

Quality Assurance Guidance Document

Revision 1.5

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:

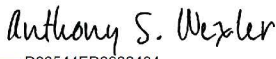


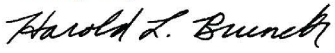


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February 28, 2023



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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	<p>Split file into content and title pages for CSN and IMPROVE projects.</p> <p>Updated QMP content to account for major projects (IMPROVE, CSN) as well as special projects.</p> <p>Refined language regarding how AQRC works with various partners and subcontractors.</p> <p>Quality Documents (QD) created as new document category.</p> <p>Annual updates including personnel and org chart, equipment updates, document control policy, quality system assessment, and quality improvement</p> <p>Document History added.</p>

LIST OF ACRONYMS AND ABBREVIATIONS

AQMT	Air Quality Monitoring Team of AQRC
AQRC	Air Quality Research Center
AQS	Air Quality System database
DRI	Desert Research Institute
EPA	U.S. Environmental Protection Agency
FT-IR	Fourier Transform Infrared Spectroscopy
HIPS	Hybrid Integrating Plate/Sphere
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
RTI	Research Triangle Institute
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
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.

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. Currently being researched to estimate parameters such as OC and EC.

Almost all 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 ($\text{PM}_{2.5}$). 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 $\text{PM}_{2.5}$ 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 (TOA) 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 another contractor and are collected in the field by local agency personnel. $\text{PM}_{2.5}$ 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. 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

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.

Oversight of operations for the CSN program at AQRC is the responsibility of the Principal Investigator, Dr. Nicole Hyslop. Dr. Hyslop is responsible for financial oversight, staff management, program deliverables, and problem resolution.

Oversight of operations for the IMPROVE program at AQRC is the responsibility of the Principal Investigator, Sean Raffuse. Mr. Raffuse is responsible for financial oversight, staff management, program deliverables, and problem resolution.

The laboratory manager is Dr. Jason Giacomo. 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 XRF spectra, 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 and HIPS instruments. They are responsible for routine changing of samples, maintaining analysis records, processing data, performing quality control tests, and performing routine instrument maintenance such as liquid nitrogen fills and automated detector calibrations.
- Additional laboratory technician operates the TOA instruments. They are responsible for routine analysis of samples, maintaining analysis records, preparation of standard solutions, and performing routine instrument maintenance.

The AQRC Software & Analysis Group Manager is Mr. Sean Raffuse, who 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 is Dr. Young. She 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.

Dr. Young 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:

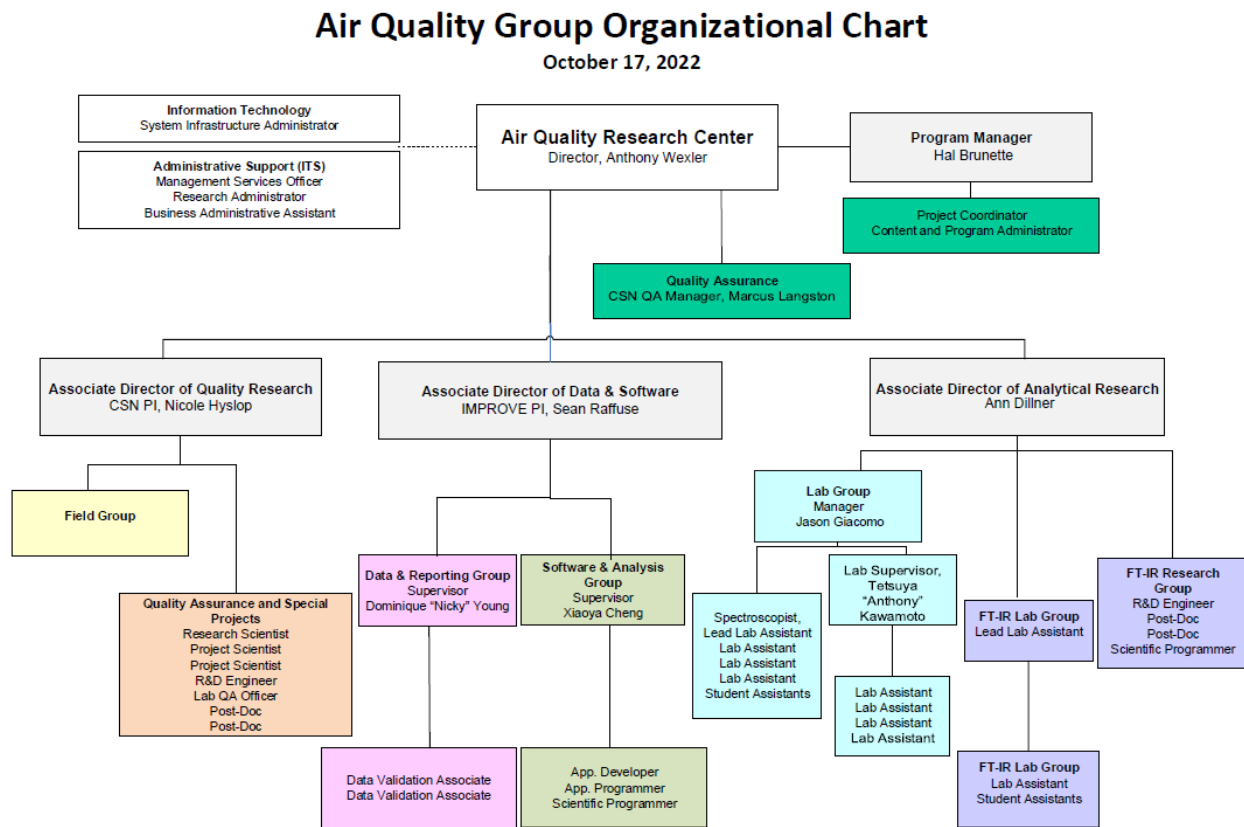
1. Preparing reports and program deliverables for sponsors, with input from other project staff;
2. Preparing and editing various project-related documents such as position descriptions, technical reports, and meeting summaries;
3. Assisting in the editing of the SOPs, QAPP, and QMP;
4. Financial tracking, 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) for the CSN program at UC Davis, and in this role, Marcus Langston reports to the AQRC Director. As such, the AQRC QA Manager can report problems to AQRC's highest level of management, independent of the project structure. In practice, the AQRC QA Manager will work closely with the Principal Investigator 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 from AQRC and RTI to assess the achievement of Measurement Quality Objectives (MQOs);
3. Performing periodic in-lab and data review audits of data quality for the AQRC and RTI laboratories;
4. Conducting an annual review 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.



