

Montana Ambient Air Monitoring Program Quality Management Plan

September 15, 2015

State of Montana Ambient Air Monitoring Program Montana Department of Environmental Quality Air Quality Bureau 1520 E. Sixth Avenue Helena, Montana 59620-0901

Purpose of the Quality Management Plan

This Quality Management Plan (QMP) establishes and documents the State of Montana, Department of Environmental Quality (DEQ), Air Quality Bureau, ambient air monitoring program (monitoring program) quality management system. A quality system is defined as "a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services." The monitoring program's quality system provides the framework for planning, implementing, documenting, and assessing monitoring program work performed for all participants and for conducting the required quality assurance (QA) and quality control (QC) activities.

The QMP meets the requirements in Title 40 Protection of Environment, Code of Federal Regulations Part 58 (40 CFR Part 58), Ambient Air Quality Surveillance, Appendix A, Section 2.¹ DEQ relies on ambient air monitoring data from the monitoring program to support a multitude of scientific, regulatory, and administrative decisions. Accordingly, efforts to document and improve, as necessary, the quality of ambient air monitoring data collection activities are among the most important functions of monitoring program staff. By the monitoring program implementing the quality system described in this QMP, the state of Montana ensures that collected ambient air data is of "known quality" and of acceptable value; consequently, the monitoring program's data collection efforts can be used with confidence to manage Montana's air resource.

Development of the QMP used the United States Environmental Protection Agency (EPA) Requirements for Quality Management Plans [(OEI I), see References]. All relevant elements of the QMP regulations and guidance are addressed in this document.

For reader convenience, footnotes and citations are hyperlinked to the online versions of the documents they reference.

¹ - <u>Title 40 Code of Federal Regulations (CFR) Part 58, Appendix A, Section 2 - Quality System Requirements.</u>

Title and Approval Sheet

Title: Montana Ambient Air Monitoring Program Quality Management Plan

The attached Montana Ambient Air Monitoring Program Quality Management Plan is approved and commits the state of Montana Department of Environmental Quality to follow the elements described within.

Signature:

Date: <u>09/01/2015</u>

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Cynthia Dingman, QA Council Chair Contracts & QA Coordinator Office of Information Technology Montana Department of Environmental Quality Date: 08/31/2015

Date: 09/02/2015

Revision Review

Title: Montana Ambient Air Monitoring Program Quality Management Plan

The September 2015 revision to the Montana Ambient Air Monitoring Program Quality Management Plan, noted as Revision 1 (see Section 1.6.1 – Quality Management Approval Process and Revision Information), has been reviewed by the monitoring program supervisors.

Ameth 1) Mano

Signature:

Date: <u>08/27/2015</u>

Annette Williams, Technical Support Services Program Manager Air Quality Bureau Permitting and Compliance Division Montana Department of Environmental Quality

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Signature:

M. Eric Merchant, Analysis and Planning Services Section Supervisor Air Quality Bureau Permitting and Compliance Division Montana Department of Environmental Quality Date: 08/19/2015

Date: 07/02/2015

Revision History

Revision	Date	Author	Section	Description of Changes
Number			Modified	
0	09/15/2010	J. Ugorowski		Initial version
1	08/01/2015	J. Ugorowski	All Sections	 Updated CFR references from 2009 to e-CFR
	,-,			Created References Section for references other than CFR references
			All Sections	Updated monitoring program organization, including:
				Air Quality Bureau
				(formerly Air Resources Management Bureau)
				Technical Support Services Program
				(formerly Air Monitoring and Analysis Program)
				Research and Monitoring Services Section
				(Jormeriy Air Monitoring Section)
				• Analysis and Planning Services Section (formerly Air Quality Policy and Planning Services Section)
				Data management staff residing directly in Technical Support Services
				Program
				(Formerly Data Management Section)
				Organization chart (Figure Attachment 1-1)
			Title and	Added "Revision Review" Sign-Off Sheet for monitoring program managers
			Approval	
			Sheet	
			1.2	1.2 QMP Scope and Applicability:
				Changed "other required" to "applicable 40 CFR Part 58" ambient air
				monitoring data collection activities
				Added reference to ARM 17.8.204 for source generated data
			1.3.1.5	Changed "other required ambient air monitoring data collection activities"
			1.0, 1.0	to "other 40 CFR Part 58 applicable ambient air monitoring data collection
				activities"
			1.4.3	Removed monitoring program supervisors and replaced with monitoring
				program management (i.e., TSS program Manager, RMS Supervisor, and APS
				Supervisor)
			1 / 5	Role of OA Manager.
			1.4.5	Added approves externally developed (e.g. contractors and consultants)
				and outside-source (i.e., industrial) generated guality system documents
				Removed evaluation of the training efforts within the monitoring
				program
			1.4.6	Added additional quality system requirements (development of QAPPs and
				SUPS) for externally contracted services
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	1.5	Removed AQS database archive for secondary data collected by permitted sources or contractors
	1.6	Renamed Section 1.6 – Monitoring Program QS Documents Approval Authority and Process to Section 1.6.1 - Monitoring Program QS Documents Approval Process and Revision Information
	1.6.1	Renamed Section 1.6.1 - QMP Approval Authority and Process to Section 1.6.1 - QMP Approval Process and Revision Information
	1.6.2	Renamed Section 1.6.2 – Project Level Document Approval Authority and Process to Section 1.6.2 – Project Level Document Approval Process and Revision Information
	1.6.2.2	Revised SOP approval to include AMS delegated staff
	1.7	Added "Changes in 40 CFR Part 58 or other air monitoring regulations that affect the monitoring program's quality system" for QMP revision requirements
	2.2.1	For quality system documentation availability, changed DEQ internet website to DEQ's Monitoring Program Quality System Documents website
	2.2.2	 Added 2014 40 CFR Part 58, "Proposed" Revisions: Network modification plan in annual network plan and periodic network assessment. Public comments received during the public comment period are referenced and addressed in the final network plan that is submitted to EPA
	2.2.2, 2.2.3, 2.3.5, 2.3.7, 5.1.4, 8, 9, 10	Removed Annual QA Report
	2.2.4	Removed Microsoft Access Reference for in-house developed databases
	3.5	Removed the QA Manager is responsible for evaluating and validating the results of training for the monitoring program staff
	4.0	Updated Procurement section to align with current processes and added Section 4.2 - Quality of Procured Goods and Services
	5.0	Added documents and records definitions
		Updated documentation and records retention periods based 2015 Monitoring Program Records Management Plan
	6.0	 Renamed Section 6.0 - Computer Hardware and Software to Section 6.0 - Computer Technology. Additional revisions included: Updated the section to reflect the current processes within the DEQ 2014 QMP Computer Technology section.
	10.0	Replaced annual QA Report with annual data certification
		Added data quality assessment

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Acronyms and Abbreviations

 APS - (DEQ) Analysis and Planning Services (Section) APTI - EPA OAQPS Air Pollution Training Institute AQB - (DEQ) Air Quality Bureau AQS - Air Quality System (EPA ambient air database) ARM - Administrative Rules of Montana ASQ - American Society for Quality 	
 APTI - EPA OAQPS Air Pollution Training Institute AQB - (DEQ) Air Quality Bureau AQS - Air Quality System (EPA ambient air database) ARM - Administrative Rules of Montana ASQ - American Society for Quality 	
AQB- (DEQ) Air Quality BureauAQS- Air Quality System (EPA ambient air database)ARM- Administrative Rules of MontanaASQ- American Society for QualityCAAClean Air Act	
AQS-Air Quality System (EPA ambient air database)ARM-Administrative Rules of MontanaASQ-American Society for QualityCAAClean Air Act	
ARM - Administrative Rules of Montana ASQ - American Society for Quality CAA Clean Air Act	
ASQ - American Society for Quality	
CAA Cloan Air Act	
CARF - Corrective Action Request Form	
CD ROM - Compact Disc Read Only Memory	
CFR - Code of Federal Regulations	
COC - chain of custody	
DEQ - Montana Department of Environmental Quality	
DQO(s) - Data Quality Objective(s)	
EPA - United States Environmental Protection Agency	
IT - Information technology	
MAAQS - Montana Ambient Air Quality Standards	
MCA - Montana Code Annotated	
NAAMS - National Ambient Air Monitoring Strategy	
NAAQS - National Ambient Air Quality Standards	
NACAA - National Association of Clean Air Agencies	
NRIS - Montana Natural Resource Information System	
OAQPS - EPA Office of Air Quality Planning and Standards	
OEI - EPA Office of Environmental Information	
OIT - (DEQ) Office of Information Technology	
PM - particulate matter	
PM ₁₀ - particulate matter (inhalable, of less than or equal to 10 micron	5)
PM _{2.5} - particulate matter (respirable, of less than or equal to 2.5 micro	าร)
QA - quality assurance	
QA/QC - quality assurance/quality control	
QAPP(s) - quality assurance project plan(s)	
QC - quality control	
QMP - quality management plan	
RMS - (DEQ) Research and Monitoring Services (Section)	
RTP - Research Triangle Park	
SLAMS - state or local air monitoring station	
SOP(s) - standard operating procedure(s)	
TSA(s) - technical systems audit(s)	

(DEQ) Technical Support Services (Program)

TSS

Glossary of Terms

air quality system (AQS) - EPA's computerized system for storing and reporting of information relating to ambient air quality data.

