APTI 470 Lesson 3: EPA Quality Policy and the Monitoring Organization

MARAMA WORKSHOP

DECEMBER 4, 2018

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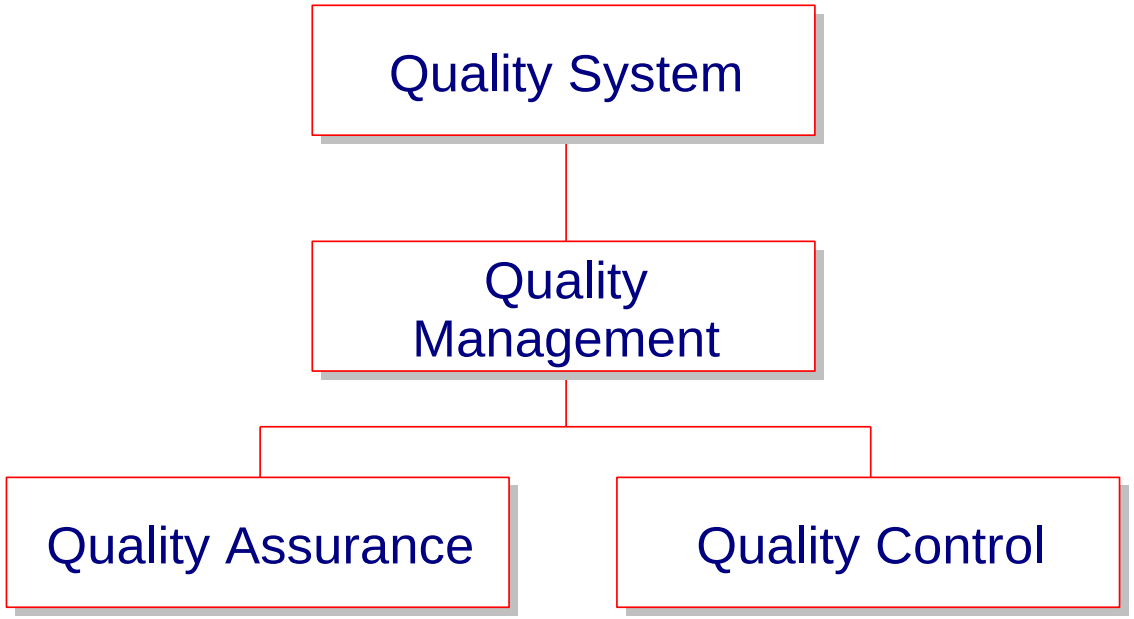
The slides presented during today's training event are an excerpt from the recently updated APTI 470 course

Presentation Agenda

- Quality systems overview
- The QA life cycle, focusing primarily on QA planning
- Required quality system documents – what they are and why they are important
  - The QMP
  - The QAPP
  - SOPs

Quality System



The sum total of the **policies** and **procedures** that are developed and implemented to ensure that quality is built into programs and work products

Covers both **policy** and **process**

Quality System Requirements

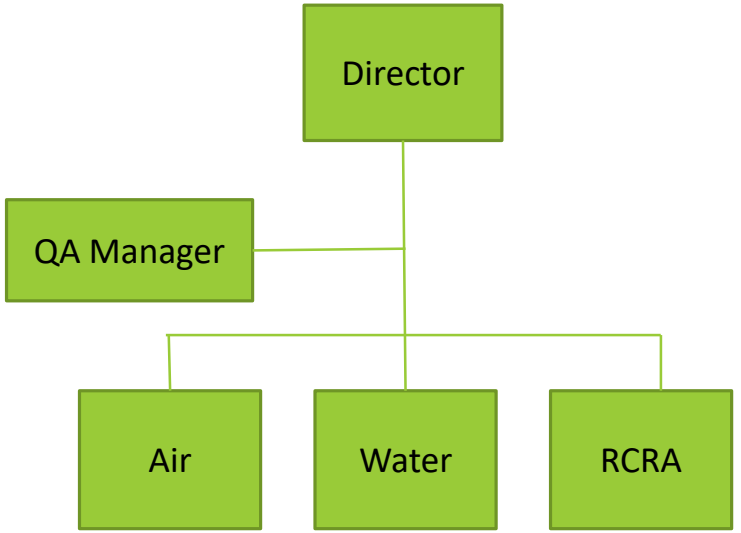
40 CFR Part 58, Appendix A, §2.1.3

The PQAO/monitoring organization's quality system **must** have adequate **resources** both in **personnel** and **funding** to plan, implement, assess and report on the achievement of the requirements specified in 40 CFR Part 58, Appendix A, as well as the organization's approved QAPP.