2.4 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

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.
- The TOA Laboratory contains six Thermal/Optical OC/EC analyzers, used for measuring carbon fractions on quartz filters.
- The FT-IR laboratory contains 3 analyzers that use the IR light spectrum to prove chemical bonds on Teflon filters. This is currently being researched.

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

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.

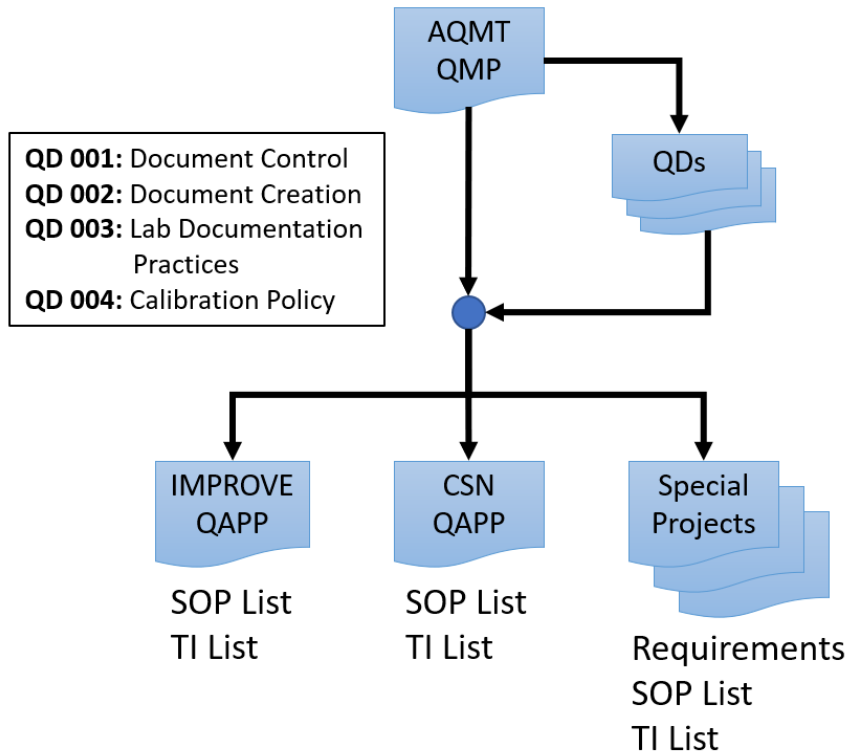
3.2.3 Management Review

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.

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 2 AQMT Documentation Hierarchy, below, shows the relationship of requirements between documents.

Figure 2. 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.

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 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.

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.

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.

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.

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.

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.

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.

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, 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.

7. COMPUTER SOFTWARE AND HARDWARE

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.

8. PLANNING AND IMPLEMENTATION OF WORK PROCESS

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 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.

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.

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.

10.2 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.

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.

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.

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>