

Quality System Training Module 2 Planning



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Topics

- EPA Planning Activities
 - DQOs/DQIs/MQOs
 - Methods FRM/FEM/ARM
 - Communication
- Monitoring Organizations
 - QMPs/QAPP/SOPs
 - Personnel/Training
 - Documentation and Records

Data Quality Objectives Data Quality Indicators Measurement Quality Objectives

Quality Assurance

E4- Part of quality management focused of providing confidence that quality requirements will be fulfilled .

Mikes- A system of activities whose purpose is to ensure that information derived from measurements are of a quality that the decision maker is willing to **risk making an inappropriate decision**

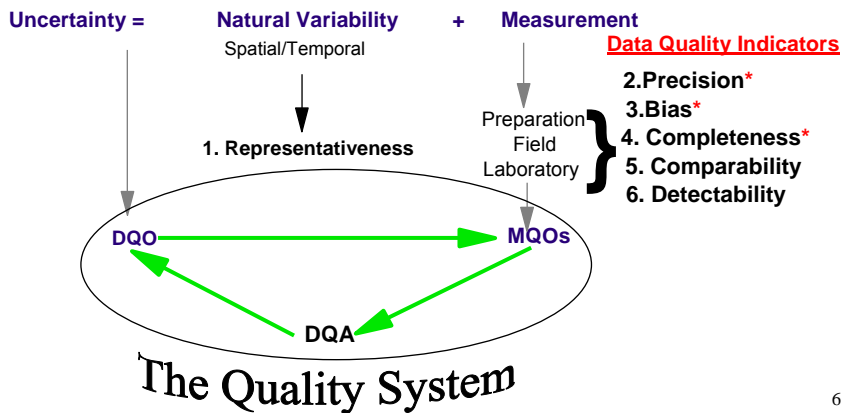
Some decisions will be inappropriate (wrong) due to

data uncertainty...

...the difference between your measurement (estimate) and the "truth"

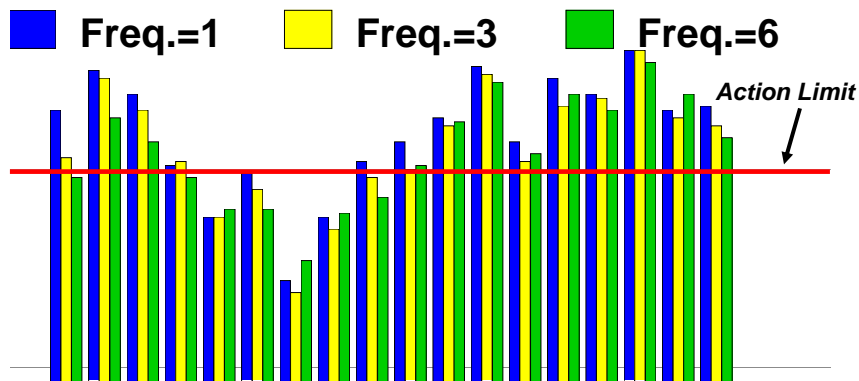
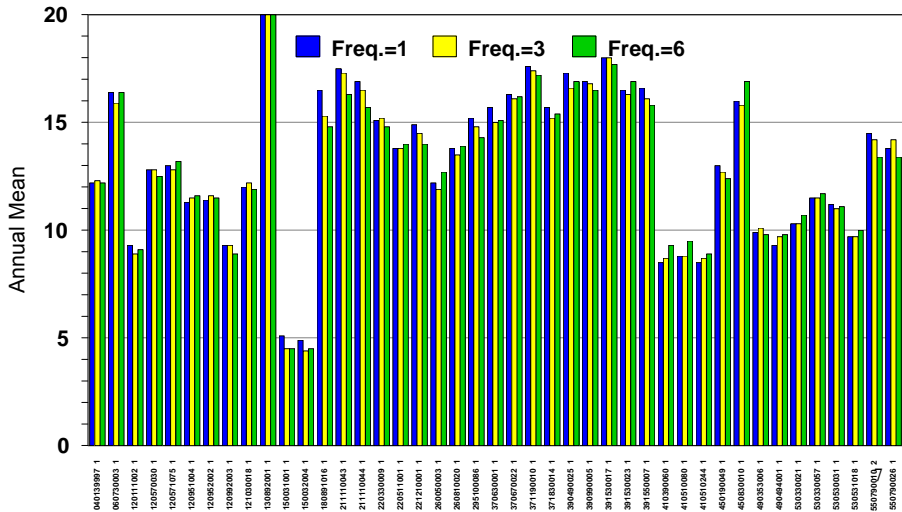
Premise 1 - All estimates have error so all decisions made with estimates have risks.
Premise 2- We can't afford 100% certainty in our decisions