Independence Requirements

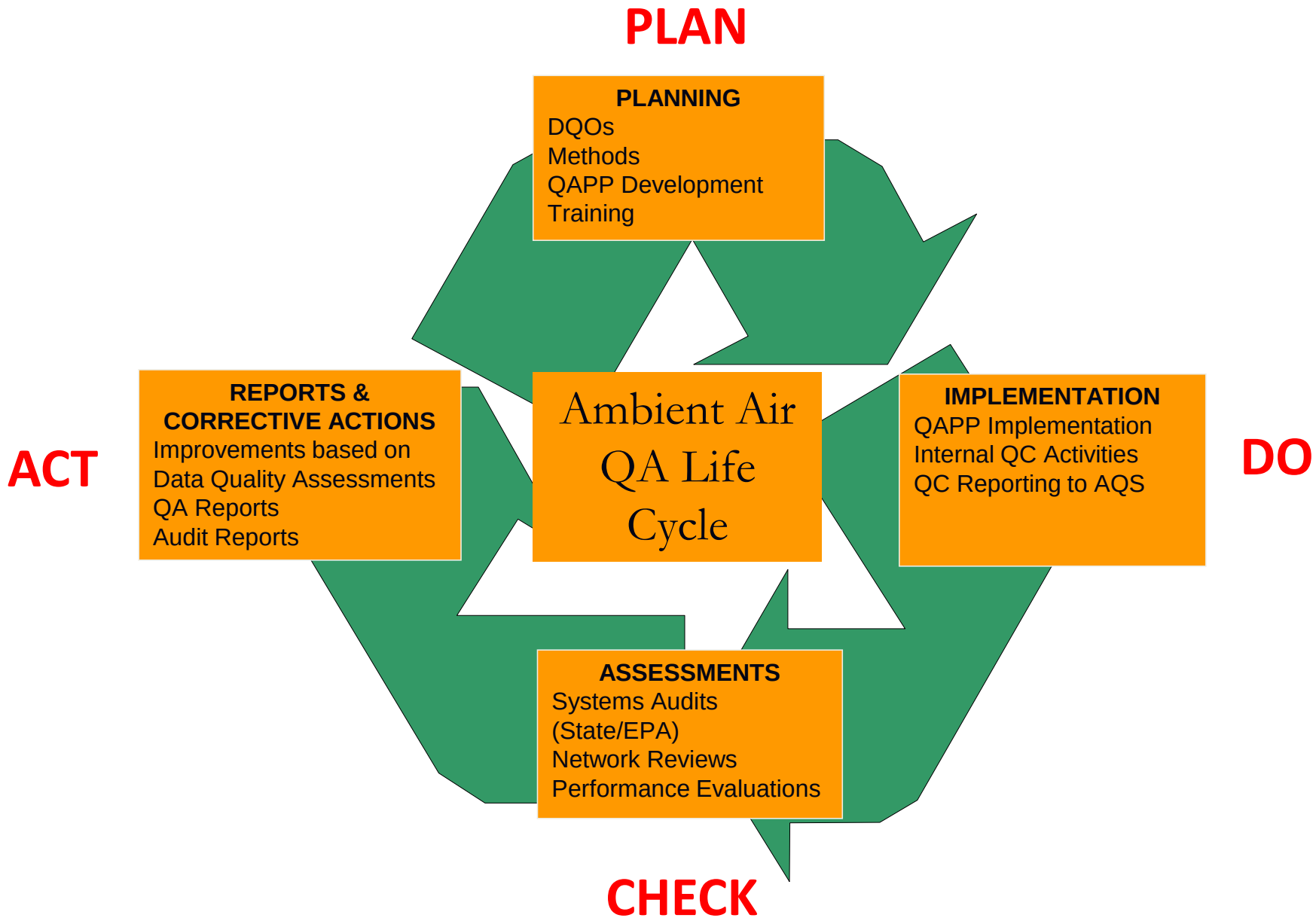
40 CFR Part 58, Appendix A, §2.2

- The PQAO **must** provide for a quality assurance management function, that aspect of the overall management system of the organization that determines and implements the quality policy defined in a PQAO's QMP
- The QA management function **must** have sufficient technical expertise and management authority to conduct **independent oversight** and assure the implementation of the organization's quality system relative to the ambient air quality monitoring program



