Section 508 Compliant ☑ Yes ☐ No

Quality Assurance Guidance Document

Revision 1.7

Quality Management Plan

Prepared for:

U.S. Environmental Protection Agency
Office of Air Quality Planning and Standards
Research Triangle Park, NC 27711

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Prepared by:

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TITLE AND APPROVAL SHEET

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DOCUMENT HISTORY

Revision	Release Date	Initials	Section/s Modified	Brief Description of Modifications
1.4	08/31/2021	SRS	All	Annual maintenance updates
1.5	2/28/2023	ML	All	Split file into content and title pages for CSN and IMPROVE projects. Updated QMP content to account for major projects (IMPROVE, CSN) as well as special projects. Refined language regarding how AQRC works with various partners and subcontractors. Quality Documents (QD) created as new document category. Annual updates including personnel and org chart, equipment updates, document control policy, quality system assessment, and quality improvement Document History added.
1.6	4/21/2023	ML	All	New contract award updates. Includes RTI information as CSN subcontractor for sample handling and gravimetric mass measurements. Program management roles and responsibilities updates.
1.7	05/31/2023	ML	Cover Page; Section 3	Updated contract number. Figure 3 simplified.

LIST OF ACRONYMS AND ABBREVIATIONS

AQMT	Air Quality Monitoring Team of AQRC
AQRC	Air Quality Research Center
AQS	Air Quality System database
AS	Analytical Sciences
DRI	Desert Research Institute
EPA	U.S. Environmental Protection Agency
FT-IR	Fourier Transform Infrared Spectroscopy
HIPS	Hybrid Integrating Plate/Sphere
ICP-MS	Inductively Coupled Plasma-Mass Spectrometry
IMPROVE	Interagency Monitoring of Protected Visual Environments
NESCAUM	Northeast States for Coordinated Air Use Management
NPS	National Park Service
OAQPS	EPA Office of Air Quality Planning and Standards
PE	Performance Evaluation
PI	Principal Investigator
$PM_{2.5}$	Particulate matter less than 2.5 microns in diameter
PM_{10}	Particulate matter less than 10 microns in diameter
PO	Project Officer
PTFE	Polytetrafluoroethylene
QA	Quality Assurance
QAPP	Quality Assurance Project Plan
QC	Quality Control
QD	Quality Document
QMP	Quality Management Plan
RTI	Research Tringle Institute International
SOP	Standard Operating Procedure
SQL	Structured Query Language
TI	Technical Information
TOA	Thermal/Optical Analysis
TSA	Technical System Audit
XRF	X-ray Fluorescence

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2. PROGRAM MANAGEMENT

The purpose of this section is to document the overall quality assurance policy, scope, applicability, and management responsibilities associated with the analytical laboratory (Air Quality Monitoring Team; AQMT) at the Air Quality Research Center (AQRC) as part of the University of California, Davis. This section describes the laboratory, organization, and management as it relates to quality assurance.

For the IMPROVE project, AQRC performs all analysis per the sponsor contract (with National Parks Service) including filter handling, gravimetric analysis, X-ray fluorescence (XRF) and Hybrid Integrating Plate/Sphere (HIPS) analysis. Other partners have contracted directly with NPS to perform other analysis and deliver data to AQRC.

For the CSN project, AQRC performs XRF, HIPS and Thermal/Optical Analysis (TOA) analysis and has subcontracted with Research Triangle Institute (RTI) for filter handling, IC, ICP-MS and gravimetric analysis. In CSN, AQRC is the prime contractor to the project sponsor.

2.1 Introduction

AQRC operates an analytical laboratory designed for the analysis of environmental samples. The laboratory conducts the following chemical and physical measurements:

- X-ray fluorescence (XRF) analysis for identifying and quantifying the elemental composition of samples. AQRC operates several analyzers to process thousands of samples every month.
- Gravimetric mass measurements to quantify the mass of samples. Mettler XPR-6UD5 microbalances are used for these measurements. The microbalances are inside environmentally-controlled automated weighing chambers.
- Hybrid Integrating Plate/Sphere (HIPS) analysis to measure light absorption ambient samples at specific frequencies.
- Thermal/Optical Analysis (TOA) to measure operationally-defined organic and elemental carbon fractions in ambient samples.
- Fourier-Transform Infrared Spectroscopy (FT-IR) probes chemical bonds and is currently being researched to estimate parameters such as OC and EC.

RTI's analytical laboratory conducts the following physical measurements:

- Ion Chromatography (IC) analysis for identifying and quantifying the ion composition of desorbed samples. IC analysis is accomplished using Thermo ICS3000, ICS6000 and Aquion ion chromatography instruments.
- Inductively Coupled Plasma Mass Spectrometry (ICP-MS) analysis for identifying and quantifying the elemental composition of samples. ICP-MS analysis is accomplished using Thermo Element 2 analyzers.
- Gravimetric mass measurements to quantify the mass of samples. A Mettler-Toledo XPR2 microbalance connected to an MTL autosampler is used for these measurements.

Most of the analytical laboratory measurements conducted in AQRC are performed in support of two federally-funded studies: 1) The Interagency Monitoring of Protected Visual Environments (IMPROVE) program is designed to measure the concentration and composition of fine particles in remote areas to document long-term trends. The resulting data support visibility data analysis under the Federal Regional Haze Rule. 2) The Chemical Speciation Network (CSN) performs similar fine particulate measurements but the monitoring sites are located in urban areas and the focus is on providing data to support the understanding of the effects of air pollution on human health.

Separate supporting quality assurance and quality control documentation, such as Standard Operating Procedures (SOPs) and Technical Information (TI) have been developed for IMPROVE and for CSN. There are, however, many similarities between the networks since many of the same analytical methods and data handling practices are employed. IMPROVE and CSN both have a separate Quality Assurance Project Plans (QAPP) that define the SOPs and TIs used.

AQRC has the experience, expertise, and equipment to perform many kinds of analysis. However, there are some parameters or processes we do not have the ability to perform in-house. AQRC works with other laboratories as necessary to complete the overall projects. The relationship can take the form of a subcontractor, partner, or coordinating data deliveries of each lab. In some cases, the other laboratories have contracted with EPA/NPS directly who provide oversight. In this case, AQRC makes sure the relationship meets all requirements of the project on an approved QAPP or other document. When AQRC chooses the lab as a subcontractor, their quality documents and policies are reviewed for compliance to the project before approval. The labs stay in regular communication and AQRC will visit the sites periodically. The results of audits within project scope are shared or an audit may be performed if necessary.

2.1.1 IMPROVE

AQRC's work in support of IMPROVE is performed with funding from a contract with the National Park Service (NPS). NPS obtains the funding to support this contract from a number of government agencies, including the U.S. Environmental Protection Agency (EPA), U.S. Forest Service, and the U.S. Fish and Wildlife Service. AQRC has operated the IMPROVE fine particle measurements program under successive contracts since 1988.

Fine particle monitoring in the IMPROVE Program is achieved using the IMPROVE aerosol sampler. The standard IMPROVE sampler has four sampling modules, designed to obtain a complete signature of the composition of the airborne particles that affect visibility. Modules 1A (polytetrafluoroethylene or PTFE), 2B (nylon), and 3C (quartz) collect fine particles smaller than 2.5 µm in aerodynamic diameter ($PM_{2.5}$). Module 4D (PTFE) collects particulate matter less than 10 microns in diameter (PM_{10}). Module A provides most of the fine particle data; analysis for $PM_{2.5}$ mass, elements from XRF, and the coefficient of optical absorption from the HIPS measurement are all performed at

AQRC. Module 2B, with a denuder before the filter to remove acidic gases, is used for ion analysis, conducted at Research Triangle Institute (RTI; Research Triangle Park, NC); this work is performed on a separate contract between NPS and RTI. Module 3C measures carbon in eight temperature fractions through a thermal optical analysis method conducted at the Desert Research Institute (DRI; Reno, NV); this work is performed on a separate contract between NPS and DRI. Approximately 20,000 filters are collected each year in each of the four modules. AQRC assembles the final ambient concentration data set for all analyses, performs data validation, and delivers the final results to the Federal Land Manager Environment Database (FED), EPA's Air Quality System (AQS) database, and the UC Davis CSN/IMPROVE Archive (CIA) database. The final results are delivered via email attachment to National Park Service personnel to submit to the FED and uploaded to the AQS and CIA databases.

