Guide to Writing Quality Assurance Project Plans for Ambient Air Monitoring Networks

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EPA-454/B-18-006
August 2018

Guide to Writing Quality Assurance Project Plans for Ambient Air Monitoring Networks

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

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Disclaimer

The statements in this document, with the exception of referenced requirements, are intended solely as guidance. This document is not intended, nor can it be relied upon, to create any rights enforceable by any party in litigation with the United States. This guidance may be revised without public notice to reflect changes in EPA's approach to implementing 40 CFR Parts 50, 53, and 58.

Mention of commercial products or trade names should not be interpreted as endorsement. Some types of instruments currently in use in monitoring networks may be described within this guide. Sometimes these products are given as a typical and perhaps well-known example of the general class of instruments. Other instruments in the class are available and may be fully acceptable.

Acknowledgements

This document began as part of a project in EPA Region 4 to develop a new tool to assist Region 4 State/Local/Tribal (SLT) air monitoring organizations with writing and/or revising Quality Assurance Project Plans (QAPPs) for ambient air monitoring networks. The initial product was developed through collaboration between Stephanie McCarthy (EPA Region 4), Jason Bodenhamer (Forsyth County Office of Environmental Assistance and Protection), and Melinda Ronca-Battista (Institute of Tribal Environmental Professionals) and shared with Region 4 S/L/Ts in October 2017.

In December 2017, an EPA QAPP Workgroup formed with a goal of finalizing the document such that it could be used as a new tool to assist personnel in any S/L/T monitoring organization across the EPA Regions. Workgroup members included EPA quality assurance (QA) and ambient air monitoring technical staff responsible for reviewing and approving QAPPs submitted by S/L/Ts. The document was peer-reviewed by additional EPA QA staff in the Regional Offices and the Office of Air Quality Planning and Standards (OAQPS). The following EPA staff are acknowledged for their contributions:

Region 1: **Robert Judge, Peter Kahn**
Region 2: Mustafa Mustafa
Region 3: **Verena Joerger, Kia Long**
Region 4: **Anthony Bedel, Stephanie McCarthy**
Region 5: **Bilal Qazzaz**
Region 9: **Mathew Plate**, Roseanne Sakamoto
Region 10: Chris Hall
OAQPS: Michael Papp

Names that appear in bold are the members of the EPA QAPP Workgroup.

QAPP Purpose

A Quality Assurance Project Plan (QAPP) is your agency's **specific** planning document for conducting a **specific** monitoring project. It is an overview of your agency's specific business rules, policies, and quality assurance/quality control (QA/QC) procedures for conducting the monitoring project – in other words, it is how your agency **plans** to **assure** the **quality** of your project's data. The QAPP is designed to help your agency produce high quality data in a consistent manner. It is designed to help improve communications with all staff involved with the monitoring project, as well as detail their responsibilities such that all parties are aware of their roles within the project. The QAPP also helps participants understand the importance of the specific monitoring project and can serve as both a training guide and legacy documentation.

40 CFR Part 58, Appendix A, Section 2.1.2 states:

> *The QAPP is a formal document describing, in sufficient detail, the quality system that must be implemented to ensure that the results of work performed will satisfy the stated objectives. [Primary Quality Assurance Organizations (PQAOs)] must develop QAPPs that describe how the organization intends to control measurement uncertainty to an appropriate level in order to achieve the data quality objectives for the [environmental data operation (EDO)]. The quality assurance policy of the EPA requires every EDO to have a written and approved QAPP prior to the start of the EDO. It is the responsibility of the PQAO/monitoring organization to adhere to this policy. The QAPP must be suitably documented in accordance with EPA requirements (reference 3 of this appendix) and include standard operating procedures [SOPs] for all EDOs either within the document or by appropriate reference. The QAPP must identify each PQAO operating monitors under the QAPP as well as generally identify the sites and monitors to which it is applicable either within the document or by appropriate reference.*

Reference 3 in the above quote is the EPA document *EPA Requirements for Quality Assurance Project Plans* (EPA QA/R-5).

The QAPP can and should contain generalities that explain specific concepts, define terms, and so forth; however, the QAPP is not a guidance document. Instead, the QAPP is the complete picture of **how** the specific project will be planned, implemented, evaluated, and reported by your agency.

Writing a QAPP requires a good knowledge of the ambient air monitoring program and quality assurance (QA) ahead of time. The QAPP writer should have access to the Code of Federal Regulations (CFR), specifically 40 CFR Parts 50, 53, and 58, and EPA guidance when preparing a QAPP, in addition to the agency's Quality Management Plan (QMP) and any other relevant policies, state regulations, and so forth. References to assist the QAPP writer are provided throughout this guide and at the end of the document in the *References* section.

The QAPP must be written and approved **before** monitoring commences. By establishing the agency's plan and business rules up front, decision-making during the project should be consistent.

Please note that when developing some agency-specific practices for a particular project, instrument testing may need to occur. Any data collected during this experimental phase should not be used in decision making.

QAPP Structure Overview

EPA Requirements for Quality Assurance Project Plans (EPA QA/R-5) specifies the required elements within a QAPP. The EPA QA/R-5 document states that the QAPP must be composed of standardized, recognizable elements covering the entire project from planning, through implementation, to assessment. Typically, there are 24 elements within a QAPP. To simplify the QAPP development process, EPA provides flexibility to agencies based on a project's specific objectives; by supporting a "graded approach," all 24 elements may or may not need to be addressed, depending on the QAPP category. See Appendix C of the *EPA Quality Assurance Handbook for Air Pollution Measurement Systems Volume II* (January 2017) for more information on the graded approach and QAPP categories. For a QAPP that is designated as a "Category 1 QAPP" – which describes projects used to directly support rulemaking, enforcement, regulatory, or policy decisions – all 24 elements must be included. With that in mind, regulatory ambient air monitoring QAPPs – such as those created for State or Local Air Monitoring Stations (SLAMS) monitoring – are Category 1 QAPPs and must discuss, to the best extent possible, all 24 elements. No element should be omitted. This guide will discuss all 24 elements of a Category 1 QAPP, but serves as a framework for other air monitoring QAPPs (i.e. Categories 2-4) as well.

There are 3 conventions for structuring the 24 elements within ambient air monitoring QAPPs. Any of these 3 structures are acceptable. One structure includes numbering QAPP elements 1 – 24 in straight numerical order. The other structures divide the QAPP into 4 sections and number them either numerically or alphabetically (for example, Section 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, and so on, **or** Section A1, A2, A3, B1, B2, B3).

The cross-walk that follows lines up the different structures.

For simplicity, the QAPP elements described in this guide will use Sections 1 – 24. Regardless of the QAPP structure's naming convention, the following describes the sections of the QAPP and what they aim to accomplish:

- Sections 1 – 9 (or Group 1 or A) describe the overall **plan** for the monitoring project (i.e., project management).
- Sections 10 – 19 (or Group 2 or B) describe **how** the plan will be implemented (i.e., data generation and acquisition).
- Sections 20 – 21 (or Group 3 or C) describe how the project will be **assessed** and at what frequency (i.e., assessment and oversight).
- Sections 22 – 24 (or Group 4 or D) describe how the resulting **data** will be evaluated (i.e., data validation and usability).

QAPP Structure Cross-Walk

Project Management (Group 1 or A)				Data Generation and Acquisition (Group 2 or B)				Assessment and Oversight (Group 3 or C)			
Section #			Section Title	Section #			Section Title	Section #			Section Title
1	1.1	A1	Title and Approval Sheet	10	2.1	B1	Network Description	20	3.1	C1	Assessment and Response Actions
2	1.2	A2	Table of Contents	11	2.2	B2	Sampling Methods	21	3.2	C2	Reports to Management
3	1.3	A3	Distribution List	12	2.3	B3	Sample Handling and Custody	Data Validation and Usability (Group 4 or D)			
4	1.4	A4	Project/Task Organization	13	2.4	B4	Analytical Methods				
5	1.5	A5	Problem Definition and Background	14	2.5	B5	Quality Control	22	4.1	D1	Data Review, Verification, and Validation
6	1.6	A6	Project/Task Description	15	2.6	B6	Instrument/Equipment Testing, Inspection, and Maintenance	23	4.2	D2	Verification and Validation Methods
7	1.7	A7	Quality Objectives and Criteria	16	2.7	B7	Instrument/Equipment Calibration and Frequency	24	4.3	D3	Reconciliation with User Requirements
8	1.8	A8	Training	17	2.8	B8	Inspection/Acceptance of Supplies and Consumables				
9	1.9	A9	Documentation and Records	18	2.9	B9	Non-Direct Measurements				
				19	2.1	B10	Data Management				

QAPP Elements

Because a QAPP is a plan, written before the project commences, its QA/QC commitments should, ideally, be written in future tense (e.g., "The agency *will* perform…).

The use of citations to reduce verbiage and redundancy in writing is encouraged. However**, the use of citations should be specific**, in order to point the reader to the particular information that is needed within the referenced material. For example, if citing the CFR, use the specific, complete reference (e.g., 40 CFR 58.16, 40 CFR Part 58, Appendix A, Section 2.3.1, etc). If citing an agency SOP, point the reader to the specific section or chapter within the SOP where the necessary information can be found (e.g., "See Data Validation SOP, Revision 1, Section 4.2(b)"). You can also use citations for specific sections within the QAPP itself, so that information does not have to be repeated verbatim. For example, "See Section 9.4 of this QAPP for more information."

Additionally, the following items are recommended best practices to enhance the appearance and usability of the QAPP, as well as improve document control.

- A **Cover Page** is recommended for the QAPP. If used, inclusion of the agency's logo is suggested.

- Include a **header** which contains the following information:
  - document control number or unique identifier,
  - the version/revision number,
  - the version/revision date, and
  - page numbering.

  Header Notes:

  1. Page X of Y format is recommended as the best numbering practice.
  2. The header generally is not included on the cover page, but will start with the first page following the cover page. However, it is acceptable to include the header on the cover page.

- An **Acronym Lis**t is recommended for the QAPP. It can be included after the cover page, prior to Section 1, or it can be included as an appendix at the end of the document. The Acronym List does not have to be long and should only include acronyms used within the QAPP.

- **References** (i.e., bibliography) can be included in the document. If compiled, it is recommended that all references be included at the end of the QAPP, as a final section or appendix.

- If this is a QAPP revision, a **Revision History** section is recommended. If used, update the Revision History section henceforward, summarizing the changes made on future revisions. Revision Histories do not need to contain lengthy explanations or detail every edit, but rather summarize the changes so that they can be more easily tracked over time. Revision Histories can be placed at either the beginning or end of the document.

Example:

Revision Number	Date	Responsible Party	Description of Change
1	1-8-16	John Operator	Section 4.0: Revised and lowered calibration scale. Added information on automated calibrations. Section 4.2. Changed audit point concentrations.
2	1-4-17	John Operator	Revised Section 4.1: certification frequency changed to annual.
3	1-8-18	John Operator	Changes throughout document as a whole due to instrument model upgrade; new figures and tables, additional QA/QC, and new maintenance requirements added.