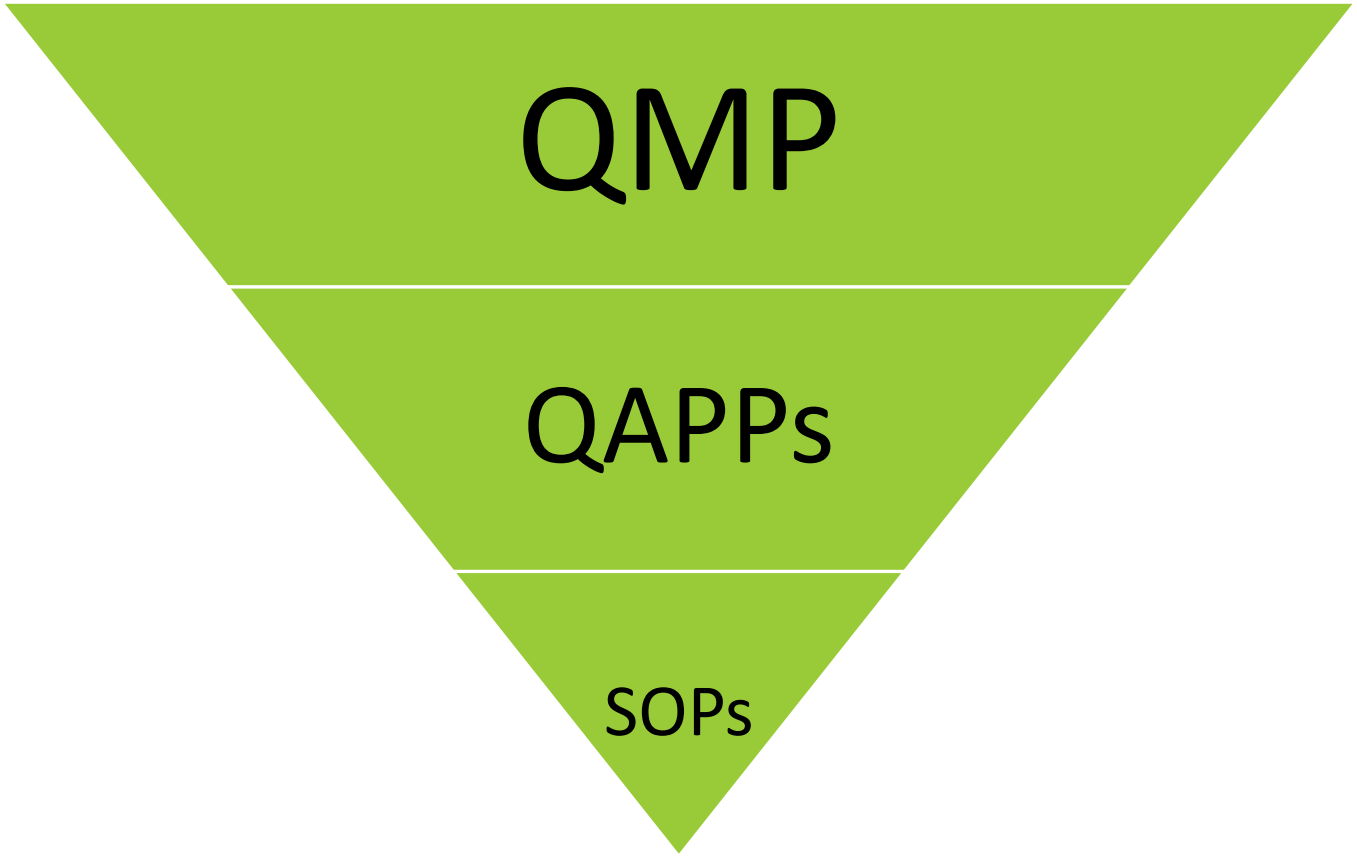
The major responsibility of the monitoring organization is the implementation of a satisfactory monitoring program, which includes the implementation of an appropriate

QA program


PLAN
PLANNING
DQOs
Methods
QAPP Development
Training
DO
IMPLEMENTATION
QAPP Implementation
Internal QC Activities
QC Reporting to AQS
CHECK
ASSESSMENTS
Systems Audits
(State/EPA)
Network Reviews
Performance Evaluations
ACT
REPORTS & CORRECTIVE ACTIONS
Improvements based on
Data Quality Assessments
QA Reports
Audit Reports
Ambient Air QA Life Cycle

Implementation of an appropriate QA program includes the development and implementation of a **QMP** and **QAPPs** for the air monitoring program