2.1.2 CSN

AQRC supports the CSN with funding from a contract with the U.S. EPA. Samples are prepared by RTI and are collected in the field by local agency personnel. $PM_{2.5}$ PTFE and nylon filter samples are collected using the MetOne SASS or SuperSASS sampler, and quartz filter samples are collected using the URG 3000N sampler. The Quartz filters are pre-fired by RTI and analyzed for contaminates by AQRC. Approximately 13,000 filters of each type are collected each year. At AQRC, PTFE filters are analyzed by XRF for elements and quartz filter samples are analyzed by TOA for carbon. As a subcontractor to UCD AQRC, RTI analyzes nylon filter samples for ions using ion chromatography. AQRC assembles the final ambient concentration data set for all analyses, performs data validation, and delivers the final results to the EPA's Air Quality System (AQS) database, the Federal Land Manager Environment Database (FED), and UC Davis CSN/IMPROVE Archive (CIA) database. The final results are uploaded to the AQS and CIA databases and delivered via email attachment to National Park Service personnel to submit to the FED.

2.1.3 Special Projects

AQRC supports a number of projects smaller than IMPROVE and CSN. Often these are a specific study over a shorter period of time. Each project will have its own set of quality documents as required by the project. If required, this QMP document can be edited with the contract and sponsor information on the cover pages. On some occasions, SOPs, TIs, forms, and other documents written for other projects may be shared with special projects as the methods, equipment, and procedures are the same.

2.2 Quality Assurance Policy

The quality assurance mission of the AQRC can be summarized as follows:

- Achieve the highest data capture possible.

- Use generally accepted best practices in science, engineering, technology, and data management.
- Quantify and understand the quality of our data. Be vigilant, introspective, and questioning. Confront problems with clarity and intellectual openness.
- Be transparent in the communication of our knowledge of our measurements. Provide data users with the information they need to conduct unbiased analyses.

The overall policy of the laboratory is intended to support this mission. AQRC staff work closely to implement the highest level of Quality Management Practices with quality assurance and quality control (QA/QC) measures. The quality policy of the laboratory is to maintain a consistent level of Quality Management to provide the most accurate, precise, and representative data available.

2.3 Roles and Responsibilities

2.3.1 AQRC Personnel

The AQRC organizational chart is shown in Figure 1. Descriptions are provided here for the AQRC management and quality assurance team.

Dr. Anthony Wexler is Director of AQRC. He is responsible for directing and implementing University and program specific policies at AQRC. Dr. Wexler holds ultimate responsibility for the financial and safety performance of AQRC.

Management and oversight of all operations at AQRC is shared by the associate directors, Dr. Ann Dillner, Dr. Nicole Hyslop, and Mr. Sean Raffuse.

Dr. Dillner, the Associate Director of Analytical Research, oversees laboratory operations and research.

Dr. Hyslop, the Associate Director of Quality Research, oversees two main groups. First is the quality assurance and special projects group. Second is field operations for the IMPROVE network.

The quality assurance and special projects group handles many of the non-routine data collection responsibilities. Whereas the lab group analyzes routine samples and records the data, Dr. Hyslop's group performs oversight and supporting functions. The quality assurance responsibilities include reviewing data, Standard Operating Procedures (SOPs), Techinical Information (TIs), continuous improvement support, reporting issues, and addressing them through quality documents such as nonconformance reports, corrective action reports, and investigations. The Quality Manager for AQRC is part of this group and leads the effort. More details found later in this document.

The special projects responsibilities include troubleshooting issues in coordination with the lab and quality oversight, investigating new methods, new equipment, and performing smaller experiments or contracted work much smaller in scope than our main contracts for CSN and IMPROVE.

Mr. Raffuse, the Associate Director of Software and Data, oversees data management and software infrastructure.

In addition to organizational responsibilities, the associate directors have management and principal investigator responsibilities for specific projects. Dr. Hyslop serves as principal investigator for the IMPROVE program at AQRC, and is the highest management level for IMPROVE. Mr. Raffuse serves as principal investigator/program manager for the CSN program at AQRC and is the highest management level for CSN. Dr. Dillner serves as principal investigator for the Cooperative Ecosystem Studies Units (CESU) Network grant. For each project, the principal investigator is responsible for financial oversight, program deliverables, and problem resolution.

The laboratory manager is Dr. Jason Giacomo. Under the direction of Dr. Dillner, he is responsible for day-to-day operation of the AQRC Laboratory Group, including setting priorities and schedules for the laboratory staff, providing guidance to staff in solving problems, directing calibrations and instrument maintenance, reviewing and assessing data quality, and approving the release of data to the Data & Reporting Group for validation.

Dr. Giacomo is assisted by several laboratory staff:

- Two Spectroscopists oversee the technical details associated with analytical analyses and laboratory quality assurance. They are responsible for reviewing calibrations, reviewing quality control test data, reviewing raw data, devising analysis protocols to meet study objectives, and diagnosing instrument problems and recommending solutions.
- Additional laboratory technicians oversee the operation of the sample handling and gravimetric weighing laboratory. They are responsible for the sample receiving, shipping, and labeling of IMPROVE samples. They are also responsible for the operation and maintenance of the gravimetric balances.
- Additional laboratory technicians operate the XRF, TOA, FT-IR and HIPS instruments. They are responsible for routine sample analysis, maintaining analysis records, processing data, performing quality control tests, preparation of standard solutions and performing routine instrument maintenance such as liquid nitrogen fills and automated detector calibrations.

The AQRC Software & Analysis Group Manager is Ms. Xiaoya Cheng. Under the direction of Mr. Raffuse, she oversees development of the SQL database and software for laboratory operations, validation, and data analysis. The AQRC Software & Analysis Group Manager oversees technical staff who share responsibilities for database management and programming. Responsibilities include:

1. Maintaining and upgrading the data management system (see Section 3.2.3) including the SQL Server database, data processing and visualization tools, and data reporting and data input forms;
2. Working with staff to identify, map, design, and implement improvements to the data management system;
3. Testing, verifying, and documenting modifications to the system;

4. Importing and processing new data and associated metadata into the database system;
5. Designing and maintaining an archival system for all data and metadata records and source files.

The Data & Reporting Group Manager role is being filled by Mr. Raffuse. He oversees data validation and delivery operations, including technical staff responsible for data validation and submission. Responsibilities include:

1. Coordinating project deliverables and documentation including tracking and coordinating tasks across multiple internal groups and external agencies to meet program deadlines;
2. Preparing and editing various project-related documents including contributing sections to the quality assurance reports, monthly reports, technical reports, and proposals;
3. Ensuring data validation documentation are maintained including designing, developing and implementing standard operating procedures for routine data processing, validation, and delivery;
4. Developing and maintaining internal and external communications with funding agencies and state validators;
5. Evaluating data characteristics and problems and guiding discussions regarding data validation practices and treatment of questionable data; and
6. Refining and developing tools necessary for effective data validation.

Mr. Raffuse supervises technical staff who:

1. Review the components of the measurements (flow rates, elemental concentration, etc.) in preparation for final data validation;
2. Work with laboratory staff to resolve problems or discrepancies encountered during data review;
3. Validate the final data set, with input as needed from data analysts;
4. Submit the CSN data set to the DART system for SLT review;
5. Communicate with SLT data validators to resolve discrepancies in the CSN data;
6. Format the data to meet AQS and FED standards; and
7. Submit the final data sets to AQS (CSN and IMPROVE) and FED (IMPROVE).

