

Quality Management Documents

Grace Tuazon, California Air Resources Board 2024 PQAO Training, February 27-28, 2024

Presentation Overview





Quality Management (QM) Documents

Quality Management Plan (QMP)



Quality Assurance Project Plan (QAPP)





Standard Operating Procedures (SOP)









QM Document Importance











Laws and regulations

PQAO common factor (consistency)

Data defensibility

Technical Systems Audit (TSA)

Training



Quality Management Plan (QMP)

Documents how an organization will:

plan, implement, and assess the effectiveness of its quality assurance (QA) and quality control (QC) operations.

Describes how an organization structures its:

- quality program,
- quality policies and procedures,
- areas of application,
- and roles, responsibilities, and authorities.



QMP continued

Origins

• Title 40, CFR, Part 58, Appendix A, Section 2.1

Tips/Resources for Development

- Addendum recommended, or can write your own
- CARB Checklist
- U.S. EPA Requirements (QA/R-2) and Standard

Frequency

• Every 5 years, or sooner



Quality Assurance Project Plan (QAPP)

Documents the:

- planning,
- implementation,
- and assessment procedures for a particular project, as well as any specific QA/QC activities.

Integrates:

all the technical and quality aspects of the project to provide a "blueprint" for obtaining the type and quality of environmental information needed for a specific decision or use.



QAPP continued

Origins

• Title 40, CFR, Part 58, Appendix A, Section 2.1

Tips/Resources for Development

- Addendum recommended, or can write your own
- U.S. EPA Example Checklist
- U.S. EPA Guidance (QA-G5), Requirements (QA-R5), and Standard

Frequency

• Every 5 years, or sooner



Standard Operating Procedures (SOP)

Describes in great detail:

the routine procedures to be followed for a specific

- operation,
- analysis,
- or action.

Ensures:

- conformance with organizational practices,
- reduced work effort,
- reduction in error occurrences,
- and improved data comparability, credibility, and defensibility.



SOP continued

Origins

• 40 CFR, Part 58, Appendix A, Section 2.1.2

Tips/Resources for Development

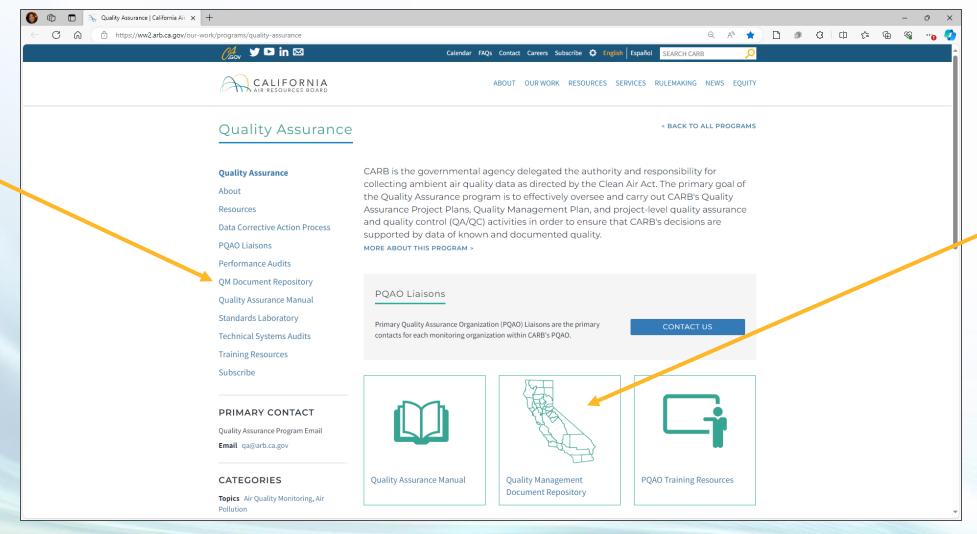
- Addendum or can write your own
- CARB Checklist
- U.S. EPA Guidance (QA-G6)
- Instrument manual