Documentation Hierarchy



BROAD FOCUS

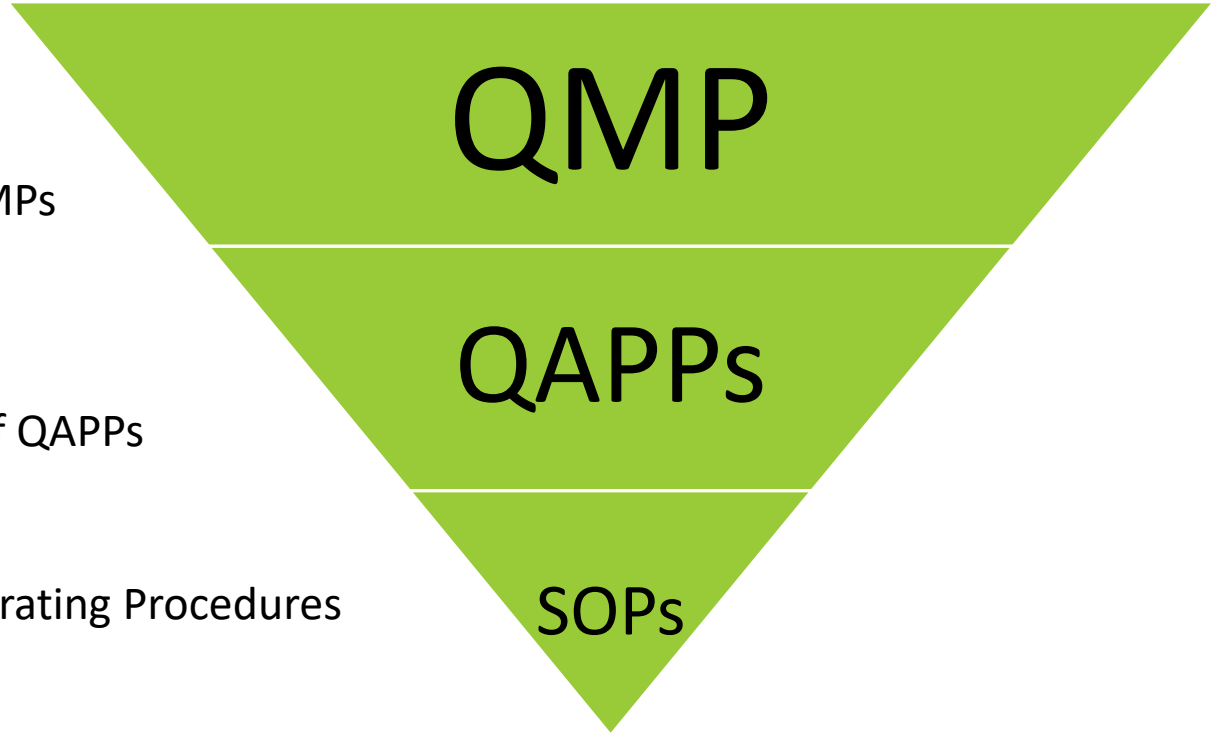
NARROW FOCUS

Requirements and Guidance

QA/R-2 EPA Requirements for QMPs
QA/G-2 EPA Guidance for Development of QMPs

QA/R-5 EPA Requirements for QAPPs
QA/G-5 EPA Guidance for the Development of QAPPs

QA/G-6 Guidance for Preparing Standard Operating Procedures



https://www.epa.gov/quality/agency-wide-quality-system-documents

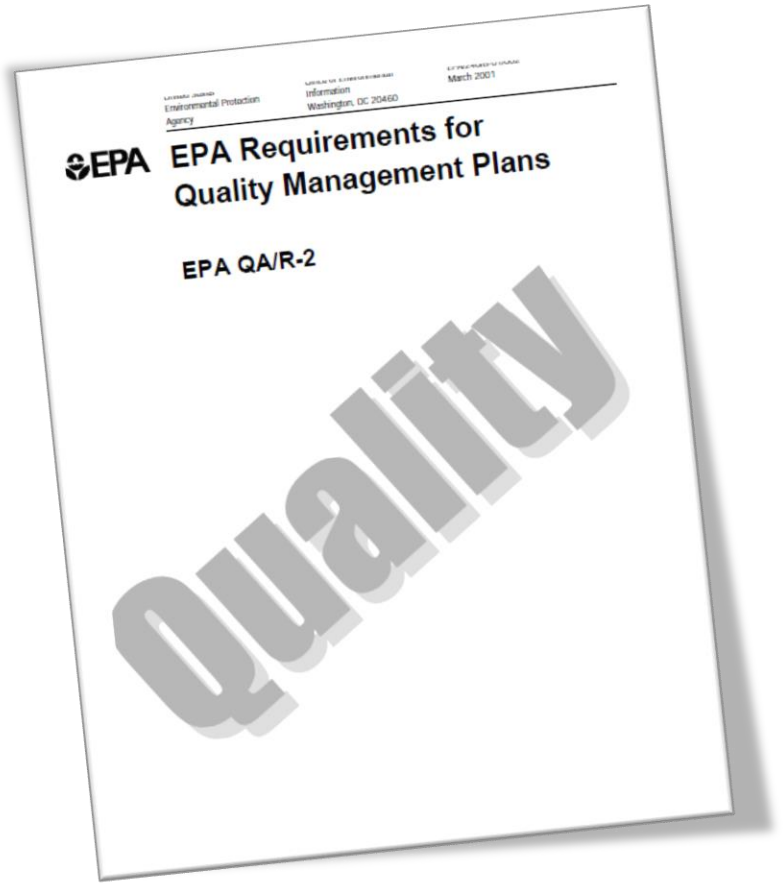
Quality Management Plan (QMP)