- If this is a **new** QAPP, a Revision History page is not needed. (***Note****: Recommend that a "0" be used as the Revision Number for a new document.*) However, if desired, a Revision History page (table) can be created that will serve as a placeholder for future revisions.

  Example:

Revision Number	Date	Responsible Party	Description of Change
0	1-3-18	Jane Author	New Document; Initial Release

Section 1: QA Project Plan Identification and Approval

Reminder: Sections 1 – 9 discuss project management.

In this section of the QAPP – which is typically just 1 page – include the following information:

- Name of the agency
- The official title of the QAPP, along with the version/revision number
- A statement that commits the agency to adhere to the requirements of the QAPP

- Placeholders for the signatures of staff members (include position titles) in the chain-of-command who need to review and approve the document, including the agency's Quality Assurance Officer/Manager (or equivalent)
- Signature line for the EPA Designated Approving Official

Example Language:

Title: _____

The attached QAPP is hereby recommended for approval and commits _____***Agency's Name***_____ *to follow the elements described within.*

Section 2: Table of Contents

For this section of the QAPP, list the titles of all sections, subsections, and appendices (if applicable) found within the document. Provide associated page numbers for all sections, subsections, and appendices.

Include a separate "List of Tables and Figures" that follows the main contents. Provide page numbers for all tables and figures. It is recommended that tables be listed first, followed by figures.

Section 3: Distribution / Notification List

For this section of the QAPP, list the names and titles of the individuals involved in the project who will be notified of the QAPP and receive a copy. This should include any partnering agencies and contractors/subcontractors who participate in the project. Include an address/location for each individual (can also include email addresses and phone numbers). The distribution list can be presented in tabular format (such as the following table structure) or the information can be detailed out in a list. Distribution/Notification can be in hardcopy form, electronic, or both.

Name	Position	Division/Office	Address/Location

The individuals in this list will be notified/receive copies of any QAPP revisions or amendments during the course of the project. Revisions and amendments must be approved prior to implementation and distribution. Please note that if the PQAO for which the QAPP is being prepared includes multiple organizations, the distribution list for the QAPP may need to be abridged. In this case, include the above information for the key project personnel, including upper management and QA staff, from all

organizations within the PQAO. Then, add a disclaimer, such as the following: "*The QAPP will be distributed to other personnel and operators beyond this list, in accordance with the organizational chart(s) presented in Section 4 of this QAPP.*"

The location of the official, controlled version of the QAPP should be identified. This could be a signed hardcopy located in a centralized records repository, an electronic version maintained on the agency's local area network (LAN), or an electronic version maintained on the agency's website (recommended), among other locations.

Section 4: Project/Task Organization

This section of the QAPP discusses the roles and responsibilities of all key players in the project, illustrating the chain-of-command and lines of communication. This section clarifies which positions have been delegated authority to complete particular tasks.

Include organizational chart(s) in this section. Is an independent QA function demonstrated in the chart(s)? If not, the verbiage in this section should clarify which position(s) serve in a QA oversight role and demonstrate, through the stated duties, the QA function. The verbiage in this section should match/clarify what is illustrated in the organizational chart. The terminology that is used to define positions should be used consistently throughout the QAPP. Ideally, the terminology should follow into the agency's SOPs as well.

Include discussion of any contractors/subcontractors or partnering agencies in this section and describe the tasks they perform. Explain the lines of communication with these partners. For example, does the laboratory QA Officer contact the agency's QA Officer when there are issues? Or, would a laboratory manager contact the Air Program Manager in such times? Describe the process established for your project.

This section of the QAPP also identifies the Primary Quality Assurance Organization (PQAO) under which the agency operates. If multiple monitoring organizations operate under a single PQAO, each monitoring organization must be identified with the QAPP and the lead agency clearly identified.

When describing the responsibilities of the key positions, answer the following questions (if applicable to your network):

- Does the agency operate under an approved quality management plan (QMP)? Is it referenced somewhere within the section?
- Who has the authority to stop work? For example, if there is a personnel/equipment safety issue in the field due to an approaching storm, who could order a site to power down? Similarly, if an assessment shows severe data quality issues, who could issue an order to halt data collection until corrective actions have been implemented?
- Who has the authority to direct work to resume after a stoppage?
- Who has authority to install additional monitors within the network, or to order monitors to be discontinued or replaced?

- Who is primarily responsible for developing the Annual Network Plan (ANP) and the 5-year Network Assessment?
- Who serves as a liaison to the EPA Regional Office and is the primary point of contact?
- Who is the "tie breaker" (i.e., final decision maker) when a disagreement exists? This is especially important with regards to data validation activities. Often, this is the agency's QA Officer/Manager (or equivalent).
- Who verifies data?
- Who validates data?
- Who certifies data?
- Who is ultimately responsible for the quality of the project's data? (This may or may not be the same person who performs data certification activities and generates the requisite reports.)
- Who is responsible for writing the agency's QAPP/SOPs? Who is responsible for revising and maintaining them? (These may not be the same individuals.)
- Who is responsible for ensuring QAPP/SOP revisions are communicated and distributed to all parties in the distribution list?
- Who is the AQS Administrator for the program? Similarly, who is responsible for AQS data entry? (These may not be the same individuals.)
- Who manages other database systems (such as EDAS, AirVision, Envidas)?
- Who manages the agency's air monitoring documents and records?
- Who tracks inventory and orders supplies/consumables, when needed? (These may not be the same individuals.)
- Who operates, calibrates, and performs required quality control (QC) checks on analyzers/samplers?
- Who performs preventive maintenance? Instrument repairs?
- Who certifies/verifies standards (if performed in-house)?
- Who tracks the certification of standards to ensure that all used within the network are National Institute of Standards and Technology (NIST)-traceable and accurate?
- Who collects physical samples, such as particulate matter (PM) and lead?
- Who conducts performance audits? Systems audits? 40 CFR Part 58, Appendix E siting evaluations?
- Who judges the success of corrective actions, once implemented, to ensure they are appropriate and effective?
- Who oversees training for the ambient air monitoring program?
- Who performs gravimetric analyses of PM filters (e.g., an individual within the monitoring program, an inter-departmental laboratory, or a contractor laboratory)?
- Who performs analyses of lead and/or air toxics samples (e.g., an inter-departmental laboratory, a contract laboratory hired by the agency, or an EPA national contract laboratory)?
- If operated in-house, who is the laboratory analyst?
- Is there a lab supervisor? If not, who oversees the work of the laboratory analyst?
- Who serves as a liaison to the laboratory, especially if laboratory activities are outsourced?
- Is there a back-up laboratory in place? If so, identify the laboratory and explain the potential responsibilities (i.e., which analyses, etc).

- If utilizing a contractor(s), who within the agency is responsible for contractor oversight and assessment of deliverables?
- Are the district/regional offices within the PQAO accounted for?
- Are all agencies operating under a multi-organizational PQAO accounted for?

Section 5: Problem Definition/Background

In this section of the QAPP, state the specific environmental problem that is to be investigated, decision to be made, or outcome to be achieved. For example, if the QAPP is being developed for a SO_2 DRR Project, then this section will detail the promulgation and implementation of the regulations related to the SO_2 DRR and provide a timeline on how the monitoring project will be carried out at your agency. Similarly, if the QAPP is for SLAMS criteria pollutant monitoring, this section will provide information on the Clean Air Act (CAA), the National Ambient Air Quality Standards (NAAQS), and the specific agency's formation of an ambient air monitoring network to determine compliance with the NAAQS.

Include sufficient background information in this section to provide a historical, scientific, and/or regulatory perspective for the project. If data has been collected in the past or this is a revised QAPP, historic information / data should be summarized. For example: An ongoing SO_2 monitoring project, where historic data showed the area to be non-attainment – which prompted an expansion of the network near a source(s) and the need for additional data.

The document review cycle for the QAPP and, ideally, its associated SOPs should be included. As a best practice, monitoring organizations should document the annual review of the QAPP, and record the review date and name/signature of the individual completing the review (even if no revisions to the document were required). The method for documenting and tracking the QAPP review cycle could be documented in this section, which is an important part of an organization's quality system. Or, this information could be presented in Section 9 of the QAPP.

When describing the project background, answer the following questions:

- What is the environmental problem / issue to be studied?
- Which specific pollutant(s) is the QAPP addressing?
- What is the background / history of the problem?
- Why is this project important?
- Is this a regulatory criteria pollutant network? If so, describe the CAA & the applicable NAAQS.
- Is a specific regulation driving the project? If so, specify which one (e.g., the SO_2 DRR). Explain how the specific regulation resulted in your agency initiating this monitoring project.
- Is this an on-going, long-term regulatory monitoring project? If so, when was the project start date? If unknown, approximate how long the monitoring network has been operational.
- Is this a short-term project? Is it regulatory or research-based?
- Is this a new QAPP or the revision of an existing QAPP? If it is a revision to an existing QAPP, when was the original QAPP developed for this project?
- How many years of monitoring data are needed to fulfill the project's data requirements?

Section 6: Project/Task Description

In this section of the QAPP, provide a **summary** of the work to be performed. If this is for a new air monitoring project (such as the SO_2 DRR example), then provide a schedule (timeline) for implementation and expected milestones. If this is for an existing SLAMS criteria pollutant monitoring network, an implementation schedule is not needed since the monitoring network is already established (and earlier versions of the QAPP can be reviewed to find this information). With this in mind, Section 5 should contain enough historical information to explain that the monitoring network has been established for (X) years; resultantly, the QAPP establishes procedures that continue to maintain the existing network.

Include a general overview of the pertinent work activities for this project, such as field activities and sampling, laboratory activities, data review and assessments, and products/reports to be generated.

Include a list or table with the assessment schedule in this section. The assessments themselves do not have to be explained in this section – instead, they should be explained later in Section 20.

Also include a table with the critical documents and records that will be maintained during this project.

***Cautionary Notes**:*

1. *An example critical document table was provided in the* Model QAPP for the $PM_{2.5}$ Program *used by many air monitoring agencies in the late 1990s/early 2000s. Do not include documents/records in this table that your agency does not actually maintain. (A common example here is "control charts.") Instead, augment this table with any documents or records that you do maintain that are unique to your agency and not included. You can describe the documents using your agency's terminology, but be sure to define those terms within the body of the QAPP.*
2. *Documents listed in this table should be discussed in more detail in Section 9. Make sure the documents listed in the table in Section 6 mesh with the documents discussed in Section 9.*

When summarizing the project, answer the following questions:

- What is the monitoring objective(s)?
- Does the section summarize the work that is required to **collect**, **document**, and **report** the ambient monitoring data? For example, for this project you will need to: design a network and deploy instrumentation; develop procedures; establish QA/QC criteria; perform assessments; validate data; and report the data to AQS.
- What measurements are expected to be taken during this project? In other words, what types of data will be collected and reported to support the monitoring objectives? (Ambient data, QA/QC data, site metadata, etc)
- What regulatory standards are pertinent to the project (e.g., SO2 DRR)?
- What are the typical field activities performed in your network to support the project?
- What are the typical laboratory activities performed in your network to support the project?