- **ambient air** means that portion of the atmosphere, external to buildings, to which the general public has access.
- ambient air monitoring data data that is intended to represent or characterize ambient air at a given boundary condition (scale) and a given time period and associated ambient air measurements collected that describes ambient air monitoring conditions.
- **ambient air monitoring data operations** work performed to obtain, use, or report information pertaining to ambient air monitoring measurements, processes, and conditions.
- assessment the evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management systems review, peer review, inspection, or surveillance.
- audit a systematic and independent examination to determine whether ambient air monitoring quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.
- **data quality assessment** a statistical and scientific evaluation of the ambient air monitoring data set to determine the validity and performance of the data collection design and statistical test, and to determine the adequacy of the data set for its intended use.
- **design** specifications, drawings, design criteria, and performance requirements. Also the result of deliberate planning, analysis, mathematical manipulations, and design processes.
- **documents** publications and forms that are generated by the monitoring program for use by the staff and public to prescribe processes, specify requirements, or establish design. Documents can be distinguished from records by their potential for revision.
- **graded approach** the process of basing the level of application of managerial controls applied to an item or work according to the intended use of the results and the degree of confidence needed in the quality of the results.
- **independent assessment** an assessment performed by a qualified individual, group, or organization that is not a part of the organization directly performing and accountable for the work being assessed.

- **inspection** examination or measurement of an item or activity to verify conformance to specific requirements.
- **management** those individuals directly responsible and accountable for planning, implementing, and assessing work.
- **management system** a structured, non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountabilities, and implementation plan of an organization for conducting work and producing items and services.
- management systems review the qualitative assessment of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained.
- monitor means an instrument, sampler, analyzer, or other device that measures or assists in the measurement of atmospheric air pollutants and which is acceptable for use in ambient air surveillance under the applicable provisions of 40 CFR Parts 50, 53, and 58, Appendix C.
- **monitoring organization** means a State, local, or other monitoring organization responsible for operating an ambient air monitoring site for which the quality assurance regulations apply.
- **organization** a company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration.
- peer review a documented critical review of work by qualified individuals (or organizations) who are independent of those who performed the work, but are collectively equivalent in technical expertise. A peer review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. The peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions.
- **performance evaluation** a type of ambient air monitoring audit in which the quantitative ambient air monitoring data generated in a measurement system are obtained independently and compared with routinely obtained ambient air monitoring data to evaluate the proficiency of an analyst or laboratory.
- **process** a set of interrelated resources and activities which transforms inputs into outputs. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

- **quality** the totality of features and characteristics of a product or service that bear on its ability to meet the stated or implied needs and expectations of the user.
- **quality assurance (QA)** an integrated system of management activities involving planning, implementation, documentation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.
- **quality assurance project plan (QAPP)** formal document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.
- **quality control (QC)** the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.
- **quality improvement** a management program for improving the quality of operations. Such management programs generally entail a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation.
- **quality management** that aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, documentation, and assessment) pertaining to the quality system.
- **quality management plan (QMP)** a document that describes the monitoring program quality system in terms of the organizational structure, functional responsibilities of monitoring program management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all monitoring data collection activities conducted.
- **quality system** a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, documenting, and assessing work performed by the organization and for carrying out required QA and QC activities.
- **records** provide evidence of activities carried out by the monitoring program and by external entities such as a regulated facility. Records can be distinguished from documents by the singular nature of their creation and use (i.e., you cannot change the information on the record because it tells what happened). Records may include completed QA/QC activity reports, photographs, drawings, magnetic tape, and other data recording media.

- specification a document stating requirements and which refers to or includes drawings or other relevant documents. Specifications should indicate the means and the criteria for determining conformance.
- standard operating procedure (SOP) a written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks.
- **technical review** a documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.
- **technical systems audit (TSA)** a thorough, systematic, on-site, qualitative audit of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system.

1. Management and Organization

This section documents the overall quality assurance (QA) policy, scope, applicability, and management responsibilities of the Quality Management Plan (QMP) as it relates to the quality systems structure.

1.1 Quality Management Plan Purpose and Organization

This QMP describes and documents the Montana Department of Environmental Quality (DEQ), Air Quality Bureau (AQB), ambient air monitoring program (monitoring program) quality system in accordance with United States Environmental Protection Agency (EPA) requirements and DEQ requirements.

Development of the monitoring program's quality system used EPA's Guidance for Developing Quality Systems for Environmental Programs [(OEI II), see References], and demonstrates conformance to the American National Standards Institute's Quality systems for environmental data and technology programs – Requirements with guidance for use (ANSI/ASQ E4-2004) [(ASQ), see References]. The QMP was prepared in accordance with the EPA Requirements for Quality Management Plans [(OEI I), see References].

1.2 QMP Scope and Applicability

The QMP is designed to meet the requirements in the Code of Federal Regulations (CFR), Air Quality Surveillance, Quality System Requirements.¹ The QMP scope is limited to National Ambient Air Quality Standards/Montana Ambient Air Quality Standards (NAAQS/MAAQS) [(AQB I), see References] compliance monitoring and applicable 40 CFR Part 58² ambient air monitoring data collection activities originating from the following sources:

- Ambient air monitoring data generated by the monitoring program, with laboratory analysis completed outside of the monitoring program.
- Ambient air monitoring data generated by the monitoring program.

Note that ambient air monitoring data generated by sources outside of the monitoring program, but submitted for review, validation, and used by DEQ's air quality compliance program for pre-construction application and permit mandated compliance determinations are subject to the provisions of the Administrative Rules of Montana (ARM) Section 17.8.204.³ Such outside source (industrial) monitoring efforts shall develop and implement project specific quality assurance project plans and standard operating procedures. For data generated by sources outside the monitoring program, the monitoring program evaluates the network sampling design based on the intended use of the collected data. Also, during review and validation of the collected data the monitoring program uses the acceptance criteria contained in the project specific quality assurance project plans and standard operating procedures.

² - <u>40 CFR Part 58 – Ambient Air Quality Surveillance</u>

³ - Administrative Rules of Montana, Title 17, Chapter 8, Subchapter 204 - Ambient Air Monitoring

The QMP outlines the primary objectives and responsibilities of the monitoring program. Monitoring program activities reside primarily within two sections of AQB Technical Support Services (TSS) Program:

- <u>Research and Monitoring Services (RMS) Section</u>: Responsible for collection and validation of ambient air monitoring data within Montana.
- <u>Analysis and Planning Services (APS) Section</u>: Provides planning and quality assurance for the monitoring program.

Additionally, monitoring program data management functions are performed by staff within the AQB-TSS program.

1.3 Statement of Quality Assurance Policy

It is the monitoring program QA policy to implement, operate, and maintain a quality assurance and quality control (QA/QC) program to ensure that all ambient air monitoring data collected and/or generated are of known and acceptable precision and accuracy. The QA policy is designed to ensure that the monitoring program produces ambient air monitoring data that supports and fulfills, in a scientifically defensible manner, the informational needs and regulatory functions of DEQ. The QA policy applies to all NAAQS/MAAQS compliance monitoring and other 40 CFR Part 58 applicable ambient air monitoring data collection activities. The monitoring program adheres to the QMP requirements to ensure that all ambient air data collection activities meet or exceed QA/QC expectations. The QA/QC program is implemented largely through:

- QA/QC training for certain identified job functions
- Use of project specific quality assurance project plans (QAPPs)
- Implementation of standard operating procedures (SOPs)

Ambient air monitoring data collection activities must be conducted in accordance with an approved QAPP and associated SOPs that meet all elements of the QMP. Note exceptions to this statement in **Section 1.5 - Ambient Air Monitoring Data Generation Policy**.