Mr. Harold Brunette is the AQRC Program Manager. As Program Manager, his responsibilities include:

1. Preparing reports and program deliverables for sponsors, with input from other project staff;
2. Preparing and editing various project-related documents such as position descriptions, technical reports, and meeting summaries;
3. Assisting in the editing of the SOPs, QAPP, and QMP;
4. Financial tracking, including preparation of budgets and submitting monthly budget summaries to the Principal Investigator;

5. Tracking the number of samples analyzed under each Delivery Order as input to the monthly invoices;
6. Coordinating subcontract activities for ion analysis with RTI;
7. Coordinating the purchasing of supplies and equipment;
8. Coordinating the recruitment and hiring of new staff, as needed; and
9. Scheduling and tracking the flow of data from the laboratories through DART and on to final submittal to ensure that schedules for each monthly submittal are met.

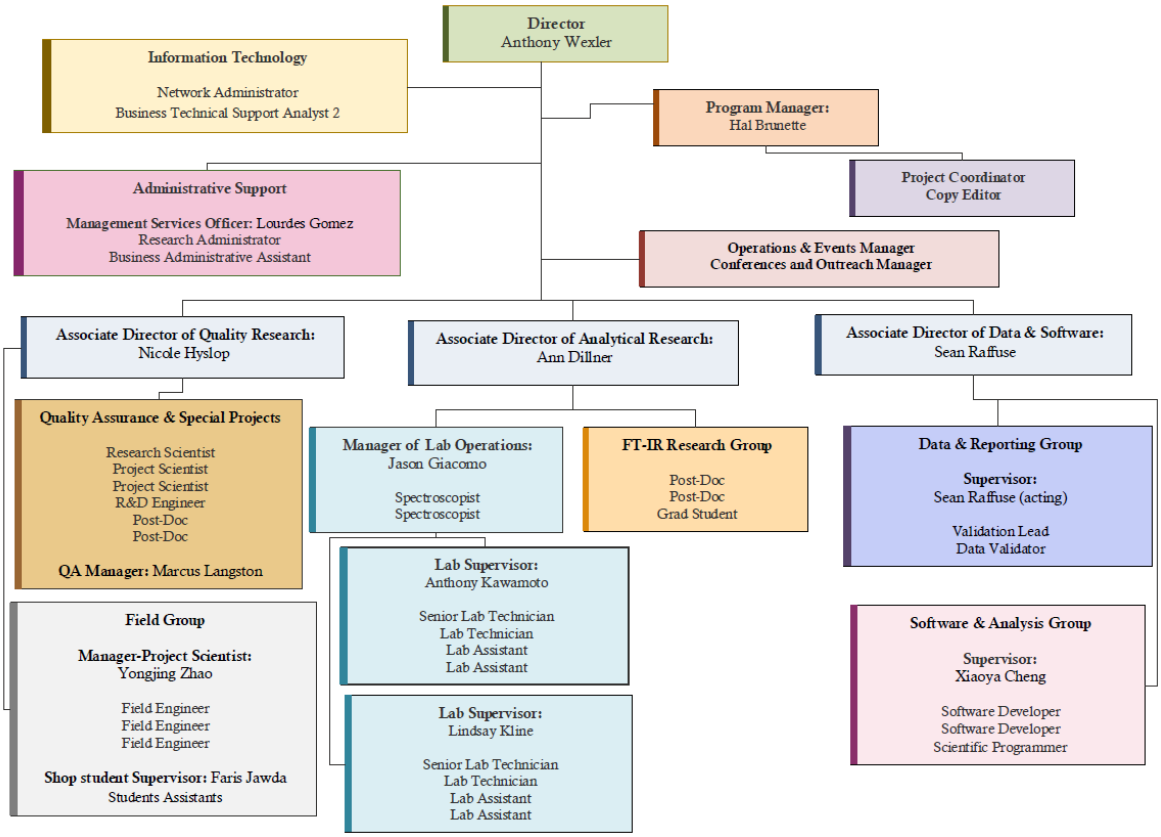
The AQRC QA Manager monitors quality assurance/quality control (QA/QC), and in this role, Marcus Langston is part of the Quality Assurance and Special Projects Group, reporting to the AQRC Associate Director of Quality Research, Dr. Hyslop.

For any project, such as CSN and IMPROVE, the AQRC QA Manager can report problems to AQRC's highest level of management, regardless of the project structure. The QA Manager is independent of all data collection, and has the authority to report any findings or concerns directly to each project PI and the AQRC director.
In practice, the AQRC QA Manager will work closely with the Principal Investigator and other managers with the expectation that most problems can be solved without involvement from the AQRC Director.

Responsibilities include:

1. Reviewing the efforts of other AQRC staff to investigate problems identified during data review and to recommend corrective actions;
2. Reviewing control charts and other data quality reports to assess the achievement of Measurement Quality Objectives (MQOs);
3. Performing periodic in-lab and data review audits of data quality;
4. Conducting periodic reviews of the SOPs, TIs, QAPP, and QMP for both AQRC and subcontractors;
5. Hosting external auditors;
6. Distributing sponsor-provided Performance Evaluation (PE) samples within AQRC and summarizing PE analysis results.

Figure 1. AQRC laboratory organizational chart. Structure as it pertains to roles and responsibilities discussed in Section 2.3.



2.3.2 RTI Personnel

The RTI organizational chart is shown in Figure 2. Descriptions are provided here for the RTI management and quality assurance team.

Dr. Keith Levine is Senior Director for the Center for Analytical Sciences (AS) at RTI. He is responsible for directing and implementing the center level program specific policies at RTI. Dr. Levine holds ultimate responsibility for the financial and safety performance for AS at RTI.

Mr. Eric Poitras will serve as the RTI Program Manager for the SHAL/GRAV Operations (and will be the SHAL Laboratory Manager). For the CSN program, Mr. Poitras is responsible for the day-to-day operations at RTI and for technical and contractual communications with the client, financial oversight, staff management, program deliverables, and problem resolution.

Ms. Tracy Dombek will serve as the RTI Program Manager for the Analytical Operations

and IC laboratory manager for the CSN program. She is responsible for the overall performance of RTI on the analytical operations and for technical and contractual communications with the client. Ms. Dombek will be responsible for all deliverables for analytical operations and providing documentation for data issues and corrective actions.

Ms. Dombek assigns task management roles and is ultimately responsible for ensuring that only fully qualified and trained staff members perform work under this contract. She will work closely with Ms. Andrea McWilliams, to ensure implementation of the quality system, ensure that necessary resources are available for performing the required analyses, and ensure that effective corrective actions are taken when required.