- Are laboratory activities contracted out?
    - Who is the contract lab?
    - Does your agency maintain copies or have access to the laboratory's QAPPs and SOPs? If so, where are these documents found (or how do you access them)?
    - How do you maintain QA oversight of the laboratory work and resulting data? Provide a brief summary of the steps taken by your agency to ensure the contract laboratory will provide services and produce data that can meet the project's objectives.
- What are the required assessments and who is responsible for completing them?

Section 7: Quality Objectives and Criteria for Measurement Data

In this section of the QAPP, define the quality objectives and criteria for the ambient air monitoring project. This section is the core of the document, because all of the agency's business rules for data quality should be summarized here – and subsequent sections of the QAPP will reference the criteria established herein.

The Data Quality Objectives (DQO) process is a series of logical steps that guides managers or staff to a plan for the resource-effective acquisition of environmental data. It is both flexible and iterative, and applies to both decision-making (e.g., compliance/non-compliance with a standard) and estimation (e.g., ascertaining the mean concentration level of a pollutant). The DQO process is used to establish performance and acceptance criteria, which serve as the basis for designing a plan for collecting data of sufficient quality and quantity to support the goals of the study. This formal 7-step process is described in the EPA document *Guidance on Systematic Planning Using the DQO Process* (EPA QA/G-4, February 2006). Please see this document for more information on the DQO process.

EPA utilized the DQO process to establish the DQOs for the criteria pollutant network; because of that, State/Local/Tribal air monitoring organizations (S/L/Ts) collecting data for NAAQS decision-making purposes do not have to go through the seven steps of the DQO process themselves. With that in mind, this section of the QAPP does not have to list the 7 steps of the DQO process and describe how EPA performed those steps. The same holds true for other monitoring programs in which EPA utilized the DQO process to establish the quality criteria that will be utilized by project participants. However, if the monitoring agency is not monitoring for NAAQS compliance, or if the project itself has additional DQOs beyond those found in the CFR, those DQOs should be described here, along with a description of the process used by the agency to develop the objectives in order to meet the needs of the data user.

DQOs are qualitative and quantitative statements that:

- Clarify the intended use of the data (*Why are the data needed?*)
- Define the type of data needed (*What measurements are required and what do they need to represent?*)
- Specify the tolerable limits on the probability of making a decision error due to uncertainty in the data (*How much measurement uncertainty can be tolerated in the data set?*)

For the S/L/Ts collecting data for regulatory decision-making purposes, the quantitative DQOs for most of the criteria pollutants can be found in 40 CFR Part 58, Appendix A, Section 2.3. These regulatory criteria establish the allowable measurement uncertainty and decision rate error in the collected data sets. Please note that monitoring organizations can establish more stringent DQOs for the criteria pollutant network than are currently stated in CFR; however, the DQOs cannot be less stringent.

Data quality indicators (DQIs) are quantitative and qualitative characteristics associated with the collected data (i.e., calculated statistics). The QAPP should list the DQIs for the monitoring project, provide brief definitions for each, and then explain how the DQIs are measured / determined by the agency.

Measurement quality objectives (MQOs) are the acceptance or performance criteria for individual DQIs. They are designed to evaluate and control various phases (sampling, preparation, analysis) of the measurement process to ensure that total measurement uncertainty is within the range prescribed by the DQOs. Therefore, MQOs should be established at various measurement phases in order to meet the DQOs.

When formalizing the quality objectives and criteria in this section, answer the following questions:

- Does the QAPP describe the process the agency used to develop its DQOs in order to meet the needs of the data user? If not, does the QAPP indicate that the project will utilize DQOs established by EPA?
- Does the QAPP contain statements that describe the qualitative DQOs?
- Does the QAPP contain the tolerable error limits (quantitative DQOs) for the pollutants measured? In other words, does the QAPP plainly describe how much uncertainty / error the agency will accept in their aggregated data sets for each of the pollutants measured?
- Does the QAPP reproduce the Data Validation Templates found in the EPA *Quality Assurance Handbook for Air Pollution Measurement Systems Volume II* (i.e., QA Handbook) and include them as the agency's MQOs? If not, does the QAPP contain tables that summarize the MQOs for each pollutant? (***Note****: MQOs don't have to be in tabular format, but it is strongly recommended for ease of use.*)
- Does the QAPP define the Data Quality Indicators (DQIs): precision, bias, accuracy, completeness, and sensitivity?
- For each DQI, does the QAPP explain how the agency measures / quantifies the specific metric? For example, has the agency determined the level of sensitivity that must be obtained in order to accurately assess whether the pollutant of interest exists at the monitoring site? For instance, with NCore, this may include utilizing trace-level monitors. For air toxics, on the other hand, this may include running laboratory analyses using SIM-mode, as opposed to full-scan.
- Are limits established for each quantitative DQI? Frequency?
- Are statistical reporting units included?
- Is representativeness appropriately addressed?
- Is comparability appropriately addressed?

***Note**: If adopting the EPA QA Handbook's Data Validation Templates and including them in the QAPP as your MQOs, most of these bullets will be adequately addressed.*

It is recommended that the data validation templates be personalized to reflect your agency. For example, it is recommended that the Information/Action column contain a reference to the agency SOP where the requirement can also be found. Similarly, tables should be removed if the pollutant is not monitored (e.g., don't include the CO template if the agency doesn't monitor for CO). Also, if the agency monitors continuous $PM_{2.5}$ using a TEOM, then the requirements for the BAMs and GRIMMs can be stricken from the template (unless the agency is planning to start utilizing BAMs and/or GRIMMs in their network, and this QAPP is being submitted in advance of the start of the new monitoring efforts).

Section 8: Training

In this section of the QAPP, identify and describe your agency's training and/or certification requirements. This section can describe the general training/career development courses for any employee within the agency; however, this section should also explain the specific ambient air monitoring training that will be provided to project participants.

Discuss how training will be provided, tracked, and documented. Discuss how proficiency will be assessed, identifying the individual(s) responsible for determining whether project participants can successfully and independently perform the monitoring activities. Additionally, the process for ensuring project participants stay current on QA and monitoring-related competencies should be described in this section as well. Finally, this section of the QAPP should identify where training records will be maintained and by whom.

See Section 4 of the QA Handbook for more information on air monitoring training programs.

When describing your agency's training requirements, answer the following questions (if applicable):

- Does each job title (position) have specific training requirements that must be fulfilled that documents the employee can fully execute the responsibilities of the position? If so, describe the requirements.
- Who makes the determination that project staff are sufficiently trained to perform assigned monitoring tasks?
- Must staff perform and pass a Proof of Competency (POC) or Demonstration of Capability (DOC) review (or equivalent)? If so, how often and where is it documented?
- Does the agency have an in-house air monitoring training program? Is it detailed in another document, such as the agency's QMP? If so, reference the document. If not, detail the air monitoring training program here.
- Does the in-house monitoring training program include written exams? If so, describe.
- Is air monitoring-specific QA training provided to all project staff? If so, by whom, in what form, and on what frequency?
- Is on-the-job training (OJT) with a senior staff member or QA Officer provided for data verification/validation activities? Explain.

- Is hands-on instruction (OJT) with analyzers/samplers provided? Explain.
- On what frequency is OJT provided?
- Does the agency host an annual workshop/training event and invite site operators and/or other monitoring staff to attend? If so, describe here. Are records kept detailing the training agenda and who attended? Are training evaluation forms completed upon workshop completion?
- Are certificates of completion issued when the project participants are found to be proficient or have completed a particular training / workshop / exam? Where are these certificates retained and by whom?
- Do project personnel complete proficiency tests (PTs), or otherwise demonstrate operations of specific air monitoring equipment in some formal fashion? Explain.
- How is the need for refresher training assessed and subsequently provided?
- Is vendor-provided training utilized? When taken, how is the training documented?
- Are EPA-provided courses utilized? AQS webinars? Air Pollution Training Institute online (self-instructional) courses?
- Which documents are required reading? The QAPP and SOPs? Examples may include instrument user manuals, EPA guidance documents, and the CFR, among others.
- How is the completion of required reading tracked and documented?
- Does the QAPP clarify which training activities (courses) are required versus which training activities are optional?

Section 9: Documentation and Records

In this section, describe your agency's document control system. In other words, the process for distributing the most current approved QAPP, as well as notifying project staff of any revisions/updates to the QAPP, and ensuring that staff utilize only the current version. This description can also be included in Section 3, Distribution List, if preferred. The section should also describe the document control process for distributing the most current version of SOPs, QA/QC forms, blank data entry forms, and so forth. These controlled documents may be maintained on the agency's LAN or website (recommended), or through other means.

Also, in this section of the QAPP, identify the project records that will be maintained, how/where the records will be stored, and any record retention requirements. This section should include information about records generated in the field (e.g., data forms, logbooks, chain-of-custody forms, etc.), records generated in the laboratory, QA reports generated, Corrective Action Reports, and so forth. Emails are also considered records; if the agency uses email as a primary means of communicating procedural updates and/or otherwise significant monitoring information, the process for retaining significant emails should be discussed.

To reduce verbiage, it is recommended that a table be included that summarizes the records that will be documented and maintained, including where they can be found within the agency. See Section 5 of the QA Handbook for more information on documentation and records.

When describing your agency's documentation and recordkeeping requirements, answer the following questions (if applicable):

- Does the QAPP explain how new copies of quality system documents (e.g., QAPPs, SOPs) are distributed to staff?
- Does the QAPP explain where "old" quality system documents are retained? Are the "old" documents archived?
- Does the agency maintain a "master list" of all current, controlled documents (such as QAPPs and SOPs)? Where is this "list" posted (such as on the agency's LAN or website)? Who is responsible for maintaining it?
- Does the QAPP describe the process for preparation, review, approval, revision, and withdrawal of SOPs? What is the frequency of SOP reviews?
- Does the agency use email to issue important notifications to staff regarding updates or changes to monitoring policies and procedures, etc? Are copies of these email records maintained and filed? If so, where?
- Does your agency have a specific records retention policy for air monitoring documentation/records? If so, state it. If not, see the general records retention requirements in 2 CFR 1500 and include those requirements within the QAPP.
- Are there any special requirements for retaining data/records/documentation that is involved in litigation?
- Does the QAPP distinguish between hardcopy and electronic documentation requirements, if applicable?
- Has your agency "gone paperless"? If so, does your agency follow the guidance in the April 2016 EPA Technical Note titled *Use of Electronic Logbooks for Ambient Air Monitoring*? Document how your agency meets this guidance.
- For handwritten documentation, are best practices listed in the QAPP to guide the reader (e.g., instructions such as use of indelible ink, single-line strikethrough for incorrect data entries with corrections to the side, initialed and dated, etc)?
- Are handwritten records, such as site logbooks, backed-up (i.e. scanned)? If so, on what frequency? Where are the scanned copies maintained?
- Does the agency utilize paper or electronic strip charts? Are those charts documented?
- Does the agency utilize any commercial or in-house developed databases where records are stored? If so, describe.
- Does the agency collect physical samples in the monitoring network? If so, are chain-of-custody forms (COCs) utilized? Where are they retained?
- Are Corrective Action Reports utilized? If so, where are they filed and maintained?
- Where are audit reports (internal and external) filed and maintained?
- Where are NIST-traceability certification records filed and maintained?
- If the agency operates an in-house laboratory, where are laboratory records filed and maintained?
- If the agency outsources any laboratory operations, where are data packages received from the contract laboratory filed and maintained?