Understanding and Controlling **Uncertainty** in Order to Minimize **Decision Errors**

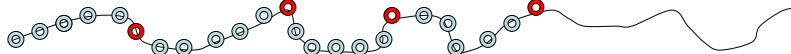


Temporal Representativeness of PM2.5 Sampling

Comparing Annual Means from Every Day sampling to those calculated from 1-in-3 and 1-in-6 frequencies. Only complete sites included.

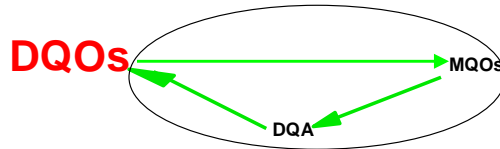


Every day sampling does not always provide the highest mean conc., but does provide the user with more confidence in the annual estimate.





1st Stop Systematic Planning



Designed to answer:

- What do you need?
- Why do you need it?
- How will you use it?
- What is your tolerance for errors?

7-Step DQO Process:

1. State the problem to be resolved.
2. Identify the decision to be made.
3. Identify the inputs to the decision.
4. Define the boundaries of the study.
5. Develop a decision rule.
6. Specify the tolerable limits on decision errors.
7. Optimize the design for obtaining the data.

The DQOs in CFR are goals.

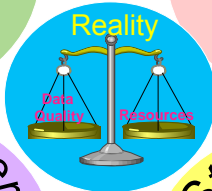
If the goals are not achieved decisions are made with less certainty

You can't always get what you want



Decision Maker
 I want the right answer!
 You have 1 million and 1 year

Technical Manager
 I'll use the very best equipment
 for the best precision and accuracy



QA Manager
 I'll try to ensure that the
 precision and bias are near
 zero

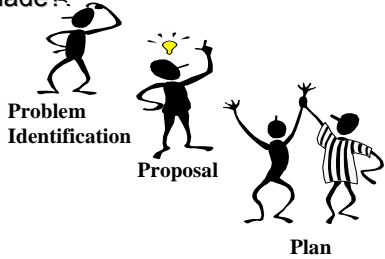
Statistician
 Give me all the samples you can.
 I don't want to make any assumptions

DQO Goal... You get what you need

Bridging the Policy/Technical Communication Gap

Issue (policy)

- **What** is the problem?
- **Why** does it need to be solved?
- **Who** are the people responsible for solving it?
- **How** will it be solved?
- **Where** is/are the problems?
- **When** do decisions need to be made?

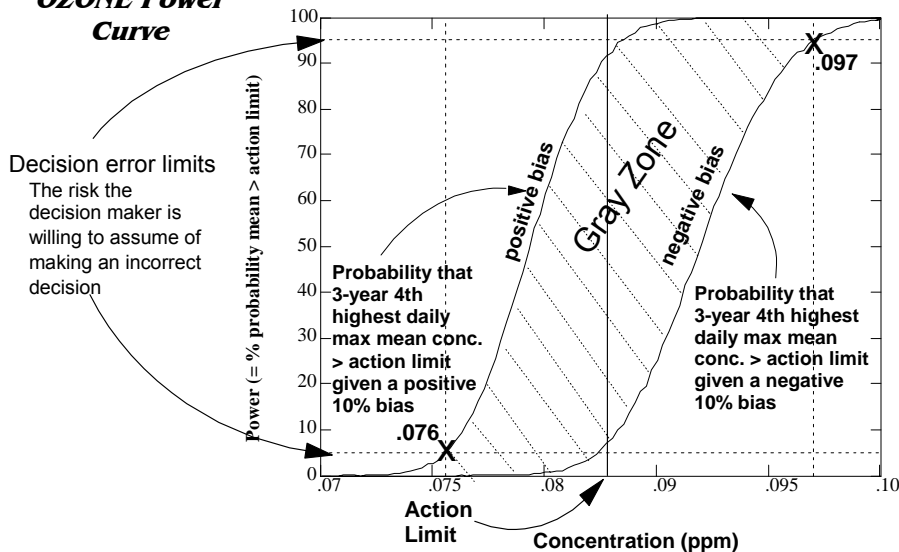


Project Specific (technical)

- **What** data needs to be collected?
- **Why** does it need to be collected?
- **Who** are the people responsible for collecting, assessing and reporting the data?
- **How** will the data be collected (SOPs) & how good does it need to be?
- **Where** specifically will the data be collected and what does it represent?
- **When** will the data be collected, how often (frequency) and reported?