1.3.1 Quality Assurance / Quality Control Objectives

Monitoring program QA/QC objectives include:

- Assure that ambient air monitoring data activities are well planned and designed to address the needs and goals of the individual project.
- Assure the production of reliable, accurate ambient air monitoring data.
- Support decisions based on the analyses of the ambient air monitoring data.
- Facilitate the timely identification of problems and implementation of corrective actions.
- Provide for continuous improvement in the monitoring program operations,

Quality Control (QC) encompasses all of the direct "internal" actions taken by the RMS Section to achieve and maintain a desired level of quality for the ambient air monitoring data collection activities. Quality control includes all of the measures taken by monitoring program management, staff, and laboratory personnel to achieve a predetermined level of ambient air monitoring data reliability. In the case of the monitoring program, QC activities are used to ensure that measurement uncertainty is maintained within established acceptance criteria for the attainment of the data quality objectives (DQOs). For additional information regarding the DQO process refer to **Section 2.3.1** - **Systematic Planning: Development of DQOs**. Quality control is applied from the planning and design stages of the monitoring effort, through the implementation stages, to the handling, storage and reporting of accumulated data.

Quality Assurance encompasses all "external" measures taken by the QA Manager, DEQ or EPA to ensure that the quality of the ambient air monitoring data collection activity meets the monitoring QA/QC objectives. Quality assurance refers to the system of activities to provide assurance that the established QC measures perform adequately. Major QA functions include:

- Reviewing and approving program planning documents
- Conducting performance evaluations and oversight assessment of ambient air monitoring collection, analysis, and data handling procedures
- Evaluating the effectiveness of implemented QC procedures

1.3.2 Independence of Quality Assurance

The monitoring program provides for a quality assurance management role in the QA Manager. The position determines and implements the quality policy as defined in this QMP. The QA Manager is functionally independent from the monitoring program sections generating, compiling, and applying environmental data, and resides in the APS Section.

1.4 Monitoring Program Authorities and Responsibilities

The monitoring program is organized as illustrated in **Attachment 1**. The charts outline the organization structure and parties associated with data collection, verification and validation, and reporting, as well as data user relationships.

1.4.1 Role of AQB Bureau Chief

The AQB Bureau Chief performs the following functions with the assistance of the TSS Program Manager, RMS Section Supervisor, and the QA Manager:

- oversees the development, revision, and implementation of the QMP
- ensures the QMP requirements are fulfilled in the most cost effective manner possible
- prioritizes the training and continuing educational needs of monitoring program staff
- develops funding proposals to accommodate these needs, as necessary

1.4.2 Role of TSS Program

The monitoring program provides ambient air monitoring data to the TSS Program for regulatory decisions. The TSS Program administers and oversees the monitoring program through the following activities:

- conducts monitoring program network planning and development
- provides monitoring program QA oversight
- supports the data management portion of the monitoring program data collection activities

1.4.3 Role of TSS Program Manager and RMS Section Supervisor

The TSS Program Manager and RMS Section Supervisor strive to improve the efficiency of monitoring program data collection activities through prudent, day-to-day allocation of monitoring program staff and other resources available within AQB. The monitoring program management (i.e., TSS program Manager, RMS Supervisor, and APS Supervisor) works closely with the monitoring program staff to ensure that all QAPP and SOP requirements are implemented in a timely, consistent, and technically appropriate fashion. The monitoring program management bring the QC training needs of the monitoring program staff to the attention of the TSS Program Manager. Finally, monitoring program management are expected to solicit input from the monitoring program staff when developing new or revised QAPPs.

1.4.4 Role of Monitoring Program Staff

Monitoring program staff play an important role in the implementation of the program. The monitoring program staff are responsible for assuring that monitoring program data collection activities are producing data of "reliable and known quality." The monitoring program staff are also responsible for developing new SOPs and/or completing revisions to existing SOPs. Monitoring program staff have a keen understanding of the technical strengths and weaknesses of monitoring program data collection activities. Therefore, monitoring program staff participation is essential in implementing the monitoring program QA policy. Efforts to document and improve, as necessary, the quality of ambient air monitoring data collected are among the most important functions of monitoring program staff.

1.4.5 Role of QA Manager

The QA Manager oversees the monitoring program planning, implementation, assessment, and reporting on the achievement of the applicable requirements of 40 CFR Part 58. The QA Manager responsibilities include:

- development of the monitoring program QMP and QAPPs
- approves externally developed ambient air monitoring QAPPs (see Section 1.4.6 Contracted Services & Supporting Technical Activities/Programs)

- approves outside-source generated ambient air monitoring QAPPs for pre-construction application and permit mandated compliance determinations (see Section 1.2 - QMP Scope and Applicability)
- maintenance of the monitoring program quality system documents (QMP, QAPPs, SOPs) including the periodic review and revisions with solicitation from the monitoring program staff
- provide QA assessment and oversight of monitoring program
- schedule, prioritize, conduct, and review performance evaluations (field audits)
- identification of the QA training needs of monitoring program staff and notification of the monitoring program management of program needs
- representation of the evolving informational needs of the monitoring program through various educational means

Additionally, the QA Manager advises monitoring program staff on QA/QC issues associated with analytical methods, sampling, and QAPP/SOPs design and implementation.

1.4.6 Contracted Services & Supporting Technical Activities/Programs

All ambient air monitoring data collection activities performed within the monitoring program or conducted by independent contractors or consultants must comply with this QMP and all DEQ air monitoring program QA/QC policies and procedures. This includes the development of QAPPs and SOPs, when applicable, that must be submitted to the monitoring program QA Manager for review and approval.

1.5 Ambient Air Monitoring Data Generation Policy

It is the monitoring program data generation policy that all ambient air monitoring data collection activities must be conducted in accordance with the applicable requirements of <u>40 CFR Part 50, 4 53, 5</u> and 58². This policy applies to data generated from the following ambient air monitoring data collection activities:

- NAAQS/MAAQS compliance monitoring.
- Other 40 CFR Part 58 applicable ambient air monitoring data collection activities.

All NAAQS/MAAQS compliance monitoring and other 40 CFR Part 58 applicable ambient air monitoring data collection activities must be adequately addressed in a QAPP, which includes DQOs, and implemented with SOPs.

When establishing QA/QC requirements for ambient air monitoring data collection activities outside NAAQS/MAAQS compliance monitoring and other required monitoring, the data generation policy is to use the 'graded approach.' The graded approach establishes the QA/QC requirements commensurate

⁴ - <u>40 CFR Part 50 - National Primary and Secondary Ambient Air Quality Standards</u>

⁵ - <u>40 CFR Part 53 – Ambient Air Monitoring Reference and Equivalent Methods</u>

with the importance of the work, available resources, and the unique needs of the ambient air monitoring data collection activity.

In the instances of ambient air monitoring data collection activities driven by public health concerns or emergencies where an immediate threat to human health or the environment exists, the monitoring program may be exempt from the preparation of QAPPs/SOPs. The reason for these ambient air monitoring data collection activity exemptions is that the situation may not be apparent or accessible after time is taken for planning activities.

NOTE: The monitoring program will respond to emergency episodes on a case-by-case basis as resources and/or capabilities allow.

1.5.1 Types or Sources of Ambient Air Monitoring Data

Ambient air monitoring data is distinguished as either *primary use data* (primary data) or *secondary use data* (secondary data). Primary data are defined as ambient air monitoring data originated by or on behalf of the monitoring program. Secondary data refers to ambient air monitoring data collected by permitted sources or contractors and submitted to the monitoring program for review and validation. Other terms such as "external data" and "data obtained from outside sources" are used to express the same concept of secondary data.

1.6 Monitoring Program Quality System Documents Approval Process and Revision Information

1.6.1 Quality Management Plan Approval Process and Revision Information

The AQB Bureau Chief administers the QMP. Because direct knowledge and familiarity with facilities, projects, and program mission are necessary for QMP development, the QA Manager is responsible for the development, maintenance, and revision of the QMP. The QA Manager and monitoring program management are responsible for QMP implementation and review at least annually to determine if it is up-to-date, accurately reflects the monitoring program's quality system, and is in compliance with current guidance and program requirements. Prior to a QMP update, the revised QMP is distributed to the monitoring program management for an opportunity to review and comment on the document. Once this internal review is complete, and comments have been evaluated and addressed, monitoring program QMP approval is acknowledged by AQB Bureau Chief and QA Manager signatures on the Approval Sheet located in the front of the QMP. The monitoring program QMP is then submitted to the DEQ QA Council for review and approval as a function of the Department's EPA approved QMP.

1.6.2 Project Level Document Approval Process and Revision Information

1.6.2.1 Quality Assurance Project Plans

Monitoring program management and the QA Manager are responsible for verifying that all QAPP and SOP requirements, as outlined in the QMP, have been met. The QA Manager has the responsibility for

developing in-house monitoring program QAPPs. Monitoring program QAPPs are critically reviewed for technical adequacy by the appropriate monitoring program management, evaluated for compliance with EPA Requirements for Quality Assurance Project Plans (EPA QA/R-5)[(OEI III.), see References] by the TSS Program Manager, and approved by the AQB Bureau Chief prior to scheduling ambient air monitoring data collection activities.