- Where are training records maintained?
- Are site files created that contain photographs, addresses, geographical measurements (GPS coordinates, Appendix E criteria), and other pertinent information regarding individual air monitoring sites? For example, some sites may have lease agreements in place, etc. that must be maintained. If so, where are these records filed within the agency?
- Who is responsible for maintaining the records and files discussed in this section?
- Is access to any of the records limited? If so, who has access? Please briefly describe the type of access (e.g., "read-only", "add", etc) granted to project personnel.
- Are electronic records backed-up? If so, how and on what frequency?
- While in storage, are records (hard copies and electronic) protected from damage, loss, and deterioration?
- When software upgrades occur, are archived records similarly updated?

Section 10: Network Description (or Sampling Process Design)

Reminder: Sections 10 – 19 of the QAPP discuss data generation and acquisition activities.

This section is referred to as "Sampling Process Design" in the EPA QA/R-5 document. For other sampling projects, this would be where you would lay out your overall design for collecting samples – e.g., map your targeted sampling areas, upwind (upstream) and downwind (downstream) sample locations, and so forth. With that in mind, for criteria pollutant ambient air monitoring, this is the section that discusses the network design and rationale. For air projects that are generating data for purposes of NAAQS compliance, the easiest way to do this in the QAPP is to reference the CFR – because it is there that the sampling design structure has been outlined. The agency must meet the network design criteria spelled out in 40 CFR Part 58, Appendix A (i.e., collocation), Appendix D (i.e., design criteria), and Appendix E (i.e., siting criteria) for the resulting data to be comparable to the NAAQS.

All monitoring stations included in the network with monitors/samplers collecting data for the specific pollutant(s) covered by the QAPP must be identified in this section. Include AQS identification numbers for each site/monitor. If the PQAO represents more than one monitoring organization, the QAPP should identify which organization is responsible for the operation of each site/monitor. The QAPP must also clearly identify the larger entity that oversees QA in the multi-organizational PQAO.

The monitoring network design and site listing should already be illustrated in the agency's ANP. The ANP should contain maps, population counts, tables with site IDs, etc. In this case, for a large SLAMS network, reference the ANP in the QAPP, and include a hyperlink to where the document can be accessed online (if it is available online). However, for smaller scale projects – such as the SO_2 DRR or a source-oriented lead monitoring project that may only include a few sites – include maps, tables, and other pertinent information within the body of the QAPP.

Network objectives, sampling schedule, sampling frequencies (i.e., number and types of samples), and so forth can be included here, too – but, these may have already been discussed in earlier sections of the QAPP (such as Sections 5 or 6). If so, to minimize redundancy, reference the earlier section(s) of the QAPP where the information is located. If not, include a few statements about these items here.

When describing your agency's monitoring network, answer the following questions (if applicable):

- What is the rationale for your network design?
- If your network is regulatory, did you cite Appendices A, D, and E to Part 58? If not, why? For example, if there is no collocation in your network, you may not need to reference Appendix A. In that case, it is recommended that a statement be included that explains that collocation is not required in the network.
- Did you cite Part 58 for operating schedules, etc? If not, why? If information is provided in an earlier section of the QAPP, provide a reference.
- Did you state or reiterate the network objectives?
- Did you include information about site types (e.g., maximum concentration, background, transport, etc)?
- Did you include information about types of monitoring stations (e.g., SLAMS, SPMS, NCore, PSD, etc)?
- If this is a single site, or a small network of monitors, did you provide the specifics about the individual site(s)/monitor(s)? For example, for a SO_2 DRR site, a statement such as: "This source-oriented site will be representative of expected maximum concentrations on a neighborhood scale."
- Did you include criteria for evaluating potential sites?
- Did you include factors that influence site selection?

Section 11: Sampling Method Requirements

This section of the QAPP describes **field work** – e.g., collecting physical samples, along with associated QC samples. The sampling methods and equipment used in the monitoring network should be identified here.

For the ambient air monitoring network, the criteria pollutant sampling methods are established within the CFR (in the appendices to Part 50). If monitoring for NAAQS comparability, the field analyzers and samplers must be federal reference or equivalent methods (FRMs or FEMs) – and the designation of those monitoring methods as FRM/FEM establishes that they have been tested and found to be acceptable for this purpose. Include a table or listing in this section that specifies the equipment makes/models used in the monitoring network, including their FRM/FEM method designation codes (if monitoring for regulatory purposes).

***Note**: If the QAPP is not for criteria pollutants, or is non-regulatory, then the QAPP will need to include more information that demonstrates that the sampling methods employed for the collected pollutants are adequate and appropriate.*

The next step is to show **how** these methods will be implemented (the "how to"). For intermittent sampling, such as particulates, lead, and air toxics, physical samples will be collected – Section 12 of the QAPP will discuss this process in more detail. For the gaseous pollutants, physical samples are not collected – but "samples" are analyzed in situ, within the analyzer itself. These analytical instruments

are sensitive to climate, so in order to describe **how** you're implementing the method, the monitoring station's design and interior shelter requirements must be discussed.

Ultimately, the "**how to**" for the analyzers/samplers is found in the individual SOPs that address the instrumentation. With that in mind, the **SOPs** associated with the QAPP should be included as appendices in order to explain precisely "how" the samples will be collected. However, at a minimum, the QAPP **must** contain a listing or table that includes the names of the SOPs for which the QAPP governs. The SOP titles, revision numbers, and dates should be included in the list/table, so the reader is directed to the most current/appropriate versions of the documents. The SOP listing can be included in this section of the QAPP or as an appendix at the end of the document, if the list is lengthy.

When describing the sampling methods employed by your agency, answer the following questions (if applicable):

- What are the sampling methods for the pollutants monitored? For example, Teledyne-API or Thermo instruments: AQS method codes for ozone would be 087 and 047, respectively.
- Are the SOPs for the sampling methods included? (Include a table, list, or attach as appendices)
- What sample probe materials are used within the network (e.g., Teflon® or glass for the criteria air pollutants, or stainless steel or glass for toxics)?
- What is the sample probe/train design? This information is needed to help clarify the method by which the "sample" is truly collected. Is a single-line candy cane used to pull the ambient air into the analyzer? Is a manifold system used? Where are the in-line filters located within the sample train? Explain.
- Do you calibrate and/or perform QC checks "through-the-probe"? If so, this design should also be discussed.
- Do the analyzers have specific shelter climate-control requirements? If so, include them. Climate control requirements can usually be found in the *List of Designated Reference and Equivalent Methods* (ORD) or in the instrument manuals.
- Does the QAPP include information about possible analyzer interferences and how they will be addressed by the agency? For example, analyzers are sensitive to dust build-up, so routine cleaning is necessary to protect the instrumentation.
- Does the QAPP discuss how the probes and sampling trains are maintained, in order to minimize interferences?
- Does the agency have any business rules on making method changes or corrections? For example, are site operators allowed to swap out instruments (methods) or probe materials as needed, or do method modifications have to be approved by someone within the management chain first?

Section 12: Sample Handling and Custody

In this section of the QAPP, provide an overview of the sample handling and custody procedures for physical samples collected. In other words, illustrate the sample's life cycle and chain-of-custody (COC). This section includes discussion of particulate, lead, and/or air toxics samples. Discuss sample handling

in the field, during transport, and through receipt at the laboratory. This section should also include information about sample transport containers and preservation methods. Include examples of sample labels, chain-of-custody forms, and/or sample custody logs, which are necessary to document the life cycle of the sample. Also include discussion of any devices used to ensure samples are not tampered with or subjected to unacceptable conditions.

COC is a method of documenting who has had possession of ("handles") the sample throughout its life cycle, in order to demonstrate the sample's integrity. Describe the COC process and required paperwork in the QAPP. For example, the COC for a $PM_{2.5}$ sample should start with the gravimetric lab analyst, who prepares the sample media (i.e., clean Teflon® filter) and then releases it to the site operator. The site operator will collect the actual sample using the prepared media, then prepare the exposed sample for transport, and finally relinquish the sample to either a commercial carrier or directly to a sample custodian at the laboratory. For each of these steps, a designated COC record should be signed and dated by the individual in possession of the sample, and a copy of the COC retained by the individual in possession of the sample.

> *Note:* A COC record can be paper or electronic and come in a variety of formats, such as carbonless triplicate forms, a hanging sample tag (e.g., attached to a summa canister), a sample bag label, etc – ***provided there is ample room for the necessary documentation and signatures***. In addition to signatures, information recorded on the COC should include, but is not limited to, the following: individual collecting the sample, time and date of sample collection, location, sample identification number, analysis required, preservatives used, sample holding time, turnaround time, organization samples were sent to for analysis, date and time.

Cite specific SOPs where more detailed information on the agency's sample handling and custody procedures can be found. If the SOPs provide options, ensure that the option(s) selected for the current project is identified in the QAPP and is clearly understood by all necessary project and laboratory personnel.

Do not leave this section blank or skip it if your project does not produce physical samples. For example, if the QAPP is a gaseous-only QAPP, there will be no physical samples to collect and, therefore, no COCs to document. Instead, state in this section of the QAPP that "COC" does not apply to this specific project because the monitors utilized analyze samples in situ. (The "chain of custody" of data, on the other hand, will be discussed in Section 19, *Data Management*.)

When describing sample handling and COC, answer the following questions (if applicable):

- Are pre-sample custody requirements and procedures included (i.e., any preparatory work to prepare the sampling media for subsequent field sampling)?
- Are post-sample custody requirements and procedures included (i.e., handling of exposed samples to ensure integrity)?
- Are there any sample holding times **in the field** that site operators must be aware of? If so, include them. For example, $PM_{2.5}$ samples must be removed from the sampler within 177 hours from the end of the sampling event.