Your management's commitment to a quality system

Organization specific

See 40 CFR Part 58, Appendix A, §2.1.1

The QMP **must** be suitably documented in accordance with *EPA Requirements for Quality Management Plans* (R-2 document)



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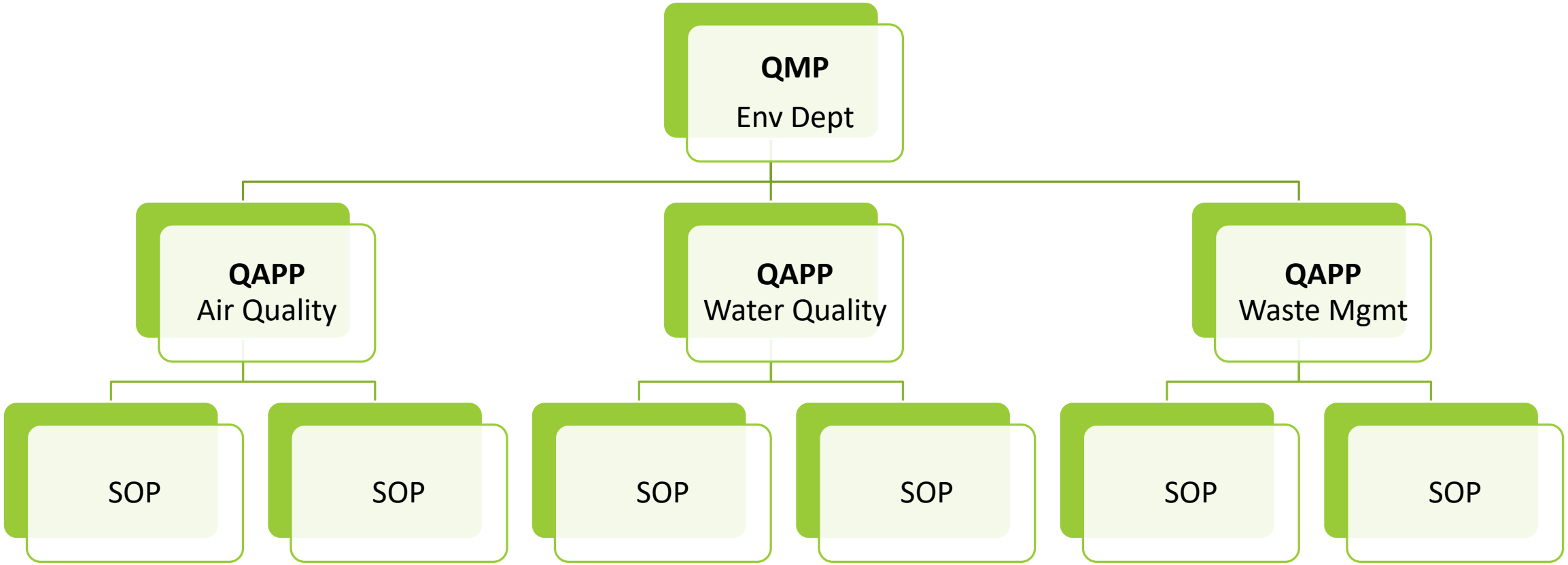
The QMP

- Is a management tool
- Is not specific to any particular project
- Describes how an organization structures its quality system
- Documents how the organization plans, implements, documents, and assesses the effectiveness of its activities supporting environmental data operations (EDOs) and other environmental programs

Example of the QMP "umbrella"