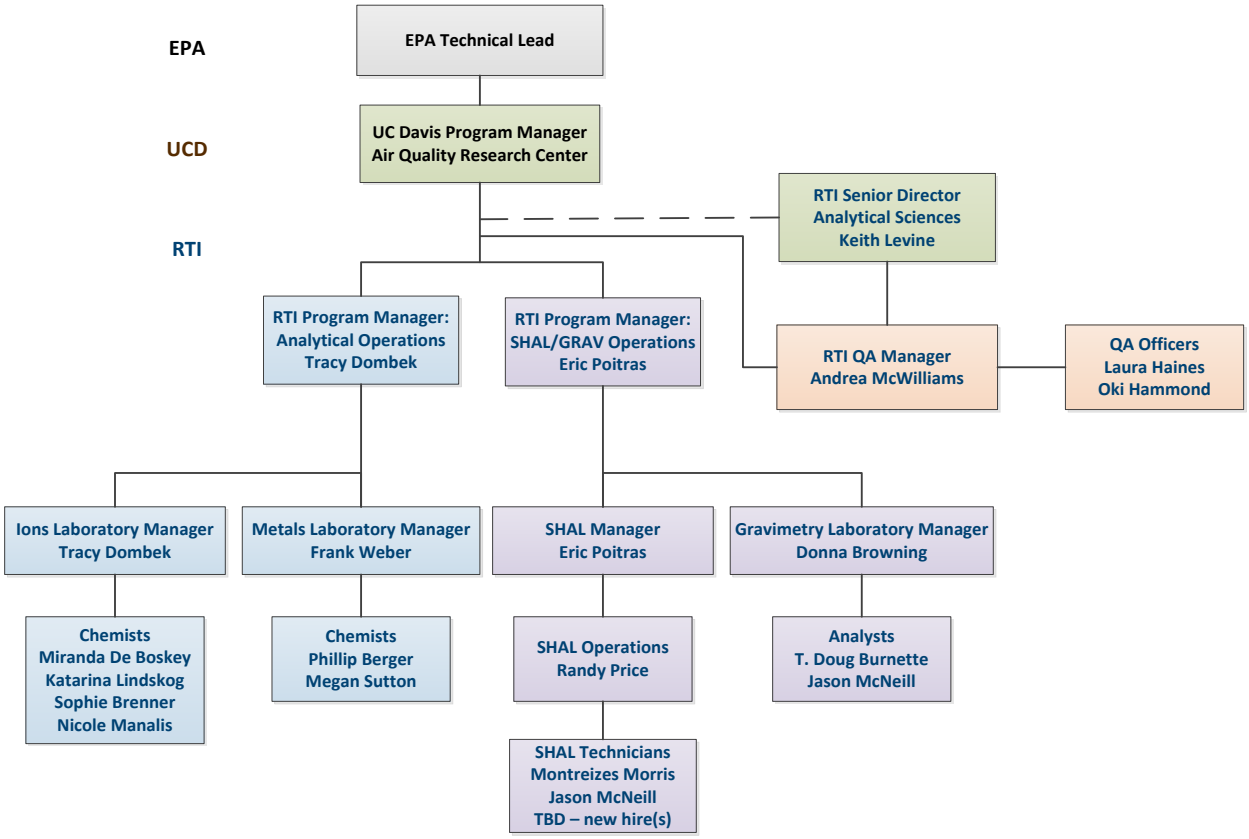
Ms. Andrea McWilliams will serve as the Quality Assurance Manager for RTI for both programs. Ms. McWilliams reports directly to Dr. Levine allowing her to report any issues to RTI's highest management level for independent oversight on the programs. Ms. McWilliams will work closely with Mr. Poitras and Ms. Dombek to ensure data quality objectives are met. She will oversee review of data and tracking and control of quality documents (e.g., SOP's and QAPP). She will also perform in-lab audits and host external auditors as needed.

RTI will utilize four Laboratory Managers for the CSN program. They are Ms. Tracy Dombek
(ions), Mr. Eric Poitras (shipping and handling), Mr. Frank Weber (metals), and Ms. Donna
Browning (gravimetry). Laboratory managers will be responsible for ensuring staff are properly
trained and utilized on the program, reviewing data and trend charts, submitting data following
QA approval, maintaining instrumentation, writing and editing SOP's, and communicating issues with project management.

QA Manager Independence and Authority on Data Quality.

Overall, the RTI QA Manager and QA Officers will have appropriate access to management support, while also maintaining independence and authority with respect to decisions on data quality. The QA staff have final review of the data to ensure quality and approve the data for
reporting. If data usability issues arise (e.g., deviations from SOPs or data quality objectives not met), the QA staff will communicate to appropriate management staff and administer corrective actions, if necessary. The QA staff have the authority to stop work, with full support from management, if data quality issues cannot be met.

Figure 2. RTI laboratory organizational chart. Structure as it pertains to roles and responsibilities discussed in Section 4.3.



2.3.3 Prime and Subcontractor Responsibilities

For CSN, the prime contractor is AQRC and maintains ultimate responsibility for data validation decisions and reporting final data to project sponsors.

For the CSN project, RTI will deliver required data for filter handling and gravimetric mass to AQRC. The data will then be integrated with lab and other data, processed, validated, and reported by AQRC to required EPA databases.

2.4 External Quality Assurance

Through its participation in IMPROVE and CSN, the AQRC is audited by the U.S. EPA OAQPS or by an assigned audit contractor. As a subcontractor to AQRC, RTI will participate in audits as requested for CSN.

3. QUALITY SYSTEM DESCRIPTION

A quality system is defined as a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities,

accountability, and implementation 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. This section will describe the principal components and implementation of the quality system.

3.1 Description of the Analytical Laboratory

The analytical laboratories at the AQRC include:

- The XRF Laboratory contains five XRF instruments, used for quantification of the elemental composition of samples.
- The Sample Handling Laboratory contains two Mettler XPR-6UD5 microbalances and two environmentally-controlled weighing chambers, used for weighing filters both before and after sampling.
- The Light Absorption Laboratory contains systems that were custom designed and built at AQRC to measure filter-based particle absorption.
- The TOA Laboratory contains six Thermal/Optical OC/EC analyzers, used for measuring carbon fractions on quartz filters.
- The FT-IR laboratory contains three analyzers to measure the carbonaceous composition of aerosol collected on Teflon filters. This is currently under investigation for potential use in the networks.

Additionally, the AQRC has unique expertise in the preparation of standard reference materials used for the calibration of the XRF and FT-IR analyzers. An aerosol generation chamber designed and built at AQRC are used for preparing standards on the same filter media as ambient samples and in the same concentration range as typical ambient samples.

The analytical laboratories at the RTI include:

- The Ions Laboratory will utilize three ICS3000, one Thermo ICS6000, and four Thermo Aquion instruments to measure ions in nylon filter extracts. The Gravimetry Laboratory contains a Mettler-Toledo XPR2 microbalance connected to an MTL autosampler unit. The microbalance and autosampler unit are in a temperature- and humidity-controlled chamber.
- The Metals Laboratory contains one Thermo SF Element 2 ICP-MS and two Thermo Q/RQ ICP-MS instruments, used to quantify the elemental composition of digested samples.
- The Shipping, Handling, and Archiving Laboratory encompasses more than 1,400 square feet of HEPA filtered space for processing filter shipments.

3.2 Quality Assurance System

3.2.1 Laboratory-Based QA/QC

Technical staff in the laboratory review quality control test data on a daily basis to monitor instrument performance. Tests include reviewing calibrations and calibration checks, reviewing XRF spectra, reviewing TOA thermograms, assessing performance against routine quality control criteria, and maintaining analysis records.

3.2.2 Data Validation

Data undergo validation checks by the Data & Reporting Group technical staff who function independently of the routine laboratory operations. Data validation is performed in batches of one to three months of processed data. The analytical data are processed to ambient concentrations; as such, they are not raw analytical data and can reveal abnormalities that might only be apparent in the final processed data. Some validation checks involve cross-comparisons from independent measurements, such as comparing sulfur measured by XRF to sulfate measured by ion chromatography.

During the data validation process the data analysts have the authority to request reanalysis of suspect samples. The proportion of samples requiring reanalysis is typically small, less than one percent of the total, but can inform problem resolution during data validation.

RTI performs data validation activities for data generated in the analytical laboratories supporting the IMPROVE and CSN programs with a similar approach to AQRC. Prior to submission of analytical data to AQRC, the data is validated by reviewing chromatograms, quality control sample data, calibration data and comparing these data against the measurement quality objectives (MQOs). Acceptable MQOs in these QC checks allow the analysis data to be validated and assure the upmost confidence in the data being reported. Suspect samples identified during the review process will be investigated and reanalyze, if necessary.

3.2.3 Management Review

Data processing and validation are discussed in weekly meetings with the Data & Reporting Group Manager. The data analysts present any major problems that were found during data validation and explain how the problems were resolved or, alternatively, why the data were declared invalid. Data are released only after all identified issues have been resolved. Sufficient supporting evidence is required to invalidate any data. In the event that data are questionable and evidence is insufficient to support invalidation, the data are handled differently in the two networks because of the different data pathways and availability of flags. In CSN, these data are reported to the Data Analysis and Reporting Tool (DART, hosted by STI) as valid with comments and a flag to indicate further review by State, Local, and Tribal validators. The validators may take further action on the data in DART but if the data are left valid, the flag applied to highlight additional review is removed prior to final delivery to AQS, FED, and CIA. Comments are not included in the delivered datasets. In IMPROVE, these data are reported as valid to FED, AQS, and CIA, typically without any qualifying flags because the available flags/statuses available in

FED is very limited. Comments are added to the data but these are not included in the delivered datasets.