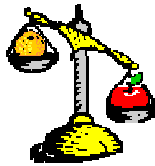
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OZONE Power Curve



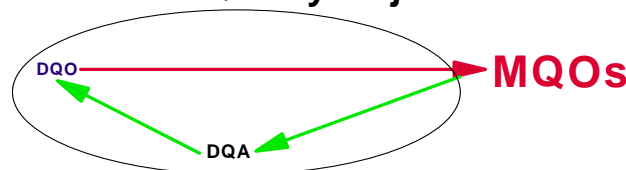
Performance Curve Gray Zones

Picking the error a decision maker can live with and the technology is capable of meeting



Measurement Input Parameters				Gray Zone (ppm)	
Daily Completeness	Minimum Hours per day	Hourly Measurement Precision (CV)	Measurement bias	Lower end point	Upper end point
75%	18	7.5	7.5	0.078	0.099
		10%	5%	0.080	0.096
			10%	0.076	0.102
			20%	0.070	0.114
		15%	5%	0.079	0.096
			10%	0.075	0.101
			20%	0.069	0.114
		20%	5%	0.078	0.095
			10%	0.074	0.100
			20%	0.068	0.112

2nd Stop of Systematic Planning Measurement Quality Objectives



MQOs-The performance criteria that provide for an estimate of a data quality indicator for:

- the overall data collection effort (meeting DQOs)
- a measurement phase

Performance criteria (number of QC samples and acceptance criteria) is established to:

- control data quality
- to meet program DQOs
- can be used to develop validation templates

Data Quality Indicators & MQOs

	PM _{2.5}	O ₃
● Representativeness	# sites/freq	# sites/freq
● Comparability	FRM/FEM/ARM	FRM/FEM
● Completeness	75%	75%
● Sensitivity (Detectability)	2µg/m ³	0.003 ppm
● Precision	10%*	7%*
● Accuracy/Bias	±10%*	±7%*

*Based on 3 years of data so any individual value can be higher than MQO
 PM_{2.5} P&B estimates are for PQAQO, gaseous P & B estimates at site level

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Federal Reference (FRM) and
 Equivalent Methods (FEM)
 40 CFR Part 53

 and Approved Regional Methods
 (PM_{2.5} only)
 40 CFR Part 58 App C

FRM/FEM

- All SLAMS monitors must be FRM/FEM (ARM PM2.5)
- Non-NAAQS monitoring has more flexibility
- NERL develops an FRM for each NAAQS
 - Based on combination of:

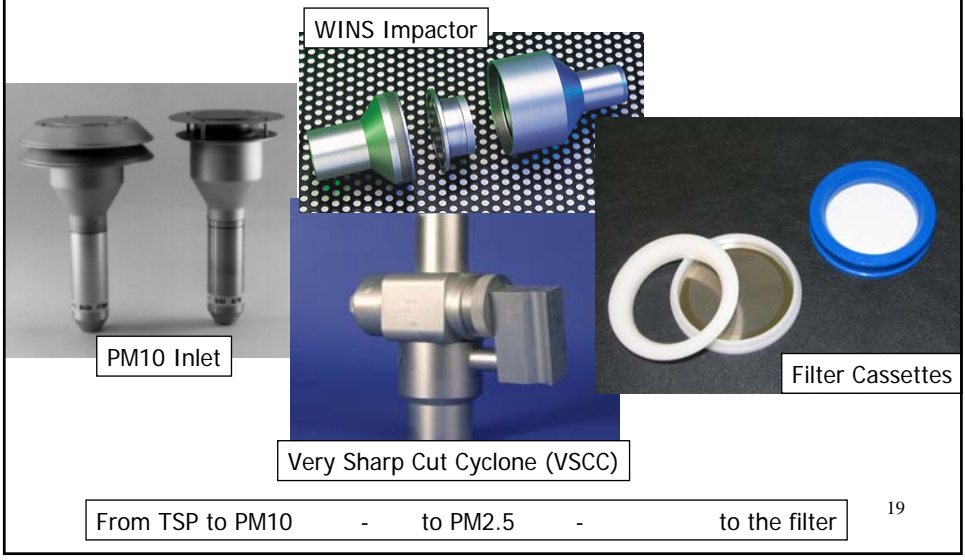
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Characteristics of Gaseous FRM/FEM Methods