Frequency

• Every 3 years, or sooner



CARB Document Repository





CARB Addendum Form

State of California California Environmental Protection Agency Air Resources Board MLD/QMS-086 (NEW 4/14) QUALITY MANAGEMENT DOCUMENT ADDENDUM	State of California California Environmental Protection Agency Air Resources Board MLD/QMS-066 (NEW 4/14) Section 5. Justification for Deviation(s) (provide explanation of why modification(s) to existing ARB document is necessary)
(District completes Sections 1 through 6 - please type) Section 1. ARB Document □ Quality Management Plan (QMP) □ Quality Assurance Project Plan (QAPP) □ Standard Operating Procedure (SOP) Section 2. District Information District Name: □ District Address: □ District Contact Name/Phone Number: □ District Signature/Date:	Section 5. Justification for Deviation(s) (provide explanation of why modification(s) to existing ARE
Section 3. Document Title (specify exact title, revision 8, and date of ARB Document(s) that your District proposes to modify) Section 4. Proposed Deviation(s) (specify exact sector(s), page number(s) and language in existing ARB document that your District proposes to modify and then specify proposed modification (including any spreadpheets or forms).	Section 6. Attachment(s) (specify attachment titles and number of pages, include modified spreadsheets or forms) Section 7. ARB Approval (competed by ARS) Namer/Phone Number:
ection 4. Proposed Deviation(s) ecify exact section(s), page number(s) and land cify proposed modification (including any spre	Signature/Date: Addendum Number Completed form must be scanned/emailed or mailed to: Quality Management Section 1927 13 th Street, P.O. Box 2815 Sacramento, California 95811 ga@arb.ca.gov or the email of your PQAO liaison
Page 1 of 2	Page 2 of 2



CARB Review and Approval Process

Monitoring organization (MO) either:

- 1. adopts an existing QM document and creates an addendum, or
- 2. writes their own.

MO staff/management reviews and submits to CARB Quality Management Branch (QMB).

CARB QMB reviews and provides feedback or approval.

Approved document is uploaded to the CARB Document Repository (or is listed and provided upon request).



CARB Review

Applicable regulations and criteria

Relevant QM documents and/or guidance documents

Documents referenced within QM document

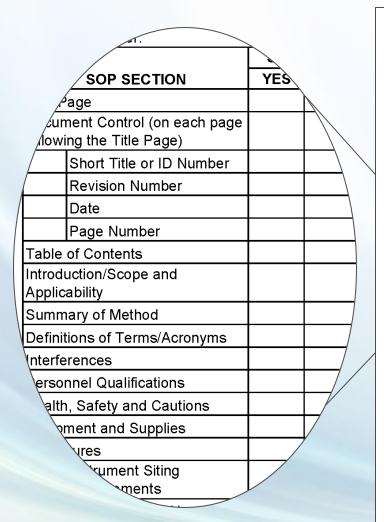
Any prior versions and any addenda

Any TSA findings that note specific items be covered

QM document checklist



SOP Checklist



Quality Management Section STANDARD OPERATING PROCEDURE Review Checklist

Agency:				
SOP Title:				
Revision Number:				Revision Date:
	SECTION PRESENT			
SOP SECTION	YES NO N		N/A	COMMENTS
Title Page				
Document Control (on each page following the Title Page)				
Short Title or ID Number				
Revision Number				
Date				
Page Number				
Table of Contents				
Introduction/Scope and Applicability				
Summary of Method				
Definitions of Terms/Acronyms				
Interferences				
Personnel Qualifications				
Health, Safety and Cautions				
Equipment and Supplies				
Procedures				
Instrument Siting Requirements				
Instrument Set-Up				
Operation				
Calibrations				
Sample Collection and Handling				
Routine Service Checks				

MLD/QMS-065 (Rev. 1/23)

California Air Resources Board

Quality Management Section STANDARD OPERATING PROCEDURE Review Checklist

SECTION PRESENT

		3LC HON FILSENT			
SOP SECTION		YES	NO	N/A	COMMENTS
Proc	edures continued				
	Preventative Maintenance and Repairs				
	Troubleshooting				
Data	Management and Record				
	Data Acquisition				
	Calculations				
	Data Storage/Transmittal				
	lity Control and Quality Irance				
Refe	rence Section				
	ADDITIONAL ITEMS	YES	NO		COMMENTS
curre	e SOP updated to reflect ent instrument model or ess being used?				
	the SOP been revised within ired frequency?				
Harris	e items in addendum been				