- Are there any sample preservation methods that operators must be aware of? If so, include them. For example, exposed $PM_{2.5}$ samples must be protected from temperatures above 25°C, and therefore, shipments should be chilled in order to maximize analytical holding time.
- Are there any sample holding times **in the laboratory** that site operators must be aware of? If so, include them. For example, if a sample must be analyzed or extracted within X number of days after sample collection ends, the operator must be aware of the requirement in order to ensure the sample is shipped to the laboratory with enough time to allow the analyst to complete the necessary analysis/extraction.
- Are procedures for packing samples for transfer/shipment included? Do the procedures include a description of the paperwork that is to be included with the samples?
- Are COC records hardcopy or electronic? Describe.
- Who is responsible for completing the COC record?
- Who is responsible for reviewing and storing the COC records?
- Are completed COCs backed-up (i.e., scanned or emailed)?
- Are there specific shipment schedules that must be followed? If so, describe them.
- Does the agency utilize custody seals when packing shipment containers? If so, describe.
- By what method are samples shipped to the laboratory? For example, hand-delivery via operator because the laboratory is within the same office building, or overnight via commercial carrier to the laboratory in another location?
- To whom are the samples shipped (e.g., a sample custodian or the lab analyst)?
- How are samples archived after analysis (if applicable)?
- Does the agency run make-up samples? If yes, include the agency's make-up sample policy/strategy in the QAPP. If no, state that make-up samples are not collected for the specific pollutant program.

Section 13: Analytical Methods

This section in the QAPP is primarily about **laboratory work**. If you are writing a $PM_{2.5}$, PM_{10}, lead, or air toxics QAPP, this would be the section where you detail the analytical methods used in the laboratory to analyze the field samples collected, along with the required analytical QC for those methods. For example, you would summarize the requirements of 40 CFR Part 50, Appendix G, for criteria lead, or summarize the analytical method equivalent to Appendix G that will be utilized by the laboratory. This section also includes a discussion of equipment needed in the laboratory for these purposes (e.g., microbalance, ICP-MS, etc). This section should include information about sample media (e.g., glass fiber filters, quartz, Teflon®), sample containers (e.g., cassettes, filter envelopes), preservation methods (e.g., ice packs), and holding times for the various sample types. Some of this information may have already been captured in Section 12; if so, reference the section. To reduce redundancy, the requirements do not have to be repeated in both sections.

For the regulatory pollutants ($PM_{2.5}$, PM_{10}, and lead), the reference methods that are to be followed are codified in the appendices of 40 CFR Part 50. For air toxics, however, there are no regulatory methods; instead the TO or IO compendia provide information on the analytical methods. To simplify this section,

cite the specific regulatory method(s), or TO or IO compendium method(s), that will be used, along with the summary of how those methods will be implemented by your agency. Also cite the SOPs where more detailed information can be found.

If you're writing a gaseous pollutant QAPP, this section should not be left blank or omitted. For criteria pollutant monitoring, including gaseous, the FRM methods can be found in the appendices to 40 CFR Part 50. With that in mind, include references to the appropriate appendix for each pollutant monitored. Explain that for gaseous pollutant analyzers, the monitoring methods are "self-contained" within the apparatus (analyzer) utilized and no additional analyses at a laboratory are required. If using an FEM, explain that the monitoring method is a designated equivalent method. The theories of operations for the gaseous monitors can be found in the instrument user manuals, which can also be referenced in the QAPP and/or SOPs to address this section. However, if you already detailed this methodology in Section 11 of the QAPP then, at a minimum, include a statement here that explains analysis at a laboratory is not required because the monitoring method(s) employed analyzes samples in situ.

When describing the analytical requirements, answer the following questions (if applicable):

- Did you cite the appropriate analytical method for **each** pollutant monitored in the network?
- Did you reference the specific analytical SOPs utilized for each method?
- Did you identify the required QC checks on the analytical equipment (e.g., method detection limit (MDL), initial calibration verification (ICV), continuing calibration verification (CCV), etc)?
- Did you identify the required QC samples for each method (e.g., blanks, replicates, duplicates, spiked samples, etc)?
- Did you identify the analytical laboratory? This is especially important if more than one laboratory is utilized because the monitoring network samples for multiple pollutant types.
- Did you specify the sample media used?
- Did you specify the laboratory quantitation and QC limits (reporting limits and acceptance criteria, respectively) to ensure project sensitivity requirements will be met?
- Did you reference or attach the laboratory QA manual and SOPs?
- Did you identify procedures to follow if laboratory failures occur?
- Did you identify the individual(s) responsible for corrective action and appropriate documentation?

Section 14: Quality Control Requirements

This section of the QAPP is about the many types of QC checks and samples performed/collected in the ambient air monitoring network. In this section, identify those required QC checks or samples for the sampling and analytical methods (discussed in Sections 11 and 13). To reduce redundancy, the laboratory calibration and QC requirements do not have to be repeated in this section, provided they were adequately described in Section 13. If not, then add them here.

A reference to the QAPP's MQO tables should be added to this section, since the tables compile the necessary QC for each pollutant. Section 14 explains the purpose and rationale for these various QC checks and samples. State the frequency for each type of QC check or sample, the acceptance criteria for the checks, as well as the associated corrective action if the acceptance criteria are not met. Reference the SOPs in this section, identifying where the procedures can be found in more detail. Recommend utilizing the same terminology in the QAPP that you use "in real life" in your agency; ideally, that terminology should carry forward to the SOPs.

For ambient air monitoring, QC checks include precision checks conducted on analyzers and samplers. Calibrations (i.e., adjustments), in general, are part of quality control. Calibration information can be included in this section, or it can be included in Section 16. Historically, in many agencies' air monitoring QAPPs, Section 16 has been used to discuss the certification/traceability of the standards that are used to complete the required calibrations.

Audits are QC checks – although, they are used for bias/accuracy determinations. Include a discussion of audits (external and internal) in this section.

Include formulas for the necessary QC calculations in this section or reference where the formulas can be found.

When describing your agency's QC activities and requirements, answer the following questions (if applicable):

- What is your calibration scale, if it is something other than the full operational scale of the analyzer? For example, your ozone analyzer may be designated as an FEM on a 0 – 500 ppb scale, but you calibrate the analyzer within that range to perform on a 0 – 200 ppb calibration scale.
- If using a calibration scale, what is the rationale for the scale selected?
- What is the calibration acceptance criterion? Is it slope? Percent difference (%d) for each point? A combination of both? Explain.
- How often are calibrations (i.e., adjustments) performed?
- How often are calibration verifications (i.e., unadjusted calibrations) performed?
- Is the acceptance criterion for unadjusted calibrations different than for adjusted calibrations?
- Are multi-point verifications or some other QC check performed prior to a calibration?
- What types of precision checks do your site operators perform on the gaseous analyzers? These checks may be referred to by a variety of names, including "1-pt QC", "biweekly", "p-checks", "PCs", "pre-cal", "P&A", "P&B", "ZPS", among others.
- Describe the precision check(s). For example, is a 1-point QC really just a single upscale concentration point (50 ppb, for example) and nothing else? Or is it a zero concentration along with the 50 ppb?
- What is the rationale for the concentration selected for the 1-point QC check? (See 40 CFR Part 58, Appendix A, Section 3.1.1)
- How often are the precision checks performed? Are they automated (i.e., controlled by a datalogger in the absence of the operator) or conducted directly by the operator? Or both?

Please explain in the document so that all checks (and how they're completed) are accounted for.

- What is the acceptance criteria for the precision checks?
- Are there reasons why some precision checks may not be valid? This is not regarding an exceedance of a percent difference acceptance criterion, but rather, something that may go wrong such that the QC check itself is invalid (e.g., the site calibrator malfunctioned, yet the datalogger still fired off an auto-program to run the check). Provide examples in the QAPP of situations in which you would not consider QC checks to be valid.
- What types of precision checks do you perform on your particulate matter samplers? Describe them and include their frequency and acceptance criteria.
- Do operators have to compute the percent difference calculation manually? Or, is the formula captured in spreadsheets or databases utilized by the operators so that they don't have to do this computation directly? Or are both methods for calculations employed? Please explain.
- Do you control chart your QC results? For example, do you plot your zero concentrations or span concentrations over time to watch for drift?
- What do you do if any of the QC checks exceed the acceptance criterion? Discuss corrective action.
- Do you have any collocated sampling in your network? If so, describe how the collocation is used as a QC check.
- What is the collocation sampling frequency?
- What is the acceptance criterion for collocated sample pair results?
- Do you collect field blanks? Trip blanks?
- What types of performance evaluations (audits) are performed in your network? Include internal and external audits. For instance, external audit examples may include a local agency that doesn't perform its own audits, but is audited by the State PQAO, as well as audited by EPA (e.g., National Performance Audit Program (NPAP), Performance Evaluation Program (PEP)).
- What is the frequency of the performance evaluations? Once a year, as in the regulations, or some other schedule?
- What are the audit levels used during performance evaluations? What is the rationale for the targeted audit concentrations? (See 40 CFR Part 58, Appendix A, Section 3.1.2.1)
- What do you do if any of the audit concentrations exceed the acceptance criterion? For low-level gaseous audits, in particular, how do you judge the results from Audit Levels 1 or 2?
- If you operate an in-house laboratory, what types of QC checks do you perform on the analytical equipment? For example, for a $PM_{2.5}$ gravimetric lab, this would include balance checks.
- If you operate an in-house laboratory, what types of QC samples do you utilize? For example, for a $PM_{2.5}$ gravimetric lab, this could include lot blanks, lab blanks, and/or long-term exposure blanks.

Section 15: Instrument/Equipment Testing, Inspection, and Maintenance Requirements

In this section, identify the equipment (field and laboratory) that needs periodic maintenance, testing, or inspection.

Describe the acceptance testing the agency will perform on its analyzers/samplers, and how this testing will be documented. Instruments used for SLAMS monitoring must be FRM/FEM, and with the purchase of an FRM/FEM, the agency has confidence that the make/model of the instrument itself has passed 40 CFR Part 53 acceptance testing requirements. However, the agency should still complete testing of individual instruments (upon receipt) to ensure the instruments are fully functional and meet performance specifications. If a newly purchased instrument does not pass in-house acceptance testing upon receipt, the instrument should be returned to the vendor while still under warranty.

Describe or reference how periodic preventive maintenance of equipment will be performed. Reference applicable SOPs where this information is maintained. Also, describe any periodic inspections that are completed in order to ensure the monitoring system itself remains in good working order.

When describing your agency's testing/maintenance activities, answer the following questions (if applicable):

- How are new instruments tested when first received from the vendor (i.e., newly purchased)? Summarize your activities, including documentation.
- Does new equipment testing include procedures to determine/quantify the method detection limit (MDL), particularly for use of low-level instruments in an NCore program? Describe any MDL testing here, along with requisite documentation and AQS reporting.
- What do you do if the instrument doesn't meet the purchase requirements or performance specifications? Explain how deficiencies found are resolved and documented.
- Do you have any SOPs that are specific to instrument performance acceptance testing? If so, reference them. If not, summarize your procedures here.
- What general preventive maintenance activities do you perform each month? Each quarter? Annually? Where can detailed descriptions of these activities be found?
- Are diagnostic checks performed before and after maintenance to document the "as found" and "as left" condition of the instrument? Where is this information recorded?
- Are instruments logbooks (or e-logbooks) kept with each instrument that document the testing, maintenance, and repairs for the individual instruments? Describe how these activities are documented and tracked.
- Do you maintain critical spare parts to prevent instrument down time? If so, which parts are usually on hand?
- Are spare analyzers maintained by your agency? Are these back-ups shelved in a maintenance shop/warehouse for future use when a field monitor malfunctions?
- If spare (back-up) monitors are maintained but shelved, are they tested on some frequency to ensure they are still functional (i.e., haven't developed "shelf disease")? What is the frequency of the testing and how/where is it documented?