- Compound specific
- Relatively unaffected by interfering compounds
- Sensitive at typical ambient concentrations
- Acceptable level of uncertainty
- Commercially viable
- Supports reliable and relatively maintenance-free operation
- Easily “QC-able”



Making the cut...part of the engineering requirements



*PM₁₀ and PM_{2.5}
Mass Measurement Techniques*

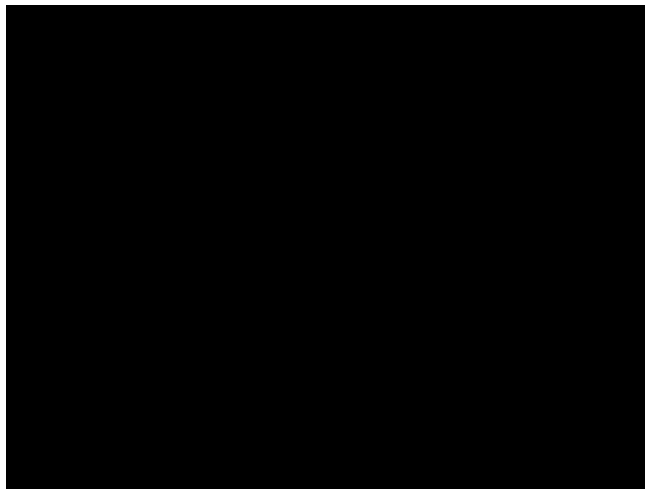
- Filter-based systems
 - Gravimetric
- Automated systems
 - Tapered Element
 - Beta Attenuation
 - Nephelometry
- Federal Reference Method (FRM)
- Federal Equivalent Method (FEM)
- Approved Regional Method (ARM)

FRM/FEM

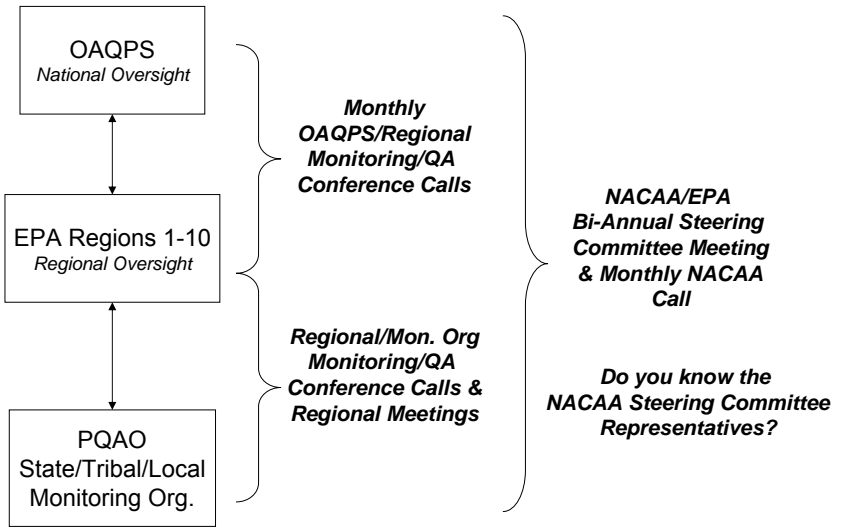
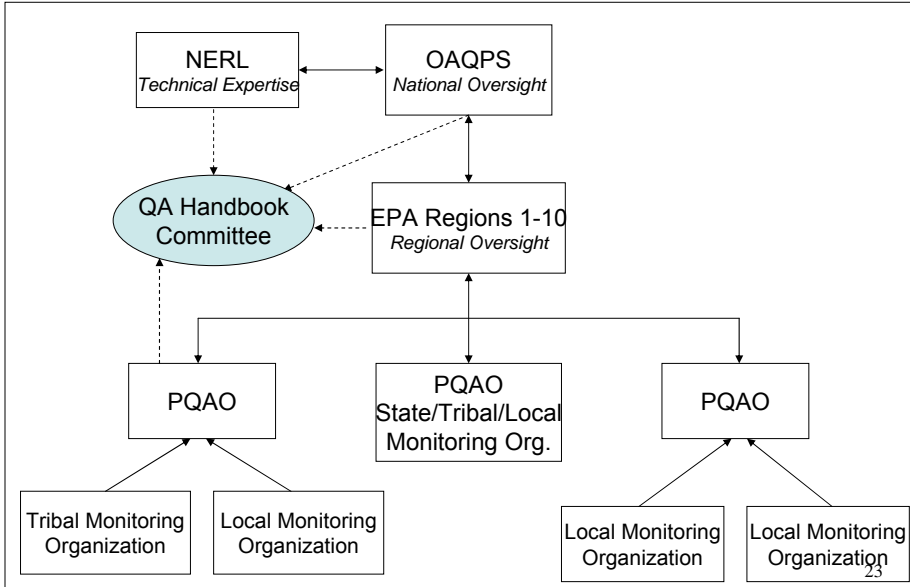
- FRM developed for each NAAQS
- NERL designates FEM based on acceptance criteria to produce “FRM-Like” values.
- FRM/FEM approval in Federal Register and posted to AMTIC
- NERL approves first ARM in Region and RA and approve others in Region