In addition, externally developed and outside-source QAPPs are reviewed and approved by the QA Manager and appropriate monitoring program supervisor. Revisions to a previously approved QAPP must undergo the same review and approval process as the original version.

1.6.2.2 Standard Operating Procedures

Monitoring program staff develop and maintain standard operating procedures annually. During initial development and annual maintenance, each SOP is reviewed by the QA Manager and approved by the TSP Program Manager, RMS Section Supervisor, or delegated staff, for the specific ambient air monitoring data collection activities to which it relates. If a SOP originates from an external contractual agreement and does not meet monitoring program criteria, it is returned to the contractor for revision and resubmitted to the program for final approval.

SOPs for activities currently in place and preceding the QMP approval were not rewritten, but were evaluated for compliance with QMP and QAPP requirements. Documentation of the SOP annual review are found in the maintenance list and schedule that is maintained under the responsibility of the QA Manager.

1.7 Monitoring Program Quality System Documents Period of Applicability

1.7.1 QMP Period of Applicability

The monitoring program QMP is reviewed annually and revised, as necessary, to ensure the continued production of known quality ambient air monitoring data. Conditions requiring revision or renewal of DEQ QA Council-approved QMP include:

- Expiration after five calendar year life span following date of DEQ QA Council approval;
- Major changes in monitoring program mission and responsibilities, such as changes in the delegation of a program;
- Re-organization of existing functions that affect the monitoring program; and
- Changes in 40 CFR Part 58 or other air monitoring regulations that affect the monitoring program's quality system.
- Assessment findings requiring corrective action and response.

A revised QMP is submitted to the DEQ QA Council within six months following any of the above listed conditions.

1.7.2 Project Level Document Period of Applicability

Quality Assurance Project Plans for long-term projects must be reviewed at least annually by the QA Manager for continued relevancy and must be revised as necessary.

Appropriate monitoring program staff and the QA manager review SOPs at least annually for continued relevancy. SOPs previously issued, but no longer in use, are maintained as outlined in **Section 5.0** - **Documentation and Records**.

2. Quality System and Description

The monitoring program quality system provides the framework for planning, implementing, documenting, and assessing the monitoring program work performed and executing the required QA/QC activities. This section details the principle components comprising the monitoring program quality system. In addition, this section describes how ambient air monitoring data flows through the monitoring program.

2.1 Quality System Components

Descriptions of the individual important aspects of the monitoring program quality system components are explained below. **Figure 2-1** illustrates the development of the monitoring program quality system.

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Figure 2-1. Monitoring program quality system components.

- **Policy And Regulations:** EPA directives and regulations determine what QA is required for the monitoring program. The standards and regulations pertinent to the monitoring program include:
 - Consensus Standards EPA's quality system is based on the document: ANSI/ASQ E4-2004. This document describes a basic set of mandatory specifications and non-mandatory guidelines by which a quality system for ambient air monitoring programs involving ambient air data collection activities can be planned, implemented, and assessed.
 - Internal Policies are those policies developed specifically by the EPA. The EPA Quality
 Policy CIO 2105.0 [(EPA I), see References] expresses the EPA policy in regard to the quality
 system development, implementation, and maintenance for all EPA organizations and nonEPA organizations performing work on behalf of EPA using EPA funding through extramural
 agreements. The EPA QA Orders adhere to ANSI/ASQ E4-2004 under the authority of the
 Office of Management and Budget.
 - External Policies Refers to the CFR. The references to the external regulations are those that apply to the quality system requirements for external funding. Those most important to the monitoring community are 40 CFR Parts 30,⁶ 31,⁷ and 35,⁸ but are not specific to ambient air monitoring.
 - Ambient Air -The consensus standards, internal, and external requirements then funnel to the EPA Headquarters and Regional programs where additional QA requirements and guidance, specific to an ambient air monitoring program, are included in the EPA Quality Assurance Handbook for Air Pollution Measurement Systems: "Volume II: Ambient Air Quality Monitoring Program" (EPA QA Handbook Volume II). [(OAQPS I), see References] Ambient air requirements include documents such as the Clean Air Act (CAA) and <u>40 CFR Part 50⁴, 53⁵, and 58²</u>, which are specific to ambient air monitoring.
- **Program:** Refers to the monitoring program's overall quality system. At this level, the program quality system features documentation in the form of a QMP. The QMP is an essential component of the monitoring program quality system and may be viewed as the "umbrella" document. The QMP includes the system assessments, annual reviews and planning documents, training and communications, and other supporting system elements.
- **<u>Project</u>**: The monitoring program QMP is supported by specific QAPPs for the individual ambient air monitoring projects. A QAPP is the "blueprint" by which ambient air monitoring projects are implemented and assessed, and how specific QA/QC activities are applied.

⁶ - <u>40 CFR Part 30 – Uniform Administrative Re Uniform Administrative Requirements for Grants and Agreements</u> with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations.

⁷ - <u>40 CFR Part 31 - Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments.</u>

⁸ <u>40 CFR Part 35 - State and Local Assistance</u>.

2.2 Program Level Quality System

2.2.1 Quality System Documentation

The QMP provides the basis for discussing changes and improvements to the monitoring program quality system. All monitoring program staff are required to read and be familiar with the QMP to ensure that they understand and follow the monitoring program quality management process. Following DEQ QA Council approval, a copy of the monitoring program QMP is posted on <u>DEQ's</u> <u>Monitoring Program Quality System Documents website</u> [(AQB II), see References].

2.2.2 Annual Review and Planning

The monitoring program quality system review, planning processes, and support documentation include, but are not limited to:

- Annual Monitoring Network Plan: In accordance with 40 CFR Part 58, subsection 58.10,⁹ the monitoring program produces an annual monitoring network plan. The network plan provides for the establishment and maintenance of the Montana ambient air quality surveillance system for all State run monitoring stations. The annual monitoring network plan also includes a discussion of the purpose of each monitor and provides evidence that siting and operation of each monitor meets the requirements in 40 CFR Part 58, Appendices A, B, C, D, and E. Additionally, the annual monitoring network plan includes proposed network State or Local Air Monitoring Station (SLAMS) modifications. Further, a network modification plan that implements the findings of the network assessment is included the network plan. The network modification plan is due no later than the year after submittal of the network assessment. The planning process also provides an opportunity for all county stakeholders and concerned parties to provide input into network activities. Finally, the network plan is available for public comment for 30 days on <u>DEQ's internet website</u> prior to EPA Region 8 Administrator submittal by July 1st each year. Public comments received during the public comment period are referenced and addressed in the final network plan that is submitted to EPA.
- <u>Periodic Network Assessment</u>: In accordance with 40 CFR Part 58, subsection 58.10 (d), a fiveyear interval network assessment is completed by the APS Section. The first monitoring network assessment, following promulgation of the 2006 monitoring rule, was sent to EPA in July 2010. The periodic network assessment is designed to determine if the network meets the monitoring objectives defined in 40 CFR Part 58, Appendix D. Pertinent issues include whether new sites are needed or existing sites are no longer needed and can be terminated to support air quality characterization for areas with relatively high populations of susceptible individuals (e.g., children with asthma). New technologies are evaluated for possible incorporation into the ambient air monitoring network. For any sites that are being proposed for discontinuance, the monitoring program must consider the effects on other data users, such as nearby States and

⁹ - <u>40 CFR Part 58.10 - Annual monitoring network plan and periodic network assessment</u>

Tribes or health effects studies. Specific to the State of Montana, the periodic network assessment also identifies needed changes to respirable particulate matter (PM) of less than or equal to 2.5 microns ($PM_{2.5}$) population-oriented sites, an estimate of air quality status at inhalable PM of less than or equal to 10 microns (PM_{10}) maximum concentration site, adjustments to PM_{10} monitoring schedules, and alternative site increased PM_{10} sampling frequency. Finally, the periodic network assessment findings are used to identify a plan and schedule for system modifications. The 5-year assessment findings and the schedule for implementing the findings, identified as the "network modification plan," are included in the following year's annual network plan. The network assessment is submitted to the EPA Region 8 Administrator.

• <u>Strategic Planning</u>: To aid in developing current and future ambient air monitoring goals the monitoring program utilizes the components of the strategic plan available on the EPA National Air Monitoring Strategy website [(Air and Radiation I), see References] such as the Monitoring Strategy Document, Ambient Air Monitoring Strategy for State, Local, and Tribal Air Agencies [(OAQPS II), see References]. Additionally, the findings of the 5-year periodic network assessments, discussed above, are important elements of the monitoring program's long-term strategic planning.

Additional information regarding monitoring program quality system planning is referenced in **Section 7.0 - Planning**.

2.2.3 System Assessments

A review of the management system may be completed by EPA Region 8 representatives or an independent third party contracted by the DEQ. Management systems reviews are normally performed at three-year intervals as part of the EPA Region 8 Technical Systems Audit (TSA). Review findings are shared with the AQB Bureau Chief and monitoring program management.