Section 16: Instrument Calibration and Frequency

In ambient air monitoring, calibrations are considered a type of quality control procedure. Therefore, calibrations can be discussed in the QC section of the QAPP (Section 14). In order to reduce redundancy, though, if calibration requirements and frequency are discussed in the earlier section, then reference that section instead of repeating the information. If calibrations are not discussed in Section 14, then include the information here.

An element of calibration that is critical to the ambient air monitoring program that should be elaborated on in this specific section is that of traceability. For criteria air pollutant data being used for regulatory decision-making purposes, the gaseous and flow standards used to calibrate ambient air monitoring instruments must be traceable to NIST. In general, for any air monitoring program, when calibrating an instrument, the calibration standard should be NIST-traceable, and of higher accuracy than that of the working standard used to periodically test the instrumentation. These concepts should be explained in the QAPP, along with your agency's method for ensuring traceability of standards back to NIST.

When explaining the hierarchy of standards, use terminology that is understood by project staff and utilized in your SOPs. But, ensure that terminology is defined. For example, your agency may utilize a rootsmeter for in-house hi-volume PM_{10} orifice certifications/verifications. You may refer to the rootsmeter in-house as a "local primary standard". The QAPP should define such "local primary standards", their certification/verification requirements, and frequencies.

When describing your agency's calibration standards, answer the following questions (if applicable):

- Do you sample for ozone? If so, discuss your photometers.
- Which photometer levels (i.e., Levels 2, 3, or 4) are utilized in your network and how often are they certified/verified? Explain the hierarchy. Identify the standards by the Level number for ease of understanding, but you can also use your agency's terminology to describe the standards. For example, "The agency's ozone bench standard (i.e., Level 2)."
- Do you sample for CO, SO_2, or NO_2? If so, discuss your gas cylinders **and** your gas dilution calibrators, which contain mass flow controllers which must be verified on a set frequency.
- Do you sample for low-volume particulates? If so, discuss your flow rate transfer standards, as well as any manometers, thermometers, or barometers that may be needed for sampler calibrations.
- Do you sample for high-volume particulates? If so, discuss your orifices and/or variable plates.
- Are analytical methods performed in-house? If so, describe the laboratory standards and reagents which require certification and discuss that process. For example, in a $PM_{2.5}$ weigh lab, the primary set of mass reference standards (i.e., weights) should be recertified annually.
- Who conducts the certifications/verifications described in this section? Are they certified by the vendor or certified in-house? Explain for each standard type.
- If certified/verified in-house, what is the **standard of higher authority (accuracy)** that is used to conduct the certification? Explain for each standard type. Clearly identify in the QAPP which standards the agency considers to be the primary standards. For example, an aneroid

barometer can be calibrated against a Fortin-type mercury barometer, which is a primary standard.
- State the certification frequency for each standard type.
- How are certifications/verifications documented?
- How are certifications/verifications tracked in order to ensure standards do not expire?

Section 17: Inspection/Acceptance Requirements for Supplies and Consumables

In this section of the QAPP, briefly summarize how critical supplies and consumables in your monitoring program are inspected and accepted for use. This may include stating acceptance criteria for the necessary supplies and consumables.

For regulatory ambient air monitoring, most of the parts needed will be issued by the vendor of the FRM/FEM instrument in use. Consumables, such as calibration gases, must be EPA Protocol cylinders and other supplies, such as sample lines and fittings, must be Teflon® or glass. With this in mind, the CFR has established some of the "acceptance criteria" for the supplies and consumables.

When describing your agency's inspection/acceptance of supplies, answer the following questions (if applicable):

- Are critical supplies and consumables identified? If not listed within the QAPP, cite where this information can be found.
- Are acceptance criteria stated, if necessary?
- How are use of supplies and consumables tracked?
- Who is responsible for tracking/ordering supplies and consumables?
- Is documentation maintained that demonstrates the supplies/consumables are acceptable for use?
- Are procedures in place – such as labeling – to help ensure supplies/consumables are used before their expiration dates?
- Does the agency have any policies regarding the use of expired materials?

Section 18: Non-Direct Measurements

The purpose of this section is simply to identify types of data that the agency may use to support the ambient air monitoring program that they did not directly generate/collect themselves. These additional data may be needed for project implementation or decision making. For example, in order to determine the number of sites needed in a metropolitan statistical area (MSA), population counts must be obtained – so census data may be used. Similarly, if completing a source-oriented monitoring project, facility emissions data, along with wind rose data, may need to be obtained for purposes of modeling, etc. in order to determine maximum expected concentration areas and so forth.

With this in mind, identify the anticipated types of data needed for the monitoring project, if applicable. If non-direct measurement data are used, briefly discuss any data quality limitations or concerns, if applicable.

Section 19: Data Management

In this section of the QAPP, describe how the ambient air monitoring data will be managed, tracing the path of data generation in the field/laboratory to the final data use and end storage (i.e., AQS). In other words, this section describes the data's flow path from the "cradle to the grave." It can also be thought of as describing the **data's "chain-of-custody"**, illustrating all the processes and people who have influenced each data point over the course of its life cycle.

It is suggested that this section be organized by topics that mimic the flow path of the data, simply for ease of understanding. A flow diagram in this section is recommended to help the reader visualize how the data is collected and processed.

In this section, identify and describe all data handling equipment and procedures to process, compile, and analyze the data, including any computer hardware and software, or paper-based processes. Discuss the frequency and process for verifying the accuracy of the telemetered data. If data are transferred amongst entities (e.g., from laboratory to agency) using email, describe this process – including how the emails with attached data are incorporated into the data management system and eventually archived. If data is managed manually, discuss how data transformations and algorithms are verified. Whether manual or automated, discuss the frequency and process for verifying the accuracy of the final-reported data.

Data security and back-up is also a critical function that should be discussed in this section of the QAPP. Describe the process for ensuring original, unaltered data is retained and never overwritten. Discuss how data is backed-up and at what frequency. (*Note: Daily back-up is recommended.*)

In short, this section should include a discussion of each of the following elements of data management:

- Data collection and recording
- Data reduction/transformation (i.e., how the data is aggregated into the hourly or daily sample concentrations, and later into the design values)
- Data transmittal (e.g., electronic via telemetry, download onto hand-held electronic devices, manual via data entry forms)
- Data verification/validation
- Data storage and retrieval

When describing your agency's data management system, answer the following questions (if applicable):

- How and where are data stored? Most likely, monitoring data is stored in multiple locations in your agency. For example, data may be stored inside the analyzer/sampler. It may be stored on

a site computer and/or site datalogger. It may also be stored in a central polling computer in the main office. Explain how it works in your network.

- What type of data acquisition system is in use?
- How is data transferred from the monitoring station to the central office? For example, is it via telemetry using telephone lines and a modem?
- Is data transmitted by hand (e.g., data entry forms) or electronically for intermittent samples?
- Are paper or electronic strip charts used?
- How is data transferred from the laboratory to the air monitoring agency?
- How are data aggregated? What are the averaging times of the instruments? For example, is 1-minute data collected from the analyzers? How do dataloggers (or equivalent) reduce the data to calculate hourly averages?
- How is data integrity maintained? Is raw, unaltered data maintained such that the agency can always see or retrieve the original data? If so, where and how is the raw data maintained?
- Are procedures to process, compile, and analyze data included in a specific SOP? If so, which one(s)? Cite any applicable data handling, processing, and/or validation SOPs.
- Are there procedures in place to test or periodically audit the acceptability of the hardware and software configurations? If so, describe.
- Who is responsible for each data management task?
- What security measures are in place to ensure data is not unintentionally modified or deleted?
- How is data backed-up?
- What is the frequency of back-up?
- Are recovery measures tested?
- How are the final data stored and archived?
- How long are data retained?
- When software upgrades occur, are archived data(bases) similarly updated such that data is still accessible during its retention period?

Section 20: Assessment and Response Actions

Reminder: Sections 20 – 21 of the QAPP discuss project oversight and assessment.

In this section of the QAPP, describe the assessments your agency performs or participates in, in order to ensure the air monitoring activities are being conducted as planned and are generating acceptable data. State the frequency and purpose of each assessment – some of which are derived from the CFR. Include the approximate schedule of the assessment activities (again, some are in CFR), and identify the assessment participants. A table or chart summarizing the assessments and their required frequencies is recommended. ***Note****: The assessments described in this section should mesh with the assessments listed previously in Section 6.*

At a minimum, this section should include a brief discussion on the following types of assessments:

- Annual Network Plans, which should include Appendix E siting criteria evaluations
- 5-Year Network Assessments

- Technical Systems Audits (TSAs)
- Internal systems audits (if applicable)
- Performance Audits (internal and external)
- Data quality assessments (DQAs)
- Annual data certification

Cautionary Notes:

1. *Previous Model QAPPs discussed Management Systems Reviews (MSRs) in this section. MSRs are not currently conducted by OAQPS, so do not include MSRs in the QAPP – unless someone within your agency is tasked with conducting them. If that is the case, please describe the internal MSR.*
2. *Previous Model QAPPs discussed "Annual Particulate Matter Network Reviews." This is hold-over language from previous requirements. With the advent of the ANP required in 40 CFR 58.10, all pollutants monitored are reviewed at the same time and reported in one document.*
3. *Previous Model QAPP language on TSAs is very detailed with multiple subsections. Your QAPP does not need to contain that much detail about EPA TSAs and TSA reports. Instead, summarize the information. However, if your agency conducts **in-house** systems audits – and does so in the manner that is described in the Model QAPP – then keep the language, but make sure it is clear that the TSA process being described is not an EPA Regional Office process, but rather that of your agency.*
4. *Audits of Data Quality (ADQs) occur during EPA TSAs. Previous Model QAPP language described the data audit that EPA completes. However, your agency should conduct some type of ADQ in-house on a prescribed frequency – ideally, monthly. Whatever your in-house data audit process is, you should describe it in this section of the QAPP, but make it a stand-alone section (and not a subsection of EPA TSAs). If the ADQ is conducted during an internal systems audit, then state so. (For more information on ADQs, see Section 4.4 of the EPA Quality Assurance Guidance Document* Conducting Technical Systems Audits of Ambient Air Monitoring Programs *(EPA-454/B-17-004, November 2017.)*
5. *Previous Model QAPPs discussed the "Annual QA Report," and that DQAs would be included in the annual QA report. Currently, monitoring agencies complete annual data certification packages for SLAMS in accordance with 40 CFR 58.15.*

Also in this section of the QAPP, describe how and to whom the results of the assessments shall be reported. Along those lines, discuss how response actions to non-conforming conditions shall be addressed and by whom. Include a discussion of stop work orders, where appropriate.

