result in a new version number. The revision history includes software version numbers and changes to software. Version control is regulated as discussed in CES' QMP.

Data output from the excel spreadsheet is typically in mass per unit area (e.g. ng/cm²) and is recorded in a MS Access data base along with the chain-of-custody and sample information. A hard copy print out of the mass per unit area which includes sample number and operator is made for each sample and kept on file at CES. The MS Access data base is backed-up periodically onto an external drive. Back-up frequency is dependent on the quantity and sensitivity of new information.

Security

CES management has enacted security safeguards to ensure the integrity, availability, and confidentiality of the LIMS data. The QAM is responsible for maintaining data integrity and security. CES safeguards include:

- Password protection access using MS Windows 95 password system.
- Data verification checks for manual data entry.
- Uninterruptable power supply for the computer. (APC Back-UPS Pro 650)
- Surge protector.
- Stand-alone XRF personal computer (isolation from Intra- and Internet).
- Required document control procedures as outlined in the QMP.
- Routine back-up of data onto Iomega Zip Disks or Seagate Tape Drives. The back-up data is also subject to document control procedures and are stored in safe, dry remote locations. Back-up occurs at least once a week.
- Security awareness training and performance evaluations of employee adherence to security protocols.
- Use of Norton utilities to ensure no viruses are in the computer

Hardware

Descriptions of the XRF analyzer can be found in the XRF SOP and Spectrace Operating Manual. The QuanX has been installed in accordance with manufacturer's recommendations and is tested for acceptance criteria as outlined in the XRF SOP. A

maintenance journal is kept to document routine and non-routine maintenance actions and the acceptance testing results following repair.

11.4 *Quality Systems*

The GALP is an integral part of CES Quality System. For this reason, the CES QMP requires annual audits which include software and hardware checks and testing as well as evaluations of the GALP practices. Quality Improvement in the GALP is encouraged through performance evaluations and feedback from CES employees.