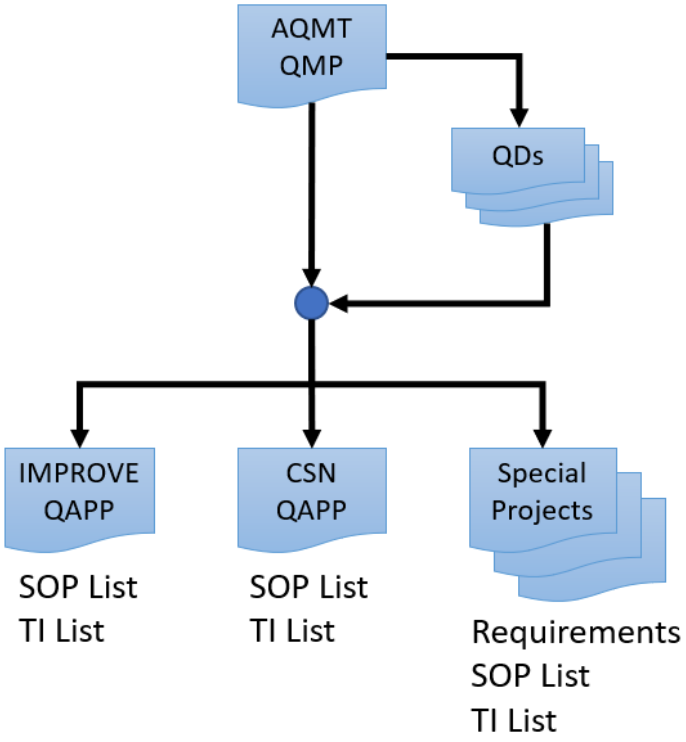
RTI conducts management system reviews on an annual basis to evaluate whether the management system is performing as intended for the program. The reviews are designed to evaluate the RTI laboratory and to ensure that all project staff are following the appropriate policies and procedures and that the laboratory is meeting the requirements of the program. The Laboratory Director, Laboratory Manager(s), QA Manager, and Program Manager will schedule a meeting to review the quality system and the laboratory's testing and calibration activities to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements in the quality system and laboratory operations. The review will also consider the outcome of recent internal audits, performance audits, any changes in the volume and type of work conducted, feedback from AQRC, corrective actions, and other relevant factors. The results from this meeting will be documented, and a copy of the report will be kept in the QA Manager's files for the program. The Laboratory Manager(s) must address and document the resolution of any deficiencies.

3.3 Quality Documents

Several quality documents support and describe the air quality measurement operations at AQRC. Special projects may use some or all of the following, but typically have a smaller scope of requirements for a focused study. Figure 3 below, shows the relationship of requirements between documents for AQMT.

RTI uses the same hierarchy of document types for the CSN project, however, some documents such as the QDs are currently only used in AQRC program management. As prime contractor, AQRC can assist RTI with any documentation requirements that come up during the course of the contract.

Figure 3. AQMT Documentation Hierarchy.



3.3.1 Quality Management Plan (QMP)

This QMP (described herein) outlines the management structure and how the QA system is implemented. The QMP is reviewed and updated annually.

Development and revision of the QMP is the responsibility of the prime contractor, AQMT of the AQRC, with input from subcontractors and project sponsors.

3.3.2 Quality Documents (QD)

The Quality Documents expand on the documentation requirements that are used at AQMT. They are a subset of the QMP and apply to all current or future projects. These are reviewed annually with the QMP. The current QD documents follow:

- QD 001: Document Control Practices
- QD 002: Document Creation
- QD 003: Laboratory Documentation Practices
- QD 004: Calibration Policy

3.3.3 Quality Assurance Project Plan (QAPP)

The main projects AQMT work on, IMPROVE and CSN, both have a QAPP specific to the requirements of the project. The QAPP goes into detail the quality assurance measurements, tolerances, and methods. The QAPP also contains a list of SOPs and TIs necessary to complete the work.

3.3.4 Standard Operating Procedures (SOP)

Each aspect of the laboratory and validation process has an SOP that describes the procedures that are used. Each SOP is reviewed and updated annually. The SOPs can be found at:

IMPROVE – http://vista.cira.colostate.edu/Improve/sops/

CSN – https://aqrc.ucdavis.edu/documentation

3.3.5 Technical Information (TI) Documents

Many of the SOPs have supporting TI documents that describe specific procedures in further detail. Each TI is reviewed and updated annually.

3.3.6 Appendices

Appendices contain technical information that needs to be documented. This can include designs or other supplementary material that does not fit into an SOP or TI.

3.3.7 Forms

AQMT relies on several standard forms for routine work and non-routine investigations and documentation of issues. The major forms and policies are contained in QD-001

3.3.8 Amendments

Amendments are used to inform project sponsors of major changes to documents while the revision process is in-between cycles or in-process. Regular revisions of average importance do not need an amendment and can go through a normal revision process.

3.3.9 External Audit Reports

External laboratory audits are described in Section 10.1. These audits are conducted by the U.S. EPA OAQPS or by an assigned audit contractor. An audit report is produced by OAQPS following each audit. AQRC and RTI staff review and comment on a draft of the audit report before it is finalized by OAQPS.

3.3.10 Annual Data Quality Reports

Data quality reports are produced annually for both CSN and IMPROVE to summarize findings and provide recommendations for changes that could improve data quality.

3.3.11 Annual Site Metadata Report

IMPROVE site metadata reports are produced and delivered annually to NPS summarizing general site and equipment problems, maintenance visits and audits, and other changes at a site.

3.3.12 Quarterly Metadata Report

Metadata is assembled and reported quarterly to OAQPS for CSN. RTI contributes to the metadata report regarding operations in the analytical laboratories.

3.3.13 Quarterly Site Status Reports

A summary of IMPROVE site status relative to the Federal Regional Haze Rule criteria is assembled and reported quarterly to OAQPS, NPS, and other stakeholders.

3.3.14 Monthly Status Reports

Status reports are produced and delivered monthly to OAQPS for CSN.

4. PERSONNEL QUALIFICATIONS AND TRAINING

4.1 Personnel Qualifications

The qualifications required for each position are listed in a Position Description on file at AQRC and UC Davis Human Resources Department. The Position Descriptions are prepared by the respective group managers and Principal Investigator to reflect the nature and duties of each position. Personnel assigned will meet the educational, work experience, responsibility, personal attributes, and training requirements for their positions.

Qualifications for positions in the laboratories include experience in collecting and analyzing quality control data. These qualifications can be met through experience in prior employment or through coursework in related fields such as analytical chemistry. These qualifications are documented for each employee through entries on their job applications and resumes.

Qualifications must be maintained throughout the course of employment. Laboratory staff routinely conduct quality control tests (replicate analyses, etc.) and analyze the results of these tests, which are reviewed by the Laboratory Manager. The Laboratory Manager will require that staff receive additional training if the test results decline and qualifications need to be refreshed.

RTI understands the importance of assigning qualified staff to work on behalf of its clients. It is RTI's policy that staff have training and experience appropriate for their assignments. This policy is reflected in an established training infrastructure (described below). It is the policy of the RTI Program Manager that all RTI staff assigned to perform CSN contract activities shall have appropriate technical and QA training.

4.2 Training

AQRC policy dictates that training is required for all staff to ensure understanding of quality requirements. Appropriate training is made available to staff commensurate with their duties. Because new employees are screened for proper qualifications before being hired, it is expected that each person will have the necessary scientific background and knowledge to perform the job. Hence, training is focused on the specific tasks performed at the AQRC. New employees typically begin by reading the SOPs and TI documents relevant to their assignment. Hands-on training is then provided by experienced staff. New employees are monitored during their initial days or weeks on the job. Employees

are allowed to work on their own once it has been verified that they are performing their job satisfactorily. Depending on the position (Figure 1), the respective manager is responsible for ensuring that training is sufficient. Employee performance is monitored throughout the year; findings and recommendations are documented in an annual performance review. Any need for additional training is documented in the written performance review.