QMP Approval

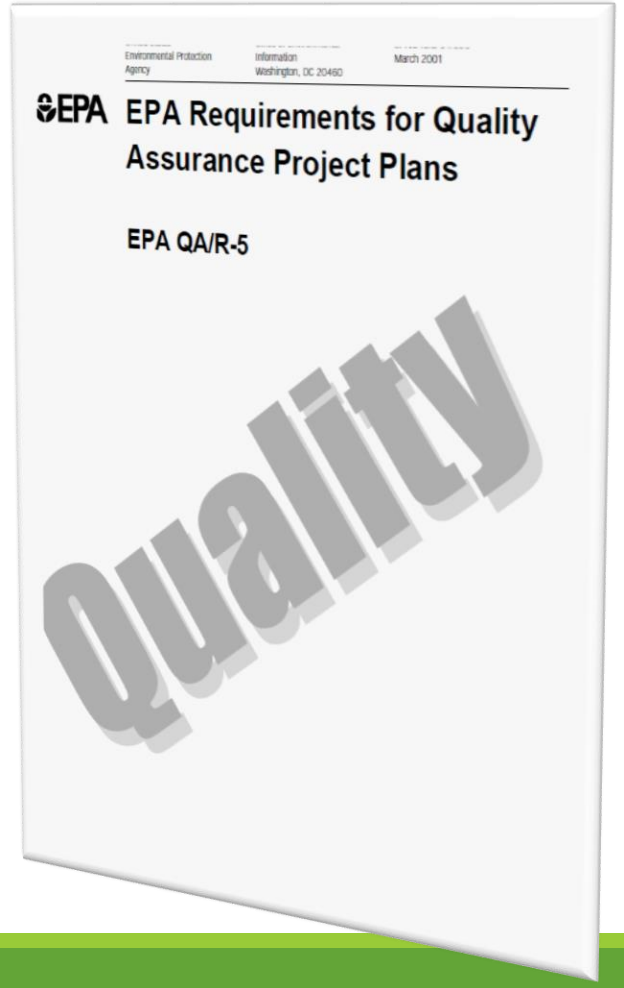
- Approved and signed by the senior management of the organization
  - This certifies that the organization has conducted an internal review of the document and that management has concurred with its content
- Submitted for review and approval to the appropriate EPA Office
- EPA-approval of the QMP will be valid for no more than **5 years**
- The organization must implement a review / revision schedule that ensures the QMP is updated and resubmitted to EPA prior to expiration of the 5-year period

Quality Assurance Project Plan (QAPP)

Your commitment to implement a quality system for a specific measurement(s)

See 40 CFR Part 58, Appendix A, §2.1.2

The QAPP **must** be suitably documented in accordance with *EPA Requirements for Quality Assurance Project Plans* (R-5 document)



Graded Approach

- Provides flexibility to the monitoring organizations to help with writing QAPPs
- Four-tiered project category approach
- Category I involves the most stringent QA approach; Category 4, the least stringent
- Amount of detail or specificity required for each element will be less as one moves from Category I to IV

Category	Programs	DQO
Category 1 Projects include EDOs that directly support rulemaking, enforcement, regulatory, or policy decision. Also includes research projects of significant national interest (monitored by the EPA Administrator)	SLAMS PSD NCore IMPROVE CastNet	Formal DQOs
Category 2 Projects include EDOs that complement other projects in support of rulemaking, regulatory, or policy decisions. Such projects results can be combined with those from other projects to provide necessary info for decisions.	Speciation Monitoring Toxics monitoring	Formal DQOs for national objective. Flexible DQOs for localized objectives.
Category 3 Projects performed as interim steps in a larger group of operations. Short duration. Include those producing results that are used to evaluate and select operations for future work.	SPMs One-time studies Local Scale Air Toxics Grants	Flexible DQOs
Category 4 Projects involving EDOs to study basic phenomena or issues	Education / Outreach	Project Objectives or goals

Table 2 QAPP Elements

QAPP Element		Category Applicability
A1	Title and Approval Sheet	I, II, III, IV
A2	Table of Contents	I, II, III
A3	Distribution List	I,
A4	Project/Task Organization	I, II, III
A5	Problem Definition/Background	I, II, III
A6	Project/Task Description	I, II, III, IV
A7	Quality Objectives and Criteria for Measurement Data	I, II, III, IV
A8	Special Training Requirements/Certification	I
A9	Documentation and Records	I, II, III
B1	Sample Process (Network) Design	I, II, III, IV
B2	Sampling Methods Requirements	I, II, III,
B3	Sample Handling and Custody Requirements	I, II, III
B4	Analytical Methods Requirements	I, II, III, IV
B5	Quality Control Requirements	I, II, III, IV
B6	Instrument/Equipment Testing, Inspection & Maintenance	I, II, III
B7	Instrument Calibration and Frequency	I, II, III
B8	Inspection/Acceptance Requirements for Supplies and Con.	I,
B9	Data Acquisition Requirements for Non-direct Measurements	I, II, III
B10	Data Management	I, II
C1	Assessments and Response Actions	I, II,
C2	Reports to Management	I, II,
D1	Data Review, Validation, and Verification Requirements	I, II, III
D2	Validation and Verification Methods	I, II
D3	Reconciliation and User Requirements	I, II,

See Appendix C of the QA Handbook for more information

QAPP Content Requirements

Sections 1 – 9:

Project Management

- Describe the overall **plan** for the monitoring project

Sections 10 – 19:

Data generation and Acquisition

- Describe **how** the plan will be implemented

Sections 20 – 21:

Assessment and Oversight

- Describe how the project will be **assessed** and at what frequency

Sections 22 – 24:

Data Validation and Usability

- Describe how the resulting **data** will be evaluated

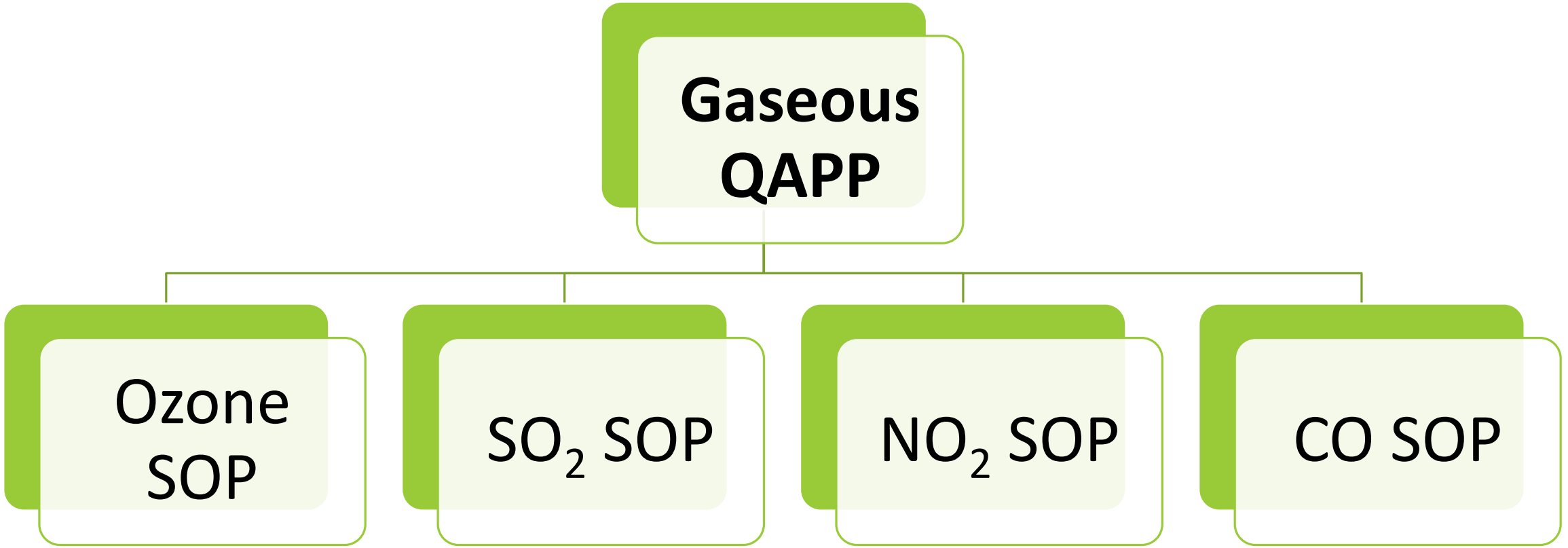
The QAPP must contain SOPs!

40 CFR Part 58, App A, §2.12

"The QAPP **must** be suitably documented in accordance with EPA requirements…**and include SOPs**…either within the document or by appropriate reference."

- Add a table listing all SOPs for which the QAPP governs,
- Add an Appendix listing the relevant SOPs, or
- Attach individual SOPs as appendices

Example of the QAPP "umbrella"



Why are QAPPs important?

- Planning document – saves money & time
- Developed in advance, so there are no later misunderstandings
- Provides direction to all parties involved in the project
- Improves communication amongst all staff
- All information referenced in one document
- Public document in case of litigation
- Serves as a future training tool and legacy documentation

QAPPs are *real* working documents!

- The organization is held accountable to the procedures they formalize in their QAPPs
- The organization can be more stringent than EPA requirements in the QAPP, but they cannot be less stringent
- Stated procedures should reflect the **true** activities of the agency, not the ideal

Tools are currently available online that can help organizations write QAPPs more easily.

- EPA's Guide to Writing QAPPs for Ambient Air Monitoring Networks
- ITEP's Online QAPP Curriculum

Talk to your EPA Regional Office about additional resources that are available to assist you with QAPP writing!

QAPP Approval

- Routed through the organization's chain-of-command for internal review and approval, including the Quality Assurance Manager
  - All parties must sign and date the Approval Page of the QAPP (which is the first of the required 24 elements)
  - Approval commits the organization to implement the project in accordance with the stated requirements
- Submitted to the EPA for review and approval
  - Period of performance starts from the date of EPA approval
  - AQS will be updated with the date of the QAPP approval

QAPP Revision

- QAPPs should be reviewed **annually** and revised, if needed
- All QAPPs must be revised and resubmitted for approval at least **every 5 years**
- If there are major changes before expiration of 5-year period, the QAPP should be revised and resubmitted through the appropriate chain-of-command
- The approval date in AQS will change upon resubmission and final approval, and the 5-year clock starts again
- Know your grant requirements!