2.2.4 Supporting System Elements

The following requirements apply to monitoring program database sources:

- <u>Utilization of a Central Database</u>: All continuous ambient air monitoring data collected by or for the monitoring program is stored in a "central" data polling computer system.
- <u>Additional Monitoring Program Databases:</u> PM QA/QC activity reports reside in-house developed applications and databases.

Any other databases in use by the monitoring program or its contractors are subject to the standards outlined in the QMP.

All monitoring program database systems are "beta" tested before they are first used and any time programming changes are made. Beta testing consists of taking a set of "dummy" data and processing it

through the new or modified version of a computational computer program before incorporating the changes into the monitoring program's data storage, validation, and submittal processes. Periodically, a beta test is performed to validate whether or not computations are being performed in the same manner as they were at the time of the last change. All changes and beta tests are documented in an electronic log or table. The QA Manager periodically reviews the database information by hand calculating selected data sets to validate accuracy of data reporting. Affected monitoring program managers identify any major data quality weaknesses of the database system and establish a plan and timetable, for any improvements. Formal database user manuals with established QA/QC procedures for all monitoring program database systems are required.

Additional supporting system elements such as monitoring program procurement of items and services and supplementary information regarding computer hardware/software are referenced in **Sections 4.0** - **Procurement of Items and Services** and **6.0** - **Computer Technology**, respectively.

2.2.5 Training/Communications

The monitoring program provides adequate training in the applicable policies, procedures, and requirements of maintaining a quality system at all levels in the program. Training will be consistent with the role of the individual staff member in the overall quality system, but may be more comprehensive.

The monitoring program does not currently implement a formal, comprehensive training program on quality systems. Training is currently arranged primarily on an ad hoc basis depending on need, funding, and availability. Overall, availability of training is heavily dependent on courses offered by EPA, Western States Air Resources Council [(WESTAR), see References] and National Association of Clean Air Agencies [(NACAA), see References], interstate organizations, and, to a much lesser extent, private training entities.

Additional information regarding the monitoring program training is referenced in Section 3.0 - Personnel Qualifications and Training.

2.2.6 Implementation

All monitoring program management and staff are expected to carry out their responsibilities under the QMP. Monitoring program management are expected to foster an appreciation for the role of QA/QC among their monitoring program staff. In turn, monitoring program management shall carefully consider the QA/QC opinions and insights of monitoring program staff. The quality and credibility of the monitoring program ultimately depends on the willingness of all employees to work as a team, learn from their mistakes, and continually strive for improvement. Additional information regarding the monitoring program quality system implementation of work processes is referenced in **Section 8.0** - **Implementation of Work Processes**.

2.3 Project Level Quality System

2.3.1 Systematic Planning: Development of DQOs

The development of DQOs is mandatory under EPA QA/R-5. DQOs may be a simple statement of why data is being collected and what data outputs are considered significant. Others require a complete statistical approach as described in the EPA document Guidance on Systematic Planning Using the Data Quality Objective Process (EPA QA/G-4) [(OEI IIII), see References]. QAPP reviewers must assure that the QAPP specifically addresses the technical adequacy of DQOs. DQOs are intended to accomplish the following:

- Clarify the objectives;
- Define the most appropriate types of data to collect;
- Determine the most appropriate conditions under which to collect the data; and,
- Specify the level of uncertainty that is acceptable as the basis for establishing the quantity and quality of data needed.

2.3.2 Quality Assurance Project Plans

All NAAQS/MAAQS compliance or other required field sampling and laboratory analysis must be conducted in accordance with an approved QAPP to ensure the DQOs are met. All NAAQS/MAAQS compliance or other required ambient air monitoring data collection activities conducted by, on behalf of, or submitted to the monitoring program must be addressed in a project-specific QAPP. Quality assurance project plans must be developed per requirements specified in EPA QA/R-5 or approved alternative format outlining the required elements for outside sources. Consistent with EPA Region 8, the elements defined in EPA QA/R-5 must be addressed adequately before a QAPP may be approved. **Table 2.1** provides a summary of required QAPP elements.

Ambient air monitoring data collection activities that would be covered in a QAPP include, but are not be limited to, ambient air monitoring data, observing and recording field observations, and performing analyses in the field and in field laboratories. Physical measurements and observations in the field would include meteorological measurements, barometric pressure, temperature, etc. The QAPP must describe ambient air monitoring data methods of collection, analyses, transportation, and documentation for each of these activities.

All analytical work performed must be as specified in a project QAPP, and must meet minimum standards as defined in the SOPs as referenced in **Section 2.3.3 - Standard Operating Procedures**. Any additional QA/QC and deliverable requirements that are contained in the technical specifications in a project QAPP must also be performed, documented and provided. Failure to comply with these requirements may result in rejection of data.

NOTE: The QAPP requirement is subject to ambient air monitoring data generation policy exemptions presented in **Section 1.5 - Ambient Air Monitoring Data Generation Policy**.

Project Management	
A1 Title and Approval Sheet	The elements in this group address the basic area of
A2 Table of Contents	project management, including the project history and
A3 Distribution List	objectives, roles and responsibilities of the participants,
A4 Project/Task Organization	etc. These elements ensure that the project has a
A5 Problem Definition/Background	defined goal, that the participants understand the goal
A6 Project/Task Description	and the approach to be used, and that the planning
A7 Data Quality Objectives for Measurement Data	outputs have been documented.
A8 Special Training/Certification	
A9 Documents and Records	
Measurement/Data Acquisition	
B1 Sampling Process Design	The elements in this group address all aspects of
B2 Sampling Methods Requirements	project design and implementation. Implementation of
B3 Sample Handling and Custody Requirements	these elements ensure that appropriate methods for
B4 Analytical Method Requirements	sampling, measurement, and analysis, data collection
B5 QC Requirements	or generation, data handling, and QC activities are
B6 Instrument/Equipment Testing, Inspection, and	employed and properly documented.
Maintenance	
B7 Instrument/Equipment Calibration and	
Frequency	
B8 Inspection/Acceptance of Supplies and	
Consumables	
B9 Non-direct Measurements	
B10 Data Management	
Assessment/Oversight	
C1 Assessments and Response Actions	The elements in this group address the activities for
C2 Reports to Management	assessing the effectiveness of the implementation of
	the project and associated QA/QC activities. The
	purpose of assessment is to ensure that the QA Project
	Plan is implemented as prescribed.
Data Validation and Verification Methods	The elements in this group address the QA activities
D1 Data Review, Validation, and Verification	that occur after the data collection or generation phase
D2 Validation and Verification Methods	of the project is completed. Implementation of these
D3 Reconciliation with Data Quality Objectives	elements ensures that the data conform to the
	specified criteria, thus achieving the project objectives.

Table 2-1. Quality Assurance Project Plan Required Elements

2.3.3 Standard Operating Procedures

All ambient air monitoring data collection activities incorporate the use of SOPs to document a routine, frequent task or repetitive activity. Standard operating procedures are formal written records of the methods used to implement ambient air monitoring data collection activities. Standard operating procedures document the protocols and processes used in the collection, preservation, transport,

transfer and analysis of ambient air monitoring data. As such, SOPs facilitate consistency among the monitoring program staff and serve as valuable references and training tools.

The EPA document, Guidance for Preparing Standard Operating Procedures (SOPs) [(OEI V), see References] is used as a guide in developing SOPs. SOPs are referenced in QAPPs where appropriate.

2.3.4 Ambient Air Monitoring Projects

The QA/QC objectives presented in the QMP apply to activities that are conducted directly by monitoring program staff, activities performed for the monitoring program, activities performed under EPA grants, and activities performed under any inter-governmental agreement when resulting ambient air monitoring data are intended for use in the monitoring program.

2.3.5 Technical Assessments

Monitoring program technical assessments include, but are not limited to:

- <u>Technical Systems Audits:</u> The monitoring program may be audited by the QA Manager, EPA Region 8 representatives or an independent third party contracted by the DEQ. Technical systems audits (TSA) may consider the adequacy of physical facilities, equipment, personnel, training, field and laboratory procedures, recordkeeping, data validation, and management, and other aspects of the targeted monitoring programs/projects. Most monitoring program internal TSAs are performed based upon identified need to fix inadequacies. EPA Region 8 TSAs are normally performed at three-year intervals.
- <u>Systems Audits</u>: Systems audits are systematic and objective examinations of the State and local ambient air monitoring sites. The systems audits results are used to determine whether ambient air monitoring data collection activities and related results comply with the project's QAPPs/SOPs, and are suitable to achieve its data quality goals. The EPA document Guidance on Technical Audits and Related Assessments for Environmental Data Operations, [(OEI VI), see References] serves as the principle written guidance for planning and conducting systems audits. System audits are completed at five-year intervals (if resources permit) by the QA Manager or RMS Section staff member.
- <u>Performance Evaluations (Field Audits)</u>: The primary intention of such audits is to determine whether QAPP specified practices are being followed. Field audits consist of an on-site visit to the sampling location and observing the sampling practices with performance evaluations of the sampling equipment. The project records and SOPs are reviewed and findings documented. Field audits occur throughout the year.
- <u>Laboratory Audits</u>: Audits of laboratory operations are conducted while project samples are under analysis, or performed after analysis is completed. Laboratory audits are performed at three-year intervals (if resources permit).