Recommendation:	Approve as is:	Request amendment:	
Reviewer Signature:		Date:	
Peer Reviewer Signature:		Date:	
Management Signature:		Date:	

California Air Resources Board MLD/QMS-065 (Rev. 1/23)



Common Review Findings

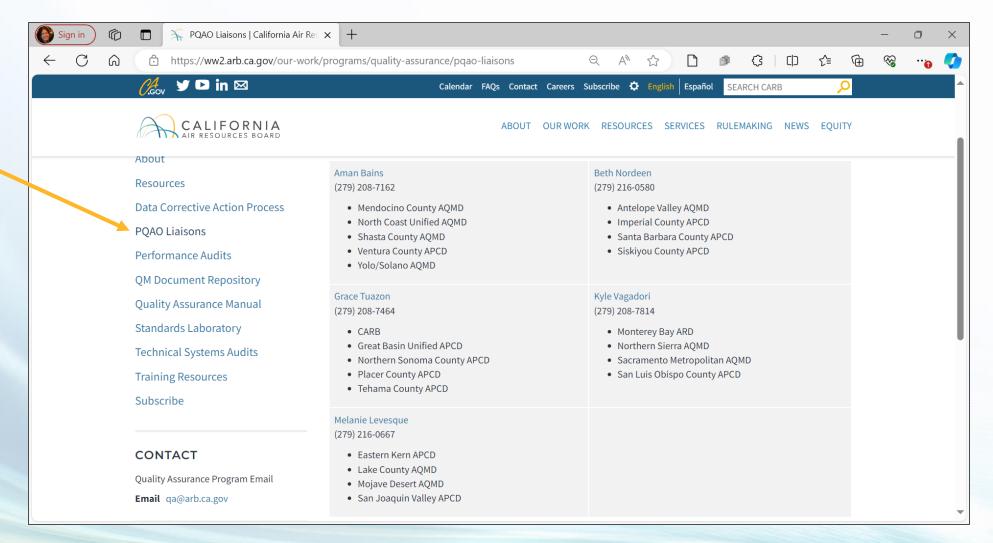
Missing sections or components

QA/QC acceptance criteria missing or inaccurate

Inconsistent use of terminology



Resources – PQAO Liaisons





Resources – Links

- CARB Quality Assurance: https://ww2.arb.ca.gov/our-work/programs/quality-assurance
- CARB Document Repository: https://ww2.arb.ca.gov/our-work/programs/quality-assurance/quality-management-document-repository
- CARB Addendum Form: please contact your PQAO liaison
- QMP
 - CARB Checklist: https://ww2.arb.ca.gov/sites/default/files/2018-09/qmp-checklist.pdf
 - U.S. EPA Requirements: https://www.epa.gov/quality/epa-qar-2-epa-requirements-quality-management-plans
 - U.S. EPA Standard: https://www.epa.gov/system/files/documents/2023-01/quality_management_plan_standard.pdf

QAPP

- U.S. EPA Example Checklist: https://www.epa.gov/sites/default/files/2015-06/documents/g5-final.pdf#page=77
- U.S. EPA Guidance: https://www.epa.gov/quality/guidance-quality-assurance-project-plans-epa-qag-5
- U.S. EPA Requirements: https://www.epa.gov/quality/epa-qar-5-epa-requirements-quality-assurance-project-plans
- U.S. EPA Standard: https://www.epa.gov/system/files/documents/2023-07/quality_assurance_project_plan_standard.pdf

· SOP

- CARB Checklist: https://ww2.arb.ca.gov/sites/default/files/2023-01/MLD_QMB_065.pdf
- U.S. EPA Guidance: https://www.epa.gov/sites/default/files/2015-06/documents/g6-final.pdf



Questions?

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