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Communication



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Monitoring Organization Planning



Air Monitoring Program Planning Meeting

Quality Management Plans
QA Project Plans and
Standard Operating Procedures

WHY QMPs, QAPPS and SOPs!!



QMP - Organization Specific

- Describes organizations quality system
- Establishes capability

QAPP - Project Specific

- Identifies the reasons for collecting data and for collecting it in a specific way
- Documents how the data are collected and how quality is maintained

SOP - Instrument/Method Specific

- Ensures consistency
 - From day to day
 - From one person to the next

QA should help you:

- **Ensure that your data are:**
 - **Adequate for the project** – are willing to risk making and incorrect decision?
 - **Scientifically valid and legally defensible**
 - Scientifically valid means that *it's accepted as a correct way to do it, and you have written it and done it in a correct way* (flow rate checks, flagged data, cleaning o-rings, etc.)
 - Legally defensible means that *you can prove that you did it the correct way* (logs, audits, chain of custody for data and filters—you have evidence)

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EPA QA Policy

All work performed by EPA organizations and by external organizations funded by EPA that involves acquisition of environmental data generated from direct measurement activities, collected from other sources, or compiled from computerized data bases and information systems **shall be covered by an Agency-approved QMP.**

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Quality Management Plans

Purpose: To document how an organization will plan, implement, and assess its Quality System

Responsibility: Senior Management

Documentation: EPA Users: *Chapter 3, EPA Quality Manual for Environmental Programs (EPA Order 5360)*

Extramural Users: *EPA Requirements for Quality Management Plans (QA/R-2)*

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Quality Management Plan General Requirements

- Mission and quality policy of the organization
- Specific roles and responsibilities with respect to QA and QC activities
- Means and structure to assure effective communication
- Processes used to plan, implement and assess work and effectiveness for QA and QC activities
- Process for continual improvement of the Quality System

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Typical Characteristics of a Good QMP

- **Clearly documented responsibilities for QA Officer/Manager**
- **QA Officer/Manager reports directly, or has unrestricted access, to senior management official**
- **Specific commitment to performing the needed assessments, and a description of the process used**
- **Clearly defined responsibilities for personnel reviewing and approving QAPPs**

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Typical Characteristics of a Good QMP

- **Clearly stated management commitment to QA and specific responsibilities documented**
- **Commitment to a specific process for systematic planning for new data collection activities**
- **Clear process for identifying resources to plan, implement, and assess the effectiveness of the quality system**
- **Process for identifying QA/QC training needs of staff**

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QMPs → QA Project Plans

- When environmental data needs to be collected or used from a secondary source in most cases QMPs will/should specify QA Project Plans be written.

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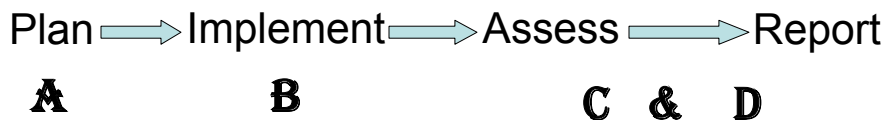
What is a QA Project Plan?

A document that describes the technical and quality activities of an **environmental data operation** (project) that should be implemented to ensure that the results of the work performed **will satisfy the data user's needs**.