Procedures and processes sometimes change. When such changes occur, the affected staff members receive additional training in the new procedures, and the relevant SOP and TI documents are amended. The respective manager is responsible for identifying when additional training is needed, determining the best training mechanism/approach, and for arranging/scheduling the training.

RTI invests a significant portion of its internal funds in training and professional development to keep staff skills and knowledge current. RTI maintains an Organizational Development and Learning (ODL) department that helps staff develop the critical skills needed to be successful in their jobs. These courses are supplied to staff members as appropriate and are incorporated into their annual work plans for the coming year.

In addition, the extensive training required to comply with health, safety and environmental regulations to protect staff is also conducted on-site by highly qualified staff from the Office of Occupational Health and Environment and other departments. Staff annually complete required training on topics such as time reporting and ethics. Employees must understand any SOPs relevant to their responsibilities and activities. A form documenting the confirmation that an employee has read and understood the SOPs is retained in the employee's training file. In addition, prior to performing new or additional tasks or activities, each employee documents that s/he has read any applicable SOP(s).

RTI's Project Manager, in consultation with the QA Manager, is responsible for personnel performance on the Program, including assessing needs, providing the resources, and monitoring the progress of professional development and general training for the program staff. Staff training files are maintained within AS and include resume, SOP read and understood documents, specialized training, and safety and compliance training. All training files are reviewed annually by staff supervisor for completeness and correctness.

4.3 Certification

Each person working in the laboratory must complete all relevant laboratory safety courses administered by the UC Davis Environmental Health and Safety Department. Each employee is issued a certificate of completion after successfully taking the course.

RTI offers similar laboratory safety courses administered by RTI's Office of Occupational Health and Environment. Documentation is provided to each employee upon completion and the documents are kept in employee training files.

5. PROCUREMENT OF ITEMS AND SERVICES

All purchases made by AQRC must conform to UC Davis procurement policies, including use of competitive bids when appropriate. AQRC ensures that new vendors can meet required specifications and test sample product before ordering larger quantities. For consumable filters, each batch received from the vendor goes through receiving checks to ensure quality and calibrate equipment. For equipment, AQRC qualifies the installation and software with test runs and compares to known data before implementing in production.

All procurements made by RTI will be planned and controlled to ensure that the quality of the items and services is known, documented, and meets the CSN technical requirements. RTI's procurement policy (see RTI's Policies and Procedures Manual, policy 13.0: Purchasing /Property Controls, procedure 13.1: Institute Procurement [September 2020]) is to acquire equipment, supplies, materials, and services based on the best quality, price, and terms, consistent with prearranged delivery requirements and specifications. RTI maintains a Government approved Federal Contractor Purchasing System, and it is the mission of the RTI Global Supply Chain to coordinate and monitor each step of the procurement process from procurement planning thorough performance and closeout to ensure best value and strict compliance with all Federal Regulations. The RTI Office of Proposal, Project, and Procurement Services (P3) SOPs and Procurement Manual are available on the RTI Intranet.

RTI's procedures for establishing, specifying, and maintaining records of quality for purchased products and equipment are in place and are available to all RTI staff. Subcontractors who provide any support services, lab services, calibration of equipment, or other work will follow RTI's policies for procurement of specific items or technical services.

6. RECORDS AND DOCUMENTATION

The Principal Investigator is responsible for ensuring documentation requirements are met, working closely with managers from different work areas as identified in Section 2.3. This section provides an overview of documentation and recordkeeping.

6.1 Document Control Policy

6.1.1 General Policy

Certain documents used by AQMT are controlled documents. This policy covers documents such as this QMP, project QAPPs, SOPs, and TIs. More documents and specific procedures are detailed in QD-001 (see Figure 2 for hierarchy). Documents in this category have controls in place to prevent unapproved or accidental edits to procedures or policies that may affect data quality. These documents must have the required approvals before being implemented.

Employees are given access to PDF documents on a networked location. These documents are the latest revision and cannot be edited. These PDFs are accessible by all staff to perform daily work. Making copies of these files is discouraged and instead linking to the folder is recommended. Old versions are moved to a restricted-access archive.

The editable file-type versions are restricted to employees with document control permissions. When other staff wish to edit a document, they can request an editable version of the document placed in a networked folder for them to do their work. The editable version will have a watermark on the page, header, or footer indicating it is a draft in case of accidental distribution or printing.

RTI employs a similar approach to controlled documents. The QA team will have full control of directories and subdirectories that the project documents are stored. All controlled documents, including SOPs, LQM, forms, spreadsheets, and external source documents will be maintained on a server in a building separate from the laboratory building. The top directory folders will have three subdirectories:

- The "Active" subdirectory will contain all controlled documents, in read-only format, with those documents being accessible to all program staff.
- The "Editable" subdirectory will contain the same controlled documents, but in Word®, WordPerfect®, Excel®, or other changeable formats. Only the Program Managers, Quality Assurance Manager or Document Control Manager will have access to this subdirectory, for the specific purpose of copying the current version of a document for editing.
- The "Obsolete" subdirectory will contain all read-only versions of any controlled document whose applicability has expired. These documents will be accessible only by the Program Manager, Laboratory Manager, or QA staff.

The servers on which the electronic quality documents are stored will be maintained and backed up by RTI's Global Technology Solutions (GTS), which supports RTI information systems and network. Backups of the servers, and thus the documents, will be performed daily on a high-performance disk subsystem and redundant server hardware. RTI data centers housing the servers are protected by uninterruptible power supplies and emergency generators. Emergency generators will be maintained and periodically load-tested by RTI's facilities staff.

6.1.2 Physical and Printed Copies of Documents

Official AQMT policy is that the PDF versions of controlled documents are official. For some operations and tasks, employees prefer having a printed copy to refer to information. This can be due to the nature of the work or the conditions. In the lab, these copies are printed and contained in binders. The binders are labeled as reference only. The footer of our controlled documents says "Electronic documents are official. Paper

copies are for reference only." These paper copies will be removed from the binders and destroyed when a new revision is released.

Field documents and manuals may not be contained in a binder, but will also be destroyed when revised. The potential need for physical documents is due to the remote nature of field work which may not have internet access or electricity at all times.

RTI's policy employs a similar approach to the printing of controlled documents. The printing of published SOPs or other required project documents is permissible in PDF format only. The printed document will contain a footer that denotes the "Printed On" date and will be only valid for 30 days until the copy must be destroyed via confidential shredding. This process is necessary to ensure the current SOP versions are in use by project staff.

6.2 Document Hierarchy and Process

6.2.1 Hierarchy

Beyond this QMP, the associated QDs, QAPP, SOPs, and TIs provide procedures and direction for each process performed, including guiding principles for monitoring and ensuring data quality. For some activities, TIs are used to provide highly detailed descriptions and instructions. The TI documents are referenced in the SOPs in order to provide a link to detailed information that is beyond the scope of the SOPs. Because they are referenced in the SOPs, the TI documents can be edited to reflect new procedures without the need to edit the SOP itself.

Ongoing log books and recordkeeping serve to document the day-to-day laboratory operations. Log books are used to document laboratory activities, such as performing a calibration or filling the liquid nitrogen dewar. Electronic information in the database records the analytical conditions associated with each sample analysis.

6.2.2 Document Creation and Review Process

The creation, revision, and review of the project QAPPs, SOPs and TIs is the responsibility of the Principal Investigator (AQRC) or Program Manager (RTI), working closely with managers from different work areas as identified in Section 2.3. The respective managers ensure that each function or procedure is covered in an SOP and its related TI documents. When equipment or procedures change, the manager is responsible for ensuring that documentation including this QMP and project QAPPs is updated accordingly. All documents are reviewed and updated annually.

6.3 Deposition and Storage of Documents and Records

Notebooks are created and maintained by each section of the laboratory. These notebooks are uniquely numbered and associated with specific instruments in each laboratory. The notebooks are intended for general comments and notes as well as for documentation of laboratory activities such as calibrations, instrument adjustments, and instrument repairs. The Laboratory Group Manager is responsible for notebook review and archiving.

The electronic data system utilized by AQRC is described in Section 7.

All documentation, both electronic and written, is retained for at least five years from the date that it was generated.