• **Data Inspection:** When results of laboratory analyses are received, an inspection of analytical deliverables is performed to determine whether the work performed was consistent with the instructions provided to the laboratory.

Technical assessment findings are shared with the monitoring program management and affected staff. Corrective actions stemming from TSAs are implemented as soon as feasible; corrective actions resulting from other types of technical assessments are implemented pursuant to **Section 9.2 - Corrective Action**.

2.3.6 Data Verification and Validation

All ambient air monitoring data is reviewed and evaluated against QA/QC criteria and validated before being uploaded into the EPA's AQS database system. RMS Section monitoring program staff are responsible for ensuring the ambient air monitoring data collected meets QC objectives before the ambient air monitoring data is uploaded to AQS. When using secondary data, it is usually not possible to review all of the metadata associated with the ambient air monitoring collection activity. However, secondary data review efforts follow similar primary data QA/QC protocols for data verification and validation. It is the policy of the monitoring program that project files and records indicate the source of the data to accurately state who produced the ambient air monitoring data because of the inherent limitations when using secondary ambient air monitoring data.

To assure the quality of the ambient air monitoring data collected and reported, practices established in the document EPA Guidance on Environmental Data Verification and Data Validation have been adopted [(OEI VII), see References]. It is the responsibility of the QA Manager to verify all QA requirements are met before the ambient air monitoring data is uploaded into AQS.

2.3.7 Data Quality Assessment

Data quality assessments (DQA) focus largely on sampling design and monitoring frequency and the general adequacy of the data relative to the stated purpose. Elements D1, D2 and D3 of EPA QA/R-5 require that QAPPs identify data assessment procedures. These elements specifically include items on how data are reviewed, validated and qualified. Element D3 requires reconciliation with stated DQOs. An assessment of the usability and limitation of the field and analytical data collected with respect to the original DQOs must be documented after completing the data collection activities.

The monitoring program may conduct a formal DQA to ensure the collected data meets the established DQOs, using the procedures detailed in the EPA document Data Quality Assessment: A Reviewer's Guide [(OEI VIII), see References]. Primarily, a DQA is performed on collected SLAMS or regulatory SPM monitoring data, which is near or at the level of the NAAQS. The DQA addresses and supports the primary monitoring objective of NAAQS compliance determinations over the standard interval (3 years). For more information on the relationship of DQAs within the monitoring program, refer to **Section 10 – Quality Improvement**.

3. Personnel Qualifications and Training

It is the monitoring program policy that appropriate training is made available to persons supporting the monitoring program commensurate with their duties, as resources allow.

3.1 Monitoring Program Staff

The monitoring program must follow and adhere to State and DEQ personnel rules and policies to ensure all monitoring program staff are qualified and meet the required job specifications. Qualifications are established by each position's Job Profile, which describes the job specifications and the education and /or experience necessary to fill that position. All job applications are reviewed by DEQ's Human Resource Office to ensure applicants meet the minimum job requirements. Monitoring program management interview qualified applicants to assess their qualifications and potential compatibility with the program.

Newly hired monitoring program staff receive on-the-job training provided by the monitoring program management, QA Manager, and senior staff. Our new hires are expected to read all pertinent instrumentation manuals, SOPs, and the QAPPs in the initial six-month probationary period. The basic knowledge and skills required for the different monitoring positions are similar; all RMS Section monitoring program staff shall be proficient at both gaseous and PM ambient air data collection activities.

Monitoring program management assure the training needs are satisfied. New hire competencies and proficiencies are evaluated at three-months and six-months during the probationary period. Annual employee performance evaluations are performed on all staff by their immediate supervisors. The field audit team members are trained by the QA Manager. Current monitoring program staff training records are maintained in the DEQ Training Log on the DEQ ShareNet website.

3.2 Site Operators

Site operators are trained for routine equipment operations, sample collection, log recording, preventive maintenance, and in-field troubleshooting. Site operator training consists of all steps needed to operate a monitoring station. Training sessions are conducted for new site installations and repeated as new site operators are employed. The monitoring program also provides site operators with ongoing telephone support for assistance on resolving operational issues. Written SOPs provide site operators with detailed guidance for all procedures. Within the monitoring program, the RMS Section Lead Worker trains monitoring program staff on all instrument calibration, maintenance, and site operator training procedures. Current records regarding site operator training activities are maintained in the Air Monitoring Training spreadsheet under the direction and responsibility of the QA Manager.

3.3 QA Manager

Prerequisites for the QA Manager position are education, training, and experience in atmospheric chemistry, QA/QC, field sampling, meteorology and statistics. On the job training starts with a review of

the current monitoring program QAPPs and associated SOPs. The QA Manager is required to be familiar with and have a comprehensive understanding of the following air monitoring regulations, guidance, and information:

- <u>40 CFR Part 50⁴, 53⁵, and 58²;</u>
- EPA QA handbooks for ambient air monitoring data collection activities: Quality Assurance Handbook for Air Pollution Measurement Systems Volume I: A Field Guide to Environmental Quality Assurance (EPA QA Handbook Volume I) [(OAQPS III), see References]; Quality Assurance Handbook for Air Pollution Measurement Systems Volume IV: Meteorological Measurement [(OAQPS IV), see References]; and EPA QA Handbook Volume II;
- EPA Agency-wide Quality System documents [(EPA II), see References]; and,
- EPA Model QA Project Plans.

Online courses available through the EPA Quality System, Training Courses on Quality Assurance and Quality Control Activities [(EPA III), see References] and EPA Air Pollution Training Institute: APTI-Learn [(EPA IV), see References] provide additional quality system and QA/QC training. QA courses are also occasionally offered through EPA Region 8 headquarters. Additionally, attending the annual EPA QA conferences and review of applicable literature, including periodicals, is recommended to remain educated on the changes to monitoring regulations and new methodologies.

3.4 Continuing Education Opportunities

Monitoring program staff are actively encouraged to pursue training opportunities whenever possible and as needed. A number of opportunities are available that provide additional certifications and skills, including but not limited to, APTI, WESTAR, and NACAA on-line and classroom training courses. Additional continuing education opportunities are available through job rotation, review of applicable publications, and attending workshops and conferences.

Methods employed in the collection and analyses of ambient air monitoring data collection are subject to continual review and improvement. Occasional conceptual or technological breakthroughs may rapidly antiquate existing procedures and protocols and require training for affected monitoring program staff.

The RMS Section Lead Worker provides training for newly-purchased equipment with new technologies. When new regulations are promulgated, the QA Manager informs all of the program staff about the implications and relevant applications.

3.5 Roles, Responsibilities and Authorities for Assessing and Allocating Training

As stated previously in this section, the monitoring program implements a training program conducted by senior staff to ensure quality in ambient air monitoring data collection activities. Monitoring program management have the primary responsibility for implementation of their programs, including ensuring adequate training of monitoring program staff.

3.6 Safety Considerations

Monitoring program staff may encounter potentially hazardous situations on the job. In addition to the routine possibility of automobile accidents, the monitoring program staff may encounter heavy equipment, slippery surfaces, toxic substances, fire or electrocution hazards, infectious microorganisms, vicious animals, belligerent persons, or other threatening situations. Injuries or illnesses resulting from such situations may limit the services of valuable staff skills. To minimize this risk, monitoring program staff must observe all safety requirements set forth in applicable QAPPs and SOPs described in **Sections 2.3.2 - Quality Assurance Project Plans** and **2.3.3 - Standard Operating Procedures**.

4. Procurement of Items and Services

Equipment and services are procured by the monitoring program through direct purchase, contracts, or cooperative agreements. All procurement procedures follow the Montana Procurement Act through DEQ's Procurement Delegation Agreement with the Montana Department of Administration and federal procurement regulations administered by the monitoring program.

4.1 Direct Purchase

AQB has the responsibility to procure all equipment and services for the air monitoring network. AQB procures equipment in two ways depending upon the scope of work in a particular contract. AQB may prepare a Purchase Order and procure equipment directly from a vendor or hire a contractor to purchase the equipment.