When describing your agency's assessments and corrective actions, answer the following questions (if applicable):

- How do you ensure the project is conducted as described in the QAPP?
- Do you conduct internal systems audits? If so, describe. Who conducts them and on what frequency?

- Do you conduct internal performance audits? If so, describe. Who conducts them and on what frequency?
- Do external entities conduct performance audits on the monitoring equipment in order to meet the CFR requirements for independent audits? For example, has the agency hired contractors to complete the audits? Or, if a local organization is part of a larger PQAO, does the PQAO conduct audits on the local's behalf? Please describe.
- Do you self-implement NPAP or PEP? If yes, describe.
- Does EPA (or its contractors) conduct NPAP and PEP audits for your agency? If yes, describe.
- Do you complete monthly or quarterly audits of data quality? If so, describe.
- Do you complete quarterly or annual DQAs? If so, describe. (See Section 15.4 of the QA Handbook for more info on DQAs.)
- Who is responsible for reporting the need for corrective actions?
- Is there a process in place that would allow any project personnel to initiate a corrective action process, if warranted? If so, describe. If included in an SOP, provide the specific reference.
- How many business days are allowed between the time the need for a corrective action is reported and the time the corrective action measure is completed?
- How are corrective actions tracked and documented?
- Who will assess the effectiveness of a corrective action measure to determine whether it successfully resolved the issue?
- Is there a process in place to communicate when corrective action measures are disputed and/or unresolved? How would such disputes be elevated? For example, would the issue be communicated to the agency's QA Manager or Director for resolution, or to the EPA Regional Office? Describe the mechanism used by the agency to resolve disputes.
- As a part of QA oversight, does the agency have any emergency/contingency plans that should be implemented when certain situations arise or when assessment(s) show that data quality/quantity is in jeopardy?

***Note**: When documenting this section of the QAPP, ensure that the individuals tasked with particular assessment roles mesh with those identified earlier in Section 4.*

Section 21: Reports to Management

This section of the QAPP is geared towards illustrating how the results of assessments are communicated up the management chain, so that all parties in the ambient air program – including the agency director (or equivalent) – are aware of data quality issues and concerns. With this in mind, in this section of the QAPP, discuss your agency's approach to this communication process. Identify the frequency and distribution of routine reports issued to inform management of the status of the monitoring network (or specific pollutant program), which includes information regarding the results of performance evaluations, systems audits, data audits, and/or any significant quality assurance problems and recommended solutions. Identify the preparer and the recipient(s) of the reports, and any specific actions management is expected to take as a result of the reports.

For a few of the regulatory-required assessments described in Section 20, the resulting document is submitted to EPA for review and approval. Usually, these documents must be routed through the agency's chain-of-command and signed by the agency director (or delegate). Identify those reports here. For simplicity, this information could be entered into a table.

Your agency should complete internal reports to management, and possibly external reports that are provided to other data users, that are beyond those required in the CFR. When writing this section of the QAPP, think about any internal or external reports you generate to share data results and concerns. Answer the following questions in the QAPP (if applicable):

- Do site operators compose a routine, monthly/quarterly report to the appropriate Field Operations Supervisor or QA Manager that summarizes the month's monitoring activities and/or highlights specific reasons for data loss? If so, discuss.
- Are routine reports prepared that discuss the results of intermittent particulate matter sampling? Thinking about $PM_{2.5}$, for example, a laboratory provides a data package with the results of the gravimetric analysis, but it is the responsibility of the agency to combine the lab and field results together and validate the data. So, is any type of report generated on a monthly/quarterly basis that summarizes the data results, highlights specific reasons for data loss, and/or provides estimates of data recovery? If so, discuss.
- Similar to the bullet above, are any reports prepared that discuss the results of criteria lead sampling? If so, discuss.
- Does anyone query AQS on a routine basis and generate data completeness reports, in order to keep management informed of any potential issues? If so, discuss.
- Is anyone charged with keeping tabs on design values, and reporting to management any concerns about specific sites because of the design value estimates? If so, discuss.
- Are written reports issued that contain the results of in-house performance audits or systems audits? How are these reports disseminated? For example, if your agency is a large PQAO with numerous district/regional offices, do you submit formal reports to those offices? Or, if your agency is a PQAO made up of multiple, smaller organizations, do you submit formal reports to the smaller organizations within the PQAO?
- If during a performance or systems audit issues are found that require corrective action, do you generate a separate Corrective Action Report that is geared towards correcting the specific issue? Or is the need for corrective action contained within the body of the main report and not separated out?

Section 22: Data Validation and Usability

Reminder: Sections 22 – 24 of the QAPP discuss how the data resulting from the project are validated.

This begins the final portion of the QAPP where everything comes together in order to determine whether or not the agency has met its overall quality goals and the resulting data collected can be used – with confidence – for its intended purpose.

In this section of the QAPP, the criteria for deciding the degree to which data has met its quality specifications should be stated. Data validators should estimate the potential effect that each deviation from the QAPP may have on the **usability** of the associated data, its contribution to the quality of the data, and its effect on decisions. In other words, the QAPP needs to explain in this section the process by which the data are deemed usable for their intended objective.

Important Definitions to include in the QAPP:

- **Verification** can be defined as confirmation, through provision of objective evidence, that specified requirements have been fulfilled.

- **Validation** can be defined as confirmation, through provision of objective evidence, that the particular requirements for a specific ***intended use*** are fulfilled.

Note*: To assist with the development of this portion of the QAPP, please review Section 17 of the QA Handbook (January 2017 edition).*

When describing how your agency determines data validity and usability, the network as a whole should be considered, as well as the life cycle of the sample. Think big picture. This section of the QAPP should tie together the following components:

- Sampling Design
- Sample Collection Procedures
- Sample Handling
- Analytical Procedures
- Calibration Procedures
- QC Procedures (e.g., 1-point QC checks for gaseous pollutants, flow rate verifications for particulates, etc)
- Data Reduction and Processing Procedures

So, when writing this section of the QAPP, think about the following questions and broadly state how your agency addresses them during data review processes:

- How do you know the sampling design conforms to EPA requirements?
- How do you know the instrument (method) used to collect the data is acceptable for the project, and how do you know the manner in which the instrument was operated is acceptable?
- Do you have procedures in place to verify that SOPs **have been followed** when collecting samples/data?
- Do you have procedures in place that ensure sample integrity throughout the sample handling process? Were they followed?
- Have the instruments used to collect the data been calibrated?
- Have routine QC checks been performed to attest that the instrument calibration has not drifted?
- Have corrective action measures been implemented, when needed?

- Do you have any specific criteria for which, when exceeded, you immediately invalidate data (i.e., control limits)? If so, include them.
- Do you have any business rules that state, if specific situations arise, data will not be usable? If so, include them.

Section 23: Validation and Verification Methods

In this section of the QAPP, describe the methods or procedures to be used when verifying and validating data, as well as documenting the process. This will most likely include describing a multi-leveled (tiered) data review approach that involves multiple staff members. Towards that end, the QAPP should describe who is responsible for each level of data review and what each level of data review entails. Verification includes both self-review and peer-review of data and records. (Some verification activities can be automated through the use of datalogger programming and/or data acquisition software packages.) Validation, on the other hand, should be independent of the data generation process and involve a more in-depth review, ensuring data meets its intended use. In agencies with limited staff, a multi-leveled (tiered) approach may be difficult to implement; however, the data review approach utilized should still provide for independence in the validation process.

In this section, describe the process to accept, qualify, or reject data. Describe how qualified and rejected data will be identified. For ease of use, it is recommended that the AQS null value codes and QA qualifier flags utilized by the agency be presented in a table or chart. It is further recommended that these tables include examples of how and when to apply specific codes and flags. For example, the agency may use "BC" (multi-point calibration) for coding data loss during a gaseous analyzer calibration, whereas "AT" (calibration) may be used when a particulate monitor is calibrated.

In addition to AQS flags and codes, the specific criteria used to review and validate data should be stated in this section of the QAPP. These criteria should have already been established in the MQO tables in Section 7 (Quality Objectives and Criteria); with that in mind, you only to need to reference the tables again here (adding a phrase such as, "*See Section 7 of the QAPP for the MQO tables against which data will be validated*".) However, if the MQOs were not presented in tabular form in Section 7, they must be included in this section of the QAPP. Moreover, it is important in this section that you clarify how **to read, interpret, and apply** the MQO tables. If adopting the Data Validation Templates found in Appendix D of the EPA QA Handbook as the agency's MQO tables, an explanation of the critical, operational, and systematic criteria categories is needed here, along with a description of how agency staff will handle data based upon this categorization.

The agency should discuss in this section how they will "bracket data" using the results of QC checks. For example, with an ozone data set, when a QC check exceeds the acceptance criterion, data will be invalidated back to the last known, passing QC check; similarly, data will be invalidated forward until the time of successful corrective action and recalibration. This bracketing concept should also be applied to laboratory data, as appropriate, when reviewing the results of sample batches and its associated QC. Weight of evidence should also be discussed in this section – which can involve using professional

judgment to make calls about overall validity and determining whether data meets the needs of the end user. For example, if QC checks on an ozone analyzer are performed at a frequency that does not meet the biweekly requirement in the CFR (i.e., critical criterion), but the *results* of the QC checks show that the analyzer operated within its established acceptance criteria, the agency may determine that the data is valid because, for its end use (e.g., NAAQS comparisons), the passing QC results provide enough empirical evidence to support the data's overall validity. As another example – when a sample has been found to deviate from multiple operational criteria, the agency may determine the data should be invalidated (as opposed to qualified) because too many operational deviations jeopardize the ability to defend the validity of the sample (and likely do not meet the needs of the end data user). In both of these scenarios, the data validator must "weigh" the evidence in order to make a final decision.