In accordance with the RTI's Policies and Procedures Manual, policy 1.0: General, procedure 1.9: Retention, Storage, Retrieval, and Destruction of RTI Records (May 2019), RTI will identify, safeguard, and preserve essential records for their important operational value. RTI will retain records in a secure and confidential manner. Obsolete records and documents will be identified and will be maintained in clearly marked separate computer directories or in separate hard-copy files. As appropriate, records will be removed to archival storage within the first year of the project and once the project is completed. RTI will maintain records for a minimum 5 years as specified by the specific program or contractual and statutory requirements. According to the RTI's Policies and Procedures Manual, policy 1.0: General, procedure 1.9: Retention, Storage, Retrieval, and Destruction of RTI Records (May 2019), records will be destroyed as soon as allowed by applicable regulations or the contract. Should the contract specify some other manner of disposition (e.g., transfer to the client), staff will follow that directive.

7. COMPUTER SOFTWARE AND HARDWARE

7.1 AQRC System

Computers and computer-related hardware are used in most phases of data collection, processing, and analysis. AQRC has an Information Technology (IT) manager who is responsible for the overall operation of the computer system and for performing nightly backups of all data. The Software & Analysis Group Manager is responsible for the database and for the code used to process the data and perform quality control assessments.

To accommodate the large number of samples from IMPROVE and CSN, AQRC has developed a sample handling and tracking system designed around a SQL-based relational database. The system is associated with work stations, each having a specific responsibility, including gravimetric, light absorption, carbon, FT-IR, and XRF analyses. The software:

- Records a log of every action at each workstation including identification of the technician, date, and other appropriate information.
- Maintains an audit trail for each filter. The status of any filter can be determined at any time.
- Performs immediate quality assurance checks of all data entered and notes any problems.
- Verifies that all steps for a given filter have been performed.
- Expedites and improves the data reduction and data validation processes of the final data set.

The sample identity information for each sample, including the time and location of sample collection, are maintained in the SQL database. Each XRF instrument has an independent database for storing analytical data during and after analysis. Data from the XRF systems are downloaded to the AQRC data system on a regular basis, usually daily. The weighing chamber records measurement data and is uploaded to the SQL database daily.

AQRC includes a centralized computer system with thin client monitors connected to a central server. The thin client system allows all data to be stored and accessed centrally in a common location. The AQRC data system is backed up daily to guard against data loss in case of failure.

7.1.1 Acceptance Testing

Over time, computer hardware and software are replaced, upgraded, or modified to meet new requirements, increase quality of the data, or improve workflows. Any employee can make improvement requests to their supervisor, which will then be evaluated for implementation.

When new hardware or software is approved, each is implemented and tested in a pilot or sandbox setting before final implementation and direct integration with final data. The teams most-directly connected to the change will evaluate the performance and impact of the new system. The process may go through several iterations before final approval and implementation.

The amount of documentation around changes will be appropriate for the impact of the project. Quality forms noted in 3.3.7 of this document are available. Networked folders, presentations, reports, and software development tools/forums are also acceptable.

Subcontractors on projects are expected to have their own acceptance testing process that conform to the overall goals outlined here. The methods and details are up to the subcontractor discretion.

7.2 RTI System

RTI Project staff will follow RTI procedures for installation, testing, use, maintenance, control, and documentation of computer software and hardware. All RTI staff are required to use and maintain their computers in a responsible manner. Project staff who use computers for design, data collection or analysis, and modeling are to ensure that all such computer systems are used according to established procedures or procedures specified in work plans or QAPPs, as well as in accordance with manufacturers' guidelines for specific software or hardware.

RTI has developed and maintains a custom-designed Laboratory Information Management System for the program also designed around a SQL-based relational database. RTI's database for sample processing and tracking was coded and is maintained by staff in the Research Computing Division.

Entries into the database system are limited to approved users based on assigned permission structures, permitting access to only the parts of the database necessary to complete work. Similar to the AQRC database, records of every action are logged at each workstation including identification of the technician, date, and other appropriate information; an audit trail for each filter is created to determine the status of a filter at any time (including required steps for each filter); automated quality assurance checks of all entered data is performed; and data reduction and validation processes are performed on relevant data sets.

RTI has an Information Technology (IT) group capable of providing support for larger network issues 24/7. Backups of the data will be maintained to prevent data loss through equipment malfunctions or human error. Because of data redundancy, virtually all data can be reconstructed from laboratory records. Backups of the main database are timed so that no more than one day's worth of data would have to be reconstructed due to a complete loss of the main database.

Database file servers, instrument systems, and other critical computer equipment are powered through an uninterruptible power supply to avoid excessive downtime and provide graceful shutdown of the operating system when power is lost. Desktop and laptop computers used in offices and laboratories will have either an uninterruptible power supply or internal batteries to avoid data loss and corruption as a result of power interruptions.

Software used in the laboratories has been developed by the respective instrument manufacturers. Upon instrument installation, input routines are tested against documented requirements through our routine series of Unit Testing, Functional Verification Testing, and System Verification Testing.

8. PLANNING AND IMPLEMENTATION OF WORK PROCESS

When required, a project develops and follows a Quality Assurance Project Plan (QAPP). Major projects such as IMPROVE and CSN each have a QAPP that sets a baseline for quality standards, deliverables, and organization. SOPs and TIs provide more details about how to achieve the requirements outlined in the QAPP. The QAPP for each project is developed in coordination with the project sponsor. On the AQRC side, the Principle Investigator, Quality Manager, Lab Manager, and other members of the leadership team contribute to the development of the QAPP. Each year the QAPP is reviewed, led by the Quality Manager, for improvements, changes, enhancements, or omissions from the previous revision. The changes are sent to project sponsor for approval before final revision is released. Ultimately the prime contractor, AQRC, is responsible for QAPP development, and may coordinate with subcontractors or partners as necessary. Smaller projects run by AQRC may not get a QAPP and will instead by governed by other documents such as contracts, SOPs, or written requirements.

The analysis of samples by XRF, HIPS, TOA, FT-IR, and gravimetric mass determination, and associated data processing and validation is typically performed using routine, established methods developed for IMPROVE and CSN. The day-to-day operations consist of implementing established procedures, not of planning and developing new ones.

However, unusual samples require planning prior to analysis, especially to ensure that analytical detection limits are sufficient to quantify the sample components. The Laboratory Group Manager (AQRC) or Laboratory Manager (RTI) identifies the need for further planning and leads the planning efforts. For XRF, in particular, several instrumental variables (such as choice of secondary targets and exposure time) can be adjusted to optimize the detection limit. Some initial screening analysis is often needed as part of the analytical planning process, which can bound the issue and aid in definition of variables.

Analyses involving IC and SF ICP-MS have multiple variables which are customizable to optimize and target atypical analytes. IC can utilize alternate columns, flow rates, eluent concentrations, temperatures and sample loops optimize method development for analytes. SF ICP-MS is tuned prior to each analytical run, however parameters such as glassware used, addition of gases, changes in hardware configuration, and quantitative scan times allow for better detectability and/or minimization of potential interferences.

9. IMPLEMENTATION OF WORK

Most of the samples analyzed at AQRC laboratories are part of IMPROVE and CSN. Implementation of sample analysis is guided by the Quality Assurance Project Plans (QAPP) that describe the process and work performed for each program. Specific procedures for XRF, HIPS, TOA, and gravimetric analysis, as well as data processing and validation, are described in the SOPs and related TI documents.

AQRC has a controlled documents policy detailed in QD-001. This document is normally an internal document and not specific to any project, but available upon request. In summary, SOPs and TIs for contracted work are controlled and have a defined revision process before implementation. The roles and responsibilities are also defined there. If processes must be changed faster than documents can be revised, a planned deviation form is available to quickly document the change until final revisions can be made to controlled documents. These policies were developed to meet existing IMPROVE and CSN contract QAPP requirements and follow standard practices for document control.