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Four Main QAPP Topic Areas:

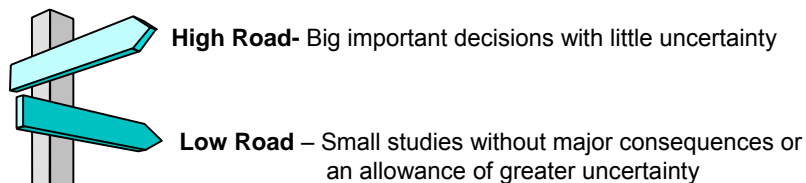
- | | |
|----------------------------------|-------------------|
| A. Project Management | 9 elements |
| B. Data Generation/Acquisition | 10 elements |
| C. Assessment and Oversight | 2 elements |
| D. Data Validation and Usability | <u>3 elements</u> |
| | 24 |



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All QAPPs Are Not Created Equal- the Graded Approach

The level of detail in each QA Project Plan will vary according to the nature of the work being performed and the intended use of the data.

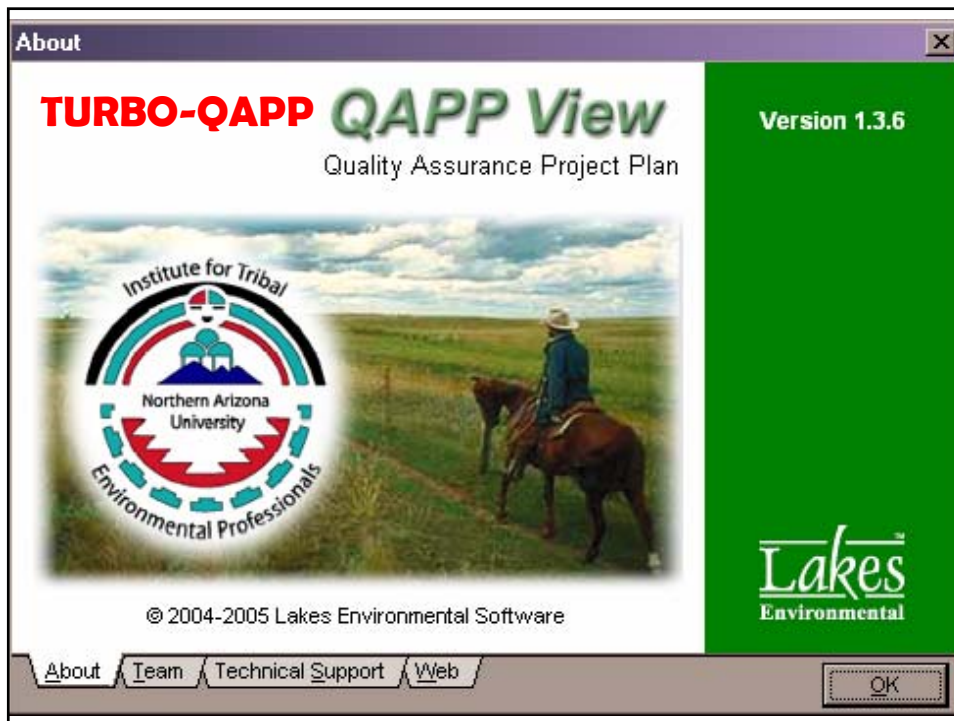


OAQPS has developed a graded approach for ambient air monitoring

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Review to ensure that:

- The plan is accurate and complete,
- Roles and responsibilities are clearly defined,
- Sufficient data will be collected using appropriate measurement and data acquisition methods,
- Planned assessment procedures will be adequate to evaluate the project, and
- There is a process to identify any limitations on the data use.



PROJECT POLLUTANTS
Ozone (O3)

I. INTRODUCTION

- II. CATEGORY
- Element 6a (A6-1). POLLUTANT
- Element 5 (A5). BACKGROUND
 - Problem Definition
 - Problem Background
- Element 6b (A6-2). METHOD
- Element 6c (A6-3). DESCRIPTION
 - Summary
 - Project Information
 - Project Schedule
- Element 6f (A6-6). PROJECT LOCATION
- Element 4 (A4). ORGANIZATION
- Element 4b (A4-2). PROJECT ORGANIZATION
- Element 7a (A7-1). DATA QUALITY OBJECTIVES
 - Stating the problem
 - Identifying the decision
 - Identify the inputs to the decision
 - Define the boundaries of your project
 - Deciding on a decision rule
 - Specifying tolerable limits on decision errors
 - Optimize the design

Project Progress 14.2%

Introduction to the QAPP

An EPA approved Quality Assurance Project Plan is required to implement any work funded by the EPA that involves acquisition of environmental data generated from direct measurement activities, collected from other sources, or collected from computerized databases and information systems.