4.2 Quality of Procured Goods and Services

Best practices have the monitoring program inspecting delivered items within two to five days of their receipt followed by notification to the vendor within one or two days thereafter regarding acceptance or non-acceptance. Vendor notification for items found to be unacceptable include requirements necessary to cure the breach and provide the monitoring program with an acceptable deliverable.

4.3 Contracts for Services and Cooperative Agreements

AQB typically awards contracts for one year with the option to extend the contract on an annual basis for up to an additional six years. When additional tasks are required during the term of a contract, AQB issues a contract modification and provides the necessary funding based upon an agreed scope of work and cost with the contractor.

Contractors may be chosen by open competition or by their ability to provide a needed service, as described in a project QAPP or SOP (See Section 1.4.6 Contracted Services & Supporting Technical

Activities/Programs). Laboratory services are generally provided by contracted services with private laboratories and/or other governmental entity laboratories. For certain types of laboratory testing, such as for metals or organic compounds, annual certifications of accreditation are required and the accreditations must be provided to the AQB.

For other types of laboratory tests, accreditation based on audits performed by licensed accreditation auditors is sufficient for validating if the laboratory can adequately perform the testing to the required standards. In the case of gravimetric laboratories, there are no standardized accreditation services available. To assure regulatory compliance within the contracted laboratory, an audit is conducted by the QA Manager, delegated DEQ representative, or EPA representative prior to any submitted samples and annually thereafter, to insure quality data. These audits focus on adherence of QA/QC activities as agreed to in the annual laboratory contract. If the QA/QC portion of the contract is not being followed, corrective actions must be taken immediately by the contract laboratory to correct the problems. If problems are not corrected in a timely manner the contract may be revoked. If deficiencies are noted during the annual audit, the contract may be modified to account for deficiencies during contract renewal. Laboratory audits are completed every 3 years (if resources permit) and the schedule is maintained by the QA Manager.

Deliverables received from contractors are reviewed by monitoring program management to ensure objectives of the applicable QAPP and/or SOP are met. Unsatisfactory work is noted, and if the condition cannot be corrected, the QA Manager is notified. Requirements addressing QA/QC activities are based on the applicable QAPP or SOP.

Cooperative agreements are used when both parties derive benefit from the service. State grants or cooperative agreements with universities or other states are examples of mutually beneficial assistance agreements.

5. Documentation and Records

The primary responsibility of monitoring program data record keeping falls upon the RMS and APS Sections, and data management staff. Monitoring program quality system documents and electronic databases adhere to the authorization processes referenced in **Section 2.0 - Quality System and Description**. Monitoring program staff review the QC documentation as part of ambient air monitoring data verification and validation to ensure that the correct QAPP/SOP implementation occurred. The QA Manager verifies the accuracy transmittal prior to AQS uploads. Documentation of contracted services such as laboratory work is reviewed during audits to ensure that completed work is accurate.

For the purposes of this QMP:

• **Documents** are publications and forms that are generated by the monitoring program for use by the staff and public to prescribe processes, specify requirements, or establish design. Documents can be distinguished from records by their potential for revision. Documents include

the monitoring program quality system documents, network plans, monitoring network assessments, QA/QC activity forms with acceptance criteria, and internal policies and guidance.

• <u>Records</u> provide evidence of activities carried out by the monitoring program and by external entities such as a regulated facility. Records can be distinguished from documents by the singular nature of their creation and use (i.e., you cannot change the information on the record because it tells what happened). Records include documentation of completed QA/QC activities, such as analyzer performance audits, calibrations, and sampler flow rate verifications.

5.1 Distribution, Storage, and Disposition of Documents and Records

The monitoring program has a structured records management retrieval system that allows for the efficient archive and retrieval of records; it is organized in a similar manner to the EPA's records management system. The system follows a coding scheme to facilitate easy retrieval of information during EPA technical systems audits and network reviews. All documents and records produced by the monitoring program are maintained according to the applicable records retention periods defined in the Montana Code Annotated (2-6-202, 2-6-401 MCA).^{10,11} At a minimum, documents and records for the monitoring program are securely stored on-site for five years or the life of the document plus one year after the document is superseded.

For more information on the monitoring program's documents and records, including type, location, backup, retention, archiving, and disposition requirements, refer to the Monitoring Program Records Management Plan.

5.1.1 QMP, QAPPs and SOPs

The monitoring program QMP, QAPP and SOP quality system documents are called "controlled" documents, and are maintained by the QA Manager. All previously issued quality system documents are maintained on-site for three years after superseded, and then offered to the Montana Historical Society for archive. It is the QA Manager's responsibility to ensure that all parties on the QAPP distribution list receive revised copies of the QAPP. It is the responsibility of monitoring program staff to ensure all affected parties receive updates to the SOPs. Previously issued QAPPs and SOPs are exchanged for new revisions electronically via email and/or hardcopy if delivered in person. For more information on controlled documents, refer to **Section 8.1 - Document Control**.

5.1.2 Annual Monitoring Network Plan

The RMS Section Supervisor is responsible for archive of annual monitoring network plan publications; ten years on-site and then offered to the Montana Historical Society for archive. Network plans are available on <u>DEQ's internet website</u> for public comment 30 days prior to EPA submittal. Additional archives are available at the Montana State Library.

¹⁰ - Montana Code Annotated (MCA), Title 2, Chapter 6, Part 2, 202 - Definitions.

¹¹ - MCA, Title 2, Chapter 6, Part 2, 401 – Definitions.

5.1.3 Periodic Network Assessment

The five-year interval periodic network assessment archive is maintained by the APS Section; ten years on-site and then offered to the Montana Historical Society for archive. Network assessments are available on <u>DEQ's internet website</u> for public comment 30 days prior to EPA submittal. Additional archives are available at the Montana State Library.

5.1.4 Quality Management System Reviews and Technical System Audits

Management System Reviews, TSA reports and correspondence are maintained 10 years on-site then offered to the to the Montana Historical Society for archive.

5.2 Electronic Data Collection and Archive

Raw electronic data is stored for a minimum of ten calendar years from the time of measurement. Monitoring data records are archived in the database files. Completed performance audit reports are maintained as electronic secure Adobe pdfs for ten years. To ensure the integrity of the data collection system, all data acquisition and management components are implemented in a client-server environment operating under Microsoft (MS) windows. Furthermore, only authorized users can access the database. Editing privileges are approved as needed. Continuous and manual monitoring database records within the "central" polling computer system are backed up nightly by the Montana Department of Administration, thereby allowing for recovery of ambient monitoring data if disaster strikes.

Most ambient air monitoring data are uploaded to the EPA's AQS database system. The EPA is responsible for maintaining the AQS database. Additionally, DEQ maintains daily archives of all "Today's Air" information located on <u>DEQ's internet website</u>.

5.3 Corrective Action

The corrective action files archive is the corrective action folder on the DEQ's network. The corrective action filings in the corrective action folder are maintained by the QA Manager; all corrective action files are maintained ten years on-site, and then discarded.

5.4 Sample Handling and Custody Requirements

The monitoring program quality system includes an effective procedure for preserving the integrity of the ambient air monitoring samples. Monitoring program custody requirements extend to all filterbased particulate samples following chain of custody (COC) procedures from operator to laboratory. Field sites use COC forms for each sample beginning with placement of the filters in the sample collection modules. Subsequent laboratory COC is maintained through all analytical steps to final sample archival.

6. COMPUTER TECHNOLOGY

DEQ's Office of Information Technology (OIT) provides central coordination and support of information technology services for DEQ. OIT provides systems administration, applications development and support services to the department and its regional offices. OIT is responsible for the planning, project management, in-house or contracted development, and implementation and maintenance of information technology solutions to provide services to the department's employees, vendors and the general public.

OIT operates a quality management system described in the OIT Quality Management Plan, OIT-QA-QMP-001 [(OIT I), see References]. This QMP details the QA components adopted by OIT to ensure that within the constraints of available resources, quality assurance activities are conducted to assure information technology systems that process, store and deliver environmental and other business data are of known quality and appropriate for their intended use. The OIT QMP was approved by the managers of OIT and the Chair of the department's QA Council.

6.1 Computer Hardware and Software

The OIT QMP presents the standards, principles and practices that implement the OIT Quality Policy and form the foundation for the OIT quality system. The QMP details the roles and responsibilities of OIT staff to procure, develop and maintain computer systems and software that protects and supports the quality of environmental data. Further, the QMP describes the processes for hardware and systems administration, IT project management and software development, database administration, and quality systems employed to manage IT operations within DEQ. Refer to the OIT Quality Management Plan for more information about the management of DEQ computer hardware and software.

7. Planning

It is monitoring program policy to employ the DQO Process using EPA QA/G-4, as its primary planning tool for data collection. The use of the DQO process ensures that ambient air monitoring data collected is adequate for its intended use.