Samples analyzed at RTI as part of the CSN networks will adhere to RTI developed and approved QAPP's. A separate QAPP will exist for each program, as the critical criteria's and level of efforts to perform the work will differ. The CSN QAPP will cover the shipping and handling, IC analysis and metals analysis. Area specific SOP's and TI documents will be developed and maintained by RTI Lab Managers.

For samples not related to IMPROVE or CSN a project-specific plan is prepared prior to sample analysis. These project plans are typically much shorter and simpler than the IMPROVE and CSN QAPPs since most of the projects involve a small number of samples. The most complex aspect of the implementation of special-project sample analysis is determination of the custom target/time application for XRF.

10. DATA QUALITY ASSESSMENTS

10.1 Independent Assessments

This section describes the quality-related assessment and reporting activities. As described in Section 2.4, U.S. EPA OAQPS conducts the independent assessments of the laboratory through Technical System Audits (TSAs) and Performance Evaluations (PEs).

TSAs are conducted by the U.S. EPA OAQPS or by an assigned audit contractor. The auditors will examine all aspects of operations to determine if processes and quality assurance systems being implemented are in alignment with the laboratory SOPs, TI documents, and with program requirements. TSA results are submitted to the Principal Investigator, Program Manager, and QA Manager.

OAQPS also conducts performance evaluations. OAQPS submits PE samples to AQRC for laboratory analysis. The PE samples for gravimetric mass typically include certified metal weights as well as exposed and unexposed (blank) PTFE filters. The PE samples for XRF, HIPS, and TOA typically include exposed and unexposed (blank) PTFE filters. OAQPS provides a report to the Principal Investigator, Program Manager, and QA Manager which includes values determined by OAQPS and AQRC with discussion of agreement between the two laboratories.

RTI will participate in performance evaluations and TSAs as required by the CSN contract. RTI facilities and personnel will be available as needed to perform these activities.

10.2 Internal Assessments

10.2.1 AQRC Internal Assessments

Frequent and ongoing assessments of the AQRC systems and processes are conducted internally. Quality control (QC) tests associated with these assessments are described in the SOP and TI documents and in the QAPP. These assessments are initiated and directed by the Laboratory Group Manager. The results are reviewed by the Principal Investigator and QA Manager.

The corrective-action process is fully defined in document QD-001. This document is normally kept internal as it is not specific to any project, but is available upon request. In summary, when corrective actions are identified as being necessary, they are planned, implemented, checked, and revised as necessary. The Quality Manager makes the final determination if the final version is sufficient.

If any disputes arise as a result of nonconformances, corrective actions, audits, or quality failures, the Quality Manager will review the process with the lead or manager of the area and determine the best course of action. Ultimately the project QAPPs must be adhered to, or sponsors contacted if they cannot be reasonably enforced due to unforeseen circumstances. Quality of the final data is the utmost important to AQRC, but must be kept in-balance with delivery dates, resources, and other priorities.

To assess the adequacy of the AQRC quality system, each year the quality manager reviews the QMP, quality documents, and project QAPPs. Updates are made and coordinated with project sponsors if anything is found to be out-of-date or deficient. On an on-going basis, SOPs and TIs are updated with new procedures of corrective actions as a result of a quality incident or deficiency. All changes are coordinated through the Associate Director of Quality research. The quality manager also reports directly to the AQRC Director when issues need to be elevated.

To assess the level of training required for AQRC personnel working on a specific project, the training matrix for that project is reviewed. The matrix contains each personnel role within AQRC and which project documents those employees should be trained on. A Learning Management System is used to implement training on initial trainings and new revisions. Smaller projects have fewer documents and may not have a training matrix. Document training can apply to multiple projects where there is overlap.

10.2.2 RTI Internal Assessments

RTI conducts internal assessments at two levels: a QC review meeting is held once per quarter and a laboratory-wide audit is performed annually to assess the laboratory quality systems and processes.

The quarterly QC meeting consists of a review of any major QA and QC events or trends that may have occurred during the preceding quarter, as well as any applicable corrective measures taken to resolve these issues. In addition, random spot checks of data may be performed to ensure compliance with laboratory SOPs.

Internal audits are conducted on a pre-determined schedule and address all elements of the management system, including a more thorough evaluation of all QA and QC operations performed in the laboratory. The QA Manager for the project is responsible for planning and organizing audits as required by the schedule and as requested by the RTI project management. The QA Manager will prepare a report for the Program Manager and the Laboratory Manager to review that summarizes the results of the internal audit, with any findings to address (if applicable).

RTI personnel conducting the assessments (e.g., quality systems, data quality, and performance evaluation) are technically knowledgeable and have the years of experience, as reflected in the personnel resumes and training files. They are not involved in the generation of the data or have conflicts of interest in the area of the assessment they are evaluating. They have been trained through hands on experience of the assessment process with other projects and ongoing mentorship within the organization.

11. QUALITY IMPROVEMENT

A variety of quality control tests are conducted routinely, including calibration checks, replicate analyses, and analysis of field blanks and laboratory blanks. The data from these tests are analyzed regularly by the Laboratory Group Manager and by other staff. The results are summarized in the Annual Data Quality Report and in special memoranda when unexpected results merit more timely attention.

In most instances the quality control tests verify that operations are normal, and that data quality is within acceptable limits. However, on occasion data quality may exceed the limits or may drift toward unacceptable levels. In those cases, action is taken to improve data quality by altering procedures or by rectifying an identified problem. The Laboratory Group Manager has primary responsibility for identifying the need for improvements in data quality.

At the lab level, the lab manager meets routinely with spectroscopists and leads in the lab to discuss quality, operations, and what can be improved. Suggestions can come from anyone, are assessed, and if approved will be moved to implementation. Improvements can be implemented physically by lab staff or may require programming by the software group. Quality issues discovered are shared with the lab manager and quality manager, documented on quality forms, and discussed in weekly management meetings. Corrective and preventative actions are implemented to address issues or mitigate their impact.

AQRC meets with project sponsors on a regular basis to discuss issues that arose, QC failures, ongoing improvements and projects, delivery schedule, and new proposals. Project sponsors have final approval on major changes that may affect delivered data whereas AQRC maintains approval on smaller changes in the lab or field in order to maintain and deliver high-quality data.

An additional form of quality improvement includes AQRC staff assessment to the approach for estimating and expressing the uncertainty of the air quality measurements. This work has revealed that the older method of building uncertainties from the “ground up” using the uncertainties of the measurements’ individual components can significantly underestimate the actual measurement uncertainty. Instead, AQRC staff employ an approach for determining uncertainty from collocated measurements, providing a more realistic and reliable estimate of the total uncertainty.

For data validation, automated processes have been developed to reduce subjectivity and semi-quantitative evaluations of plots and tables that were previously used for data validation. Statistical tests and geospatial analyses are available to the data analysts via web applications that enable expeditious data validation prior to data deliveries. These practices are in a continuous state of improvement and are documented in the associated SOP and TI documents.

RTI’s responsibility and standard practice of all project staff to identify and appropriately communicate opportunities for quality improvement to the project management staff, QA staff, and technical staff for each organization. We will conduct annual reviews of the

project quality management system that will include evaluation of corrective actions and monthly reports (especially sections on problems and resolutions). Lessons learned based on these reviews will be incorporated into program procedures and this QMP. If warranted, these improvements will be planned and documented in a Quality Improvement Plan.

A corrective action can be initiated by any RTI staff member working on the project when an event occurs that causes any deviation from the QAPP, SOP, bench sheet, or analytical method. Management affiliated with the project will review and approve all Corrective Action Reports. Corrective actions will be implemented through document revisions or staff training

12. REFERENCES

EPA QA/R-2, 2001, *EPA Requirements for Quality Management Plans*, U.S. Environmental Protection Agency, Washington, D.C.

EPA QA/G-2, 2001, *Guidance for Developing, Reviewing and Implementing Quality Management Plans*, U.S. Environmental Protection Agency, Washington, D.C.

All UC Davis IMPROVE SOPs are located:
http://vista.cira.colostate.edu/improve/Publications/SOPs/ucdsop.asp

All UC Davis CSN SOPs are located:
https://aqrc.ucdavis.edu/documentation