This software will guide you through the creation of a Quality Assurance Project Plan (QAPP). A good QAPP is used to communicate the specifications for implementation of the project design and to ensure that the project's quality objectives are achieved.

Before you begin to create your QAPP you will need to select which kind of QAPP you will be writing. Select from Ambient Air or Other in the pick list below.


Creating a QAPP for ...

Enter Name of the Tribe

Enter the name of your Tribal Office

Enter the name of tribal department

 **QAPP V**

 United States Environmental Protection Agency

Ambient Air Quality System Training
QA Strategy Workgroup

QAPPs → Standard Operating Procedures

SOP = A set of written instructions that thoroughly document a routine or repetitive activity.

- When a task is repetitive it should be documented in a SOP
 - This saves the operator from having to take detailed notes of how every minutia of the task was performed.
 - This ensures consistency in the program.
- Because SOPs constitute documentation of how a task was completed old versions of SOPs with their effective dates need to be retained.

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SOPs

- They can never be too detailed
 - Remember those coming after you
- They are easy to write!
- Look at the reference methods in CFR for the minimum requirements
- Don't reinvent the wheel –Share good SOPs- Ask vendors for electronic versions
- Use document control (see example)
- Use quality bulletins for changes (see example)



Army Field Manual

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Write SOPs first

- Use examples and pictures where you can
- Use plain simple language
- Once SOPs are written the QAPP is shorter and easier; attach SOPs to QAPP
- Short, simple, step-by-step and AVAILABLE (posted)
- EPA Guidance available (G6)
 - http://www.epa.gov/quality/qa_docs.html

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General SOP Format

- Title Page
- Table of Contents
- Procedures ([see next slide](#))
- Quality Control and Quality Assurance
- Reference Section


Procedures Section

- Scope & Applicability
- Summary of Method
- Definitions
- Health & Safety
- Cautions
- Interferences
- Personnel Qualifications
- Equipment and Supplies
- Procedures ([see next slide](#))
- Quality Assurance & Quality Control
- Data & Records Management



Finally-The Procedure



- Instrument or Method Calibration and Standardization
- Sample Collection 
- Sample Handling and Preservation
- Sample Preparation and Analysis
- Troubleshooting
- Data Acquisition, Calculations & Data Reduction
- Computer Hardware and Software

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Personnel and Training

Ambient Air Monitoring Personnel

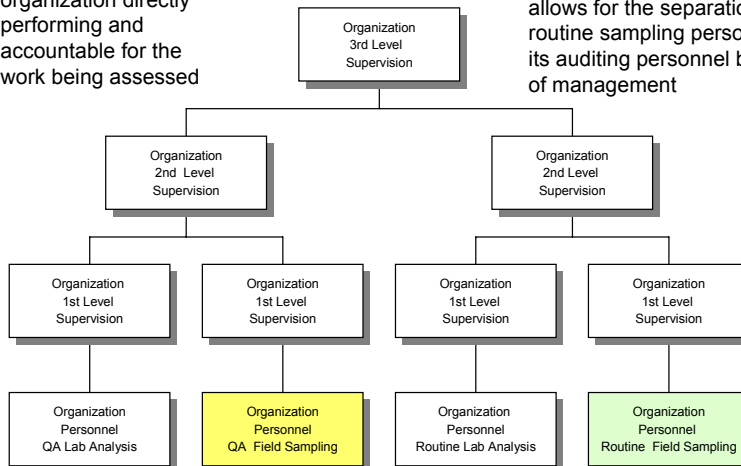
Function	Activities
Procurement	<ul style="list-style-type: none"> - Purchasing capital equipment and consumables - Developing contracts and maintenance agreements - Applying for EPA grants
Technical	<ul style="list-style-type: none"> - Setting up a monitoring site, electricity, communications - Developing standard operating procedures - Selecting and installing monitoring equipment - Calibrating equipment, performing quality control - Shelter and equipment maintenance
Data Analysis (Statistical)	<ul style="list-style-type: none"> - Understanding population and measurement uncertainty - Developing sampling designs - Developing networks to achieve objectives - Assessing/interpreting data (data quality assessments)
Quality Assurance	<ul style="list-style-type: none"> - Developing quality systems, QMPs/QAPPs - Developing data quality objectives - Implementing technical systems audits, performance evaluations - Validating data - QA reporting
Information Technology	<ul style="list-style-type: none"> - Selecting information technology (data loggers and local data base) - Developing analyzer outputs to data loggers and data transfer to local data base - Transferring data from local data base to external data repositories (AQS, etc.)