Additionally, all ambient air monitoring operations involving the generation and analysis of air monitoring data must be systematically planned and documented. To that end, use of QAPPs in the ambient air monitoring data collection activities is required. Monitoring program roles, responsibilities and processes for developing, reviewing, approving, implementing, and revising QAPPs are referenced in **Section 1.6 - Monitoring Program Quality System Documents Approval Process and Revision Information**.

Finally, the full range of planning documents employed by the monitoring program include the annual budget, work plans associated with federal grants/agreements, the annual network plan, the periodic network assessment, and the QMP. Utilizing the aforementioned documents and assessments, the planning process for the future of monitoring program is directed by the APS Section.

8. Implementation of Work Processes

A primary objective of the QMP is to ensure that all collected ambient air monitoring data or information is necessary and of expected quality for its desired use. To achieve this objective, all ambient air monitoring data collection activities are implemented by monitoring program management and staff supported by approved QAPPs and SOPs. Section 2.0 - Quality System and Description, addresses quality system implementation and Section 1.6 - Monitoring Program Quality System Documents Approval Process and Revision Information, addresses the document approval processes to ensure the QA/QC objectives are met. The QA/QC documentation and random or as needed field audits and other checks are used as tools to verify that affected monitoring program staff and site operators are following the affected QAPP and completing the work as planned.

In the event of unforeseen circumstances, any deviation from approved procedures shall be documented and reported by the appropriate monitoring program management to the TSS Program Manager and QA Manager. The significance of any deviation and any subsequent adjustments or corrective actions shall be determined by the TSS Program Manager and QA Manager with input from the appropriate monitoring program management and staff performing the work.

The monitoring program staff and supervisory expectations in the event of a departure from approved procedures shall be addressed in the approved QAPP. Obsolete QAPPs/SOPs are removed from work areas as described in **Section 5.0 - Documentation and Records**. Verification to determine that QAPPs/SOPs are current at monitoring sites occurs during systems audits and performance evaluations (field audits). Verification to determine that analytical QAPPs/SOPs are current occurs during laboratory audits.

8.1 Document Control

The purpose of document control is to provide the latest written procedures to all affected parties within the monitoring program. The monitoring program's quality system includes a system for updating formal documentation of operating procedures and issuing the latest version of the technical documents. The document control system uses standardized indexing format and provides for convenient replacement of pages that may be changed within the technical procedure descriptions based on the control format described in the EPA QA Handbook Volume I.

The indexing format includes, at the top right of each page, the following information:

- Section Identifies major one-place section
- Revision Represents the most current version of the section (the first version is represented as "0")
- Date Date of the current revision
- Page Includes both the number of the specific page, and the total number of pages in the QAPP section or total number of pages in QMP or SOP

9. Assessment and Response

9.1 Assessments

Assessments are intended to increase the user's understanding of the system being examined and to provide an objective basis for improvement. Pursuant to **Section 2.0** - **Quality System and Description**, ambient air monitoring data collection activities covered by the QMP are subject to internal and external assessments including, but not limited to, management system reviews, TSAs, performance evaluations (field audits), and data quality assessments. Primary assessment tools selected during the planning stages of a program/project shall be specified within the applicable QAPP.

The assessment and response activity for individual projects are typically addressed in "Section C" of specific monitoring program QAPPs as referenced in **Section 2.3.2 – Quality Assurance Project Plans**. Special assessments may be implemented at the discretion of monitoring program management, QA Manager, or other parties at any time. Assessment discrepancies are resolved by the corrective action process in **Section 9.2.1 - Corrective Action Process**. The QMP itself is assessed for effectiveness and revised as needed at least annually, but may be reviewed and revised whenever a problem is noted.

9.2 Corrective Action

Corrective action resulting from the assessment and oversight phase or during the data validation phase normally indicates an investigation is needed to validate the ambient air monitoring data for a certain period of time. Primarily, this action is required following the review of the QA/QC activities (such as calibrations or assessment results) that show an analyzer/sampler operated outside the established acceptance criteria. If monitoring program personnel suspect erroneous data, equipment failure, or another undesired effect, they can initiate corrective action requests, which may be issued to any monitoring program staff involved in ambient air monitoring data collection.

Short-term corrective action typically involves recalibrating an instrument found to be operating outside of the established acceptance criteria. Long-term corrective actions necessary to eliminate non-conformance with monitoring program objectives involves invalidating previously collected and submitted ambient air monitoring data. These corrective actions are normally identified during assessments such as performance evaluations (field audits). Invalidation of data may also be required following equipment repair. Long-term corrective action also includes, but is not limited to, issues resulting from monitor siting, gaseous pollutant sample residence times, and the use of defective standards to complete a check or calibrate an instrument. Implementing the long-term reporting and recording corrective action includes the following steps:

- 1. Defining the problem.
- 2. Completing the Monitoring Program Corrective Action Request Form (CARF), included in **Attachment 2**.
- 3. Assigning responsibility for investigating the problem.

- 4. Investigating and determining the cause of the problem.
- 5. Determining a corrective action to eliminate the problem.
- 6. Documenting the corrective action procedures.
- 7. Assigning and/or accepting responsibility for implementing the corrective action.
- 8. Implementing the corrective action.
- 9. Notifying the appropriate monitoring program supervisor, QA Manager or others in the chain of command.
- 10. Archiving the corrective action documentation in the monitoring program corrective action folder on the network drive.

Additionally, the corrective action investigation that occurs during the data validation process may involve a resolutions team to evaluate the data, instrument, or QA/QC activity in question in order to validate the ambient air monitoring data. This resolution process is developed in detail in the Monitoring Program QAPP, Section 21.2.5 - Resolving and Communicating Data Validation [(AQB III), see References].

9.2.1 Corrective Action Process

The monitoring program has devised a method for long-term corrective action implementation and tracking. If a procedure or inspection uncovers a discrepancy with respect to clearly written specifications, the monitoring program management, QA Manager or staff may initiate the corrective action including documenting a CARF, included in **Attachment 2**. This type of corrective action is tracked in the RMS Section network drive corrective action folder both at the time of issuance and when the corrective action is completed. The additional steps to the long-term assessment process are as follows:

- 1. Complete the CARF.
- 2. Send notification by e-mail to the monitoring program staff responsible for completing the corrective action investigation with a copy to the QA Manager and RMS Section Supervisor.
- 3. Place "original" CARF in the RMS Section network drive corrective action folder this identifies the start of the corrective action.
- 4. Conduct an investigation to identify the cause of non-conformance.
- 5. Determine the resolution to eliminate the source of non-conformance (i.e., maintenance, repair, calibration, etc.).
- 6. Include other recipients as applicable to address other required actions to correct any affected data as a result of non-conformance (i.e., data alterations, invalidations, etc.).
- 7. Identify a solution to avoid future related non-conforming events.
- 8. Implement the corrective action.
- 9. Notify issuer, QA Manager, and RMS Section Supervisor by e-mail of the completed CARF.
- 10. Obtain signatures of issuer, recipient(s), and QA Manager on the completed CARF (QA Manager responsibility).
- 11. Place the "final" completed CARF in the corrective action folder on the network drive.

9.2.2 Corrective Action Follow-up

It is the responsibility of the appropriate monitoring program management and QA Manager to review the corrective action to ensure it was implemented as designed. The following steps outline corrective action follow-up:

- 1. establish the effectiveness of the corrective action
- 2. verify that the corrective action has eliminated the problem
- 3. archive the corrective action review documentation in the RMS Section network drive corrective action tracking spreadsheet

Follow-up on long-term corrective action is the responsibility of the QA Manager. This follow-up is to ensure that the corrective action was implemented as designed.

10. Quality Improvement

Quality management system reviews of the monitoring program quality system and QA/QC activities are conducted in accordance with the EPA document Guidance on Assessing Quality Systems [(OEI VIIII), see References]. Several of the specific processes are described in **Section 2.2 - Program Level Quality System** and **2.3 - Project Level Quality System**.

The review and evaluation of the QA/QC activities during the annual data certification and EPA TSA performed every three years provide the necessary feedback for continual improvement of the monitoring program. Additionally, completed data quality assessments (DQAs) provide another means of continued quality improvement within the monitoring program. The results of DQAs are conveyed to all program/project participants, particularly where corrective actions are required to improve the quality of future projects. Further, concluded corrective actions stemming from these assessments are maintained and tracked by the QA Manager. Finally, significant DQA findings are incorporated into the ambient air QA life cycle of planning, implementation, assessment, and reporting.

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Attachment 1 – Monitoring Program Organizational Charts

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Figure Attachment 1-1. Monitoring program organization chart.

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Figure Attachment 1-2. Monitoring program data user relationships.

Attachment 2 – Monitoring Program Corrective Action Request Form (CARF)

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Figure Attachment 2-1. Monitoring program Corrective Action Request Form (CARF).