When describing your agency's verification/validation methods, answer the following questions:

- Do you have a Data Validation SOP? If so, cite it. Language for this section can be reduced by referencing the SOP, as appropriate.
- Do you utilize a weight of evidence approach when validating data, such as the one described above and in Appendix D of the QA Handbook? If so, add language to the QAPP to describe the weight of evidence approach.
- Do you utilize the EPA DASC tool? If so, how does it influence your process?
- How do you bracket data? Explain the concept here, if it has not already been explained in an earlier section.
- Which AQS null value codes do you apply to your data set?
- Do you apply AQS QA qualifier flags to your data? If so, which ones?
- Do you identify and flag data that may have been considered an outlier or exceptional event?
- Is a datalogger utilized in the project that has been pre-programmed to flag data for certain events, outliers, or anomalies? Or is <u>all</u> data verification completed by people?
- Who verifies the data? On what frequency does it occur and what does it entail?
- Who validates data? On what frequency does it occur and what does it entail?
- What is the agency's review process for laboratory-supplied data? Describe, including the frequency of the review and what it entails.
- Is there a hierarchy in this data review process that ensures multiple sets of eyes review the data? Describe the hierarchy and explain how it provides adequate independence during data validation.
- If your agency does not have a multi-leveled (tiered) data review process because of limited staffing, how does your agency maintain adequate independence when validating data? Describe the review structure in place and explain how independence is achieved.
- How is the data verification/validation process documented? For example, do site operators complete a monthly report where they have verified, flagged, and/or coded the data sets for which they are responsible, and then submitted those reports to a QA Manager (or equivalent) for additional review and validation? Or, does the QA Manager complete a report each month that describes the overall validation of the data set? Describe your process.

- Is email used to document data validation decisions? If so, describe how email is used in your agency's validation process and how those emails are retained.
- Does someone within your agency final-review data and approve its release to AQS? If so, what does that review entail and how is it documented?
- Is data verified after AQS entry to ensure the accuracy of the data submittal? If so, what does this review include and how is it documented?

***Note**: When documenting this section of the QAPP, ensure that the roles and responsibilities identified here mesh with those identified earlier in Section 4.*

Section 24: Reconciliation with Data Quality Objectives

In this final section of the QAPP, describe how the sample results (which have already been reviewed, verified, and validated against the MQOs) obtained from this project will be reconciled with the project's data quality objectives. Remember, DQOs are the qualitative and quantitative statements that describe the intended use of the data, the type of data needed, and set tolerable limits on the amount of uncertainty in the data sets so that decision makers can use the resulting data with a reasonable amount of confidence. With that in mind, the main goal of this final process is to determine whether or not you achieved your project's big picture goals. This section is also where you explain how your agency plans to continuously improve (if the project continues) – by looking at the results of various assessments and modifying the project objectives/requirements, where appropriate.

A few of the questions you may ask when reconciling your data include:

- Was the data within the QC limits?
- Is the data more or less variable (coefficient of variation) either in time or in space than expected? (Implies the sampling frequency or sampling network may need to be increased or decreased)
- Do the results of monitoring indicate a measured concentration consistently far above, far below, or near the NAAQS? Levels near the standard may indicate the need for additional and/or more frequent monitoring.
- Do the monitoring data design values indicate that monitoring may no longer be necessary?
- Have the correct amount of resources been allocated to monitoring?

Describe the process your agency utilizes here. Outline how the data will be analyzed (e.g., what questions will be answered). Describe how data anomalies will be resolved, and discuss how limitations on the use of the data will be reported to decision makers. Identify who completes this process for the agency and how it is formally documented and communicated.

For air agencies monitoring for NAAQS decision-making purposes, this section should include, at a minimum, a description of the annual data certification process using AQS as a statistical tool – and how the results of data certification drive potential changes within the monitoring network. Although additional assessments over longer periods of time (e.g., 3-year assessments) may also be completed as

part of the monitoring project, for SLAMS monitors, the annual data certification process is a key identifier in whether or not DQOs are being met (or are on target to be met). If DQOs are not met during annual data certification, then the assessment should serve as a catalyst within the agency to prompt investigation and corrective action. As such, how the results of data certification will be handled within the agency should be described here.

For example, if you generate an AMP 600 and see that a specific pollutant did not meet its DQO, that should result in multiple questions by upper management and lead to an investigation by the agency as to why the data didn't meet the objective. The investigation may show that an operator(s) did not adhere to protocols; it may show that a new make/model of instrumentation introduced into the network was a "lemon". As a result of the investigation, corrective action measures should be initiated that will result in improvements, such that the DQOs can be achieved next year. These corrective actions may include training the operators who did not adhere to protocols, or switching out the make/model of instrumentation that did not produce the desired results. Or, it could result in tightening warning limits (acceptance criteria) in the agency's SOPs so that calibrations are conducted sooner, rather than later. It may involve significant modifications to the QAPP itself.

Your project may have additional DQOs and require additional assessments beyond annual data certification. For some projects, such as NATTS, annual certification is not a component of the project – as those data are not regulatory. With that in mind, your agency may utilize a more in-depth approach to reconciling its data against the DQOs (such as performing assessments as described in the EPA document *Data Quality Assessment: A Reviewer's Guide* (EPA QA/G-9R, February 2006)). Therefore, if your agency's end-of-year (or end-of-project) analysis goes beyond the general description provided here, then detail the additional steps taken by your agency in this section of the QAPP. Answer these questions:

- What is the frequency of the analysis? Is it annual?
- What are the statistical analyses performed?
- Who performs the statistical analyses?
- What tools are used to complete the calculations?
- Do you take actions and make changes to your program and/or your QAPP as a result of these analyses?
- Do you compute new confidence limits on your pollutant data sets each year and change the acceptance criteria within the QAPP/SOPs as a result of the analysis? Explain your process.

Completed QAPP? A Few Reminders Prior to Submittal to EPA!

Check the document for the following prior to submitting for approval:

- ✓ Has the QAPP been proofread in its entirety and checked for accurate and appropriate content?
- ✓ Have all the QA/QC elements in the MQO tables (i.e., QA Handbook data validation templates) been addressed in sufficient detail?

- ✓ Is the QAPP readable? Meaning, is it written in plain language that will be easily understood by all project participants?
- ✓ Are references to regulations, guidance documents, and other documents accurate and specific? Check all citations.
- ✓ Beyond ensuring that the citations used are accurate, do the citations actually apply to what is referenced? Meaning, is the citation itself appropriate? For example, a reference to 40 CFR Part 58, Appendix D about siting, when the more appropriate regulation would be Appendix E. Check all citations for appropriateness.
- ✓ Have citations within the QAPP about the QAPP been cross-checked for accuracy? For example, if the QAPP states, "See Section 10 of this QAPP for more information", is Section 10 the correct place in the QAPP to find the necessary information?
- ✓ Have references to figures and tables in the QAPP been cross-checked for accuracy? For example, if the QAPP states, "See Figure 2 for a map of the monitoring network," is Figure 2 the referenced map of the monitoring network?
- ✓ Has the Table of Contents – its headers and page numbers – been cross-checked for accuracy?
- ✓ Has the entire document been checked for spelling, grammar, and typographical errors?
- ✓ Have associated SOPs been attached to the QAPP as appendices or appropriately referenced within a list or table(s) in the QAPP, in accordance with 40 CFR Part 58, Appendix A, Section 2.1.2? If not included as appendices, please ensure SOPs are available to EPA, upon request.
- ✓ Has the document been reviewed, approved, and signed by the appropriate individuals within the chain-of-command, including the agency's QA Manager (or equivalent)?

Note: *After the QAPP has received EPA approval, AQS will be updated to reflect the approval status and date*.

Additional References

The following provides a list of documents which may be helpful to the QAPP writer. Please note that the hyperlinks provided are current as of the date of this publication and may change in the future.

1) *QA Handbook for Air Pollution Measurement Systems, Volume II* (January 2017) https://www3.epa.gov/ttn/amtic/qalist.html
2) *Requirements for Quality Assurance Project Plans EPA QA/R-5* (March 2001) https://www.epa.gov/quality/epa-qar-5-epa-requirements-quality-assurance-project-plans
3) *Guidance for Quality Assurance Project Plans EPA QA/G-5* (December 2002) https://www.epa.gov/quality/guidance-quality-assurance-project-plans-epa-qag-5
4) *Guidance on Systematic Planning Using the Data Quality Objectives Process EPA QA/G-4* (February 2006) https://www.epa.gov/quality/guidance-systematic-planning-using-data-quality-objectives-process-epa-qag-4
5) *Data Quality Assessments: A Reviewer's Guide EPA QA/G-9R* (February 2006) https://www.epa.gov/quality/guidance-data-quality-assessment
6) *List of Designated Reference and Equivalent Methods* https://www.epa.gov/amtic/air-monitoring-methods-criteria-pollutants
7) *ITEP Online Training – QAPP 201 & 202 courses* https://itep.scholarlms.com/courses/

Other EPA guidance and Technical Assistance Documents (TADs) which may be helpful to the QAPP writer can be found on the EPA's AMTIC website at: https://www.epa.gov/amtic.

EPA policy and technical memoranda can be found at the following hyperlink: https://www.epa.gov/amtic/policy-memoranda-and-technical-guidance

Specific recent guidance and memoranda that may be especially helpful when developing QAPPs include, but are not limited to, the following:

1) *EPA Review of Monitoring Organization's QAPPs for Critical Criteria Conformance* https://www.epa.gov/amtic/policy-memoranda-and-technical-guidance
2) *Steps to Qualify or Validate Data After an Exceedance of Critical Criteria Checks* https://www.epa.gov/sites/production/files/2018-01/documents/critical_criteria_qualifier_memo_v1_0.pdf
3) *Clarification on Use of Automatic Zero Adjustments* https://www.epa.gov/sites/production/files/2017-10/documents/technical_note-zero_adjustments.pdf
4) *Clarification and Guidance on Shelter Temperature Guidance for Ambient Air Pollutant Methods* https://www.epa.gov/sites/production/files/2018-03/documents/clarifications_on_shelter_temperature_for_gaseous_pollutant_methods_03_2018_0.pdf
5) *Clarification on Statistics for Use of 1-Point QC Checks at Lower Concentrations* https://www.epa.gov/sites/production/files/2017-02/documents/tech_memo_for_1-pt_qc.pdf

6) *Technical Guidance on Identifying Annual PE Audit Levels Using Method Detection Limits and the 99th Percentile*
https://www.epa.gov/sites/production/files/2017-02/documents/annual_pe_audit_levels_using_mdls.pdf
7) *Technical Guidance on the Use of Electronic Logbooks for Ambient Air Monitoring*
https://www.epa.gov/sites/production/files/2017-02/documents/electronic_logbook_final_4_20_16.pdf
8) *Clarification on Use of $PM_{2.5}$ Field and Laboratory Requirements for Low Volume PM_{10} Monitoring to Support PM_{10} NAAQS*
https://www.epa.gov/sites/production/files/2017-02/documents/pm10-low-vol.pdf

Please be aware that the guidance listed above is current as of the date of this publication and is subject to change. The AMTIC website is updated frequently with new publications, so it should be checked routinely. The QAPP writer may wish to join the AMTIC Listserv to receive periodic updates and notifications.

The Air Pollution Training Institute (APTI) 470 course, *Quality Assurance for Air Pollution Measurement Systems*, also addresses QAPPs and quality system elements that should be addressed within QAPPs, and would be beneficial to the QAPP writer.

United States Environmental Protection Agency

Office of Air Quality Planning and Standards
Air Quality Assessment Division
Research Triangle Park, NC

Publication No. EPA-454/B-18-006
August 2018