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Independence of QA Program

Not part of the organization directly performing and accountable for the work being assessed

A management structure that allows for the separation of its routine sampling personnel from its auditing personnel by two levels of management



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QA Training

- Air Pollution Training Institute
 - 470- Quality Assurance for Air Pollution Measurement Systems
 - being revised
 - APTI 435 monitoring theory and 464-
- OAQPS Ambient Air Monitoring Group
 - Precursor Gas Training (NCore)
 - PM2.5 Performance Evaluation Program (PEP)
 - National Performance Audit Program (NPAP)
 - Speciation/IMPROVE Auditor Training
- Quality Staff Training
- Regional Planning Organizations
- Regional Office Training
- Institute for Tribal Environmental Professionals

Suggested list in Handbook

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Source-Sequence	Course Title (SI = self instructional)	Field	Lab	QC-Supv.	Data Mgt.	Mon Supv.	QA	QA Mgt.
APTI- SI:422	Air Pollution Control Orientation Course	X	X	X		X	X	X
APTI 452	Principles and Practices of Air Pollution Control	X		X		X	X	X
APTI -SI:100	Mathematics Review for Air Pollution Control	X	X					
QS- QA1	Orientation to Quality Assurance Management					X	X	X
APTI-SI:434	Introduction to Ambient Air Monitoring	X	X	X	X	X	X	X
APTI -SI:471	General Quality Assurance Considerations for Ambient Air Monitoring	X	X	X	X	X	X	X
APTI- SI:409	Basic Air Pollution Meteorology	X		X		X	X	X
APTI SI:473A	Beginning Environmental Statistical Techniques (Revised)	X	X	X	X	X	X	X
APTI-470	Quality Assurance for Air Pollution Measurement Systems			X		X	X	X
QS-QA2	Data Quality Objectives Workshop					X	X	X
QS-QA3	Quality Assurance Project Plan			X		X	X	X
APTI-435	Atmospheric Sampling	X	X	X		X	X	
No Source	Basic Electronics	X		X		X		
APTI-SI:476B	Continuous Emission Monitoring Systems - Operation & Maintenance of Gas Monitors	X		X		X	X	
APTI-474	Continuous Emission Monitoring	X		X		X	X	
APTI-SI:433	Network Design and Site Selection for Monitoring PM _{2.5} and PM ₁₀ in Ambient Air			X		X	X	
APTI-464	Analytical Methods for Air Quality Standards		X	X		X	X	
APTI	Chain Of Custody Procedures for Samples and Data	X	X	X	X	X	X	X
APTI- SI:436	Site Selection for Monitoring SO ₂	X		X		X	X	
QAQPS	AQS Training (annual AQS conference)				X	X	X	
QS- QA4	Data Quality Assessment					X	X	X
QS- QA5	Management Systems Review					X	X	X
APTI-SI:473B	Introduction to Environmental Statistics				X	X	X	SA
AWMA QA6	Quality Audits for Improved Performance					X	X	X
ASQC-STAT1	Statistics for Effective Decision Making			X	X	X	X	X

Documentation and Records



Documentation

Each organization should have a documented records management policy with the following elements addressed:

- A list of files considered the official records and their media type (i.e., paper, electronic)
- Schedule for retention and disposition of records
- Storage and retrieval system of records
- Person(s) responsible at each level of storage and retrieval for records
- Assignment of appropriate levels of security

Good documentation can help defend your data,
bad documentation will destroy the credibility of
good data.

Categories	Record/Document Types
Management and Organization	State Implementation Plan Reporting agency information Organizational structure of monitoring program Personnel qualifications and training Quality management plan Document control plan Support contracts
Site Information	Network description Site characterization file Site maps/pictures
Environmental Data Operations	QA Project Plans (QAPPs) Standard operating procedures (SOPs) Field and laboratory notebooks Sample handling/custody records Inspection/maintenance records
Raw Data	Any original data (routine and QC)
Data Reporting	Air quality index report Annual SLAMS air quality information Data/summary reports Journal articles/papers/presentations
Data Management	Data algorithms Data management plans/flowcharts
Quality Assurance	Control charts and strip charts Data quality assessments QA reports System audits Network reviews