Examples of Major Changes Prompting QAPP Revision

- NAAQS / Regulatory Revisions, such as changes to 40 CFR Part 58
- Significant revisions to EPA Guidance, such as the revised NATTS TAD
- Reorganization of organization's cabinets/departments
- Internal changes to personnel and management structure within the air monitoring organization
- Outsourcing of laboratory activities
- Participation in additional monitoring programs with different monitoring objectives (e.g., NCore & SO_2 DRR)

Standard Operating Procedures (SOPs)

The step-by-step process to complete a task so that everyone does it the same way

"How To"

See 40 CFR Part 58, Appendix A, §2.1.2

Elements that may be included in SOPs are discussed in the EPA *Guidance on the Preparation of SOPs* (G-6) document and the QA Handbook

Why are SOPs important?

- Ensure consistent implementation of an important activity
- Provide ready reference and documentation of proper procedures
- Reduce work effort
- Reduce error occurrences in data
- Improve data comparability, credibility, and defensibility
- Serve as excellent training aids
- Serve as legacy documentation

"How To's"

SOPs are step-by-step procedures designed to provide **consistency – from day to day, operator to operator**

Use strong, active language to clearly instruct the operator

- **"Press this button"**

Language that provides an operator "options" will result in inconsistency! Avoid ambiguity in the SOP and words/phrases such as:

- X *Encourage*
- X *If preferred*
- X *If desired*
- X *If applicable*

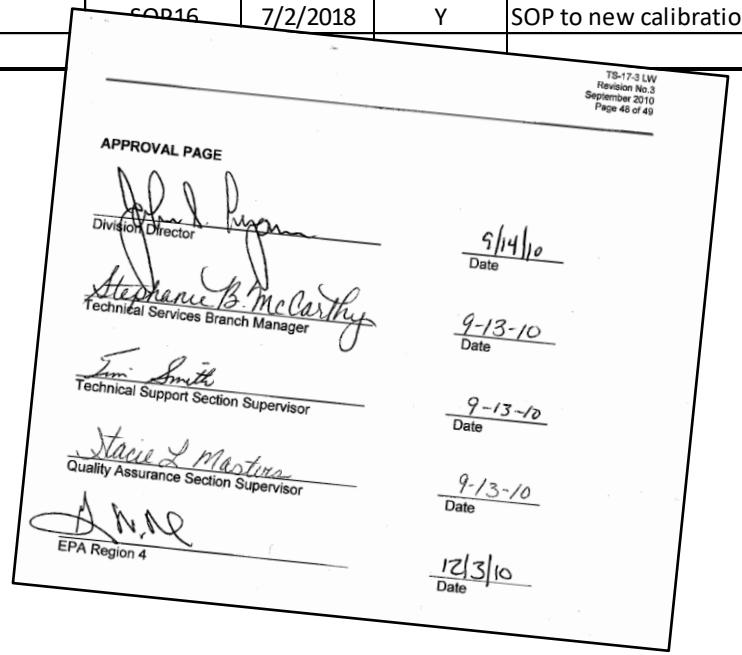
A good way to test the accuracy of the SOP is to have someone who does not operate the monitor perform the procedures as written!

This will identify areas in which the SOP needs further clarification or instruction.

SOP Best Practices

- Review SOPs annually
  - Track & document the review
- Revise as needed to keep documents current and accurate
  - Include a revision history within SOP to summarize changes
- Route SOPs for internal approval through the chain-of-command, including the QAM
  - Include a signature page

Annual SOP Review				
Document Name	**Document Number**	**Review Date**	**Changes Needed (Y/N)**	**Changes Required**
Ozone Monitoring	SOP-15	6/5/2018	N	
SO2 Monitoring	SOP16	7/2/2018	Y	New calibrator puchase din 2018 revise SOP to new calibration procedure



Summary

- "Plan, Do, Check, Act" – the phases of the QA Life Cycle
- Monitoring organizations' quality systems must implement this cycle
- QA programs are needed in all phases of measurement/data collection activity– including the field, the laboratory, and work performed by contractors
- Big ticket items of EPA's Quality Policy – codified in CFR – include independence, QMPs, and QAPPs
- The "Planning" phase of the QA cycle includes development of these documents

Summary, Continued

- QMPs establish a framework for the monitoring organization's overall quality system
- QAPPs establish the specific QA/QC that must be implemented for a particular project
- QAPPs must contain SOPs
- SOPs are "how to" documents which provide specific details on implementing specific tasks, ensuring consistency from day to day, operator to operator
- Tools and resources are available to help organizations develop these documents, which should be reflective of the organization (not the ideal)

Questions?

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