Annual Review of Quality Assurance Project Plans in EPA Region 8

Approved QAPPs must be reviewed annually!

Timetable for QAPPs

Get approved QAPPs as soon as possible!

Annual Review of Approved QAPPs

- Do this ASAP – not later than December 31
- Does review show a QAPP revision is needed?

Submit revised or draft QAPPs (if required)

- Submit to EPA by December 31

2 CFR §1500.11 Quality Assurance

(a) Quality assurance applies to all assistance agreements that involve environmentally related data operations, including environmental data collection, production or use.

(b) Recipients shall develop a written quality assurance system commensurate with the degree of confidence needed for the environmentally related data operations.

(c) If the recipient complies with EPA's quality policy, the system will be presumed to be in compliance with the quality assurance system requirement. The recipient may also comply with the quality assurance system requirement by complying with American National Standard ASQ/ANSI E4:2014: Quality management systems for environmental information and technology programs.

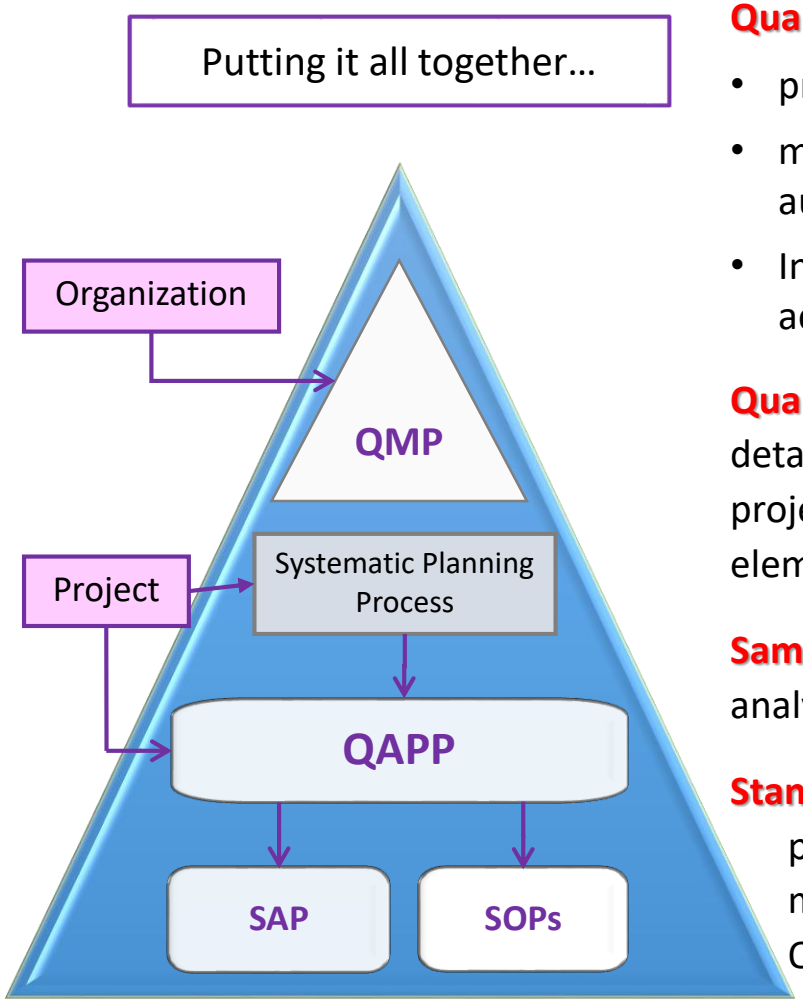
(d) The recipient shall submit the written quality assurance system for EPA review. Upon EPA's written approval, the recipient shall implement the EPA-approved quality assurance system.

(e) EPA Quality Policy is available at: *http://www.epa.gov/quality*.

(f) The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51.

[1] 79 Federal Register 76050, December 19, 2014, as amended at 80 FR 61088, Oct. 9, 2015

QA Document Types



Quality Management Plan (QMP) describes

- processes and procedures at the organizational level,
- management and staff functional responsibilities and line of authority and
- Interfaces for planning, implementing, documenting, and accessing all activities conducted.

Quality Assurance Project Plan (QAPP) is the document that details the who, what, when, where, why and how of the project objectives (data quality objectives). Include all QAPP elements (QA/R-5 and QA/G-5).

Sampling and Analyses Plan (SAP) provides the field and analytical details for the sampling event(s).

Standard Operating Procedures (SOPs) describe specific procedures (e.g., sampling techniques or field analytical methodologies) used. These are attached to the approved QA Document(s).

Environmental Data

Any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology.[1]

Environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or literature.[2]

[1] Universal definition; as defined in ASQ/ANSI E4-2014

[2] EPA Quality Manual for Environmental Programs (CIO 2105-P-01-0)

Annual Review of QAPPs (Step 1)

Gather these documents:

- Previous year's QAPP
- Previous year's QA Review Crosswalk
- Current Monitoring Strategy
- Current and previous year Workplan, SAP
- Blank R8 QA Document Review Crosswalk
- EPA QA/G-5

https://www.epa.gov/quality/managing-quality-environmental-data-epa-region-8

Annual Review of QAPP (Step 2)

Identify any changes to the program:

- Monitoring Strategy or Workplan
- Sampling and Analysis Plan (SAP)
- Sampling locations or dates
- Program scope or objectives
- Parameters
- New laboratory or Lab QA Plan
- Field instruments or methods
- Staff changes

Annual Review of QAPPs

Determine if you have "**substantive changes**"

(Substantial, meaningful, considerable)

- Affects scope, implementation, or assessment of the outcome of the project
- Impacts the technical and quality objectives of the project
- Substantive changes may occur at any time during the project

Examples of Substantive Changes

Substantive

- Add/change objectives
- New analytes/methods
- Modify QC criteria
- Data quality objectives
- Change use of data
- New laboratory
- New equipment
- New or modified SOP
- Reorganization

Not substantive

- Sampling schedule
- Change sampling locations
- Individual staff change
- Editorial changes to QAPP

Result of Annual Review

A Substantive Change is Found

Not Sure?
Call QA for help!

You must prepare a new QAPP or revise the existing one.

Upload it and a new crosswalk to MAX for full review.

Outcome of Annual Review

No Substantive Changes – QAPP update

- Submit to EPA QA Program for review:
  - New **blank** Signature Page showing the current year
  - Any change pages or addendum to the QAPP
  - Completed crosswalk – page column & changes only
- QA Program or DAO will review for completeness and verify no substantive changes.
- Route package for approval.

Example Signature Page

TRIBE NAME

QAPP Title

Version number
Version date

Covering Oct. 1, 2014 to Sept. 30, 2015

New Date

APPROVALS:

_____ _____

Name Date

Environmental Director and Program QA Manager

Tribe Name

_____ _____

Name Date

Tribal Air Program Manager

Tribe Name

Signature of an EPA program may not be required. Check with your EPA PO or QA

_____ _____

Carl Daly Date

Director, Air & Radiation Programs, EPA Region 8

_____ _____

Name Date

EPA Region 8 Project Officer

_____ _____

Linda Himmelbauer Date

EPA Region 8 Quality Assurance Manager

Annual Review of QAPPs (Step 3)

Use a blank crosswalk* to identify and document all changes needed in the QAPP

- Follow the crosswalk element by element
- Use references (EPA QA/G-5) for assistance
- Previous year's crosswalk
- This is new to everyone. If you need help, just ask!!!

*Tip: Edit previous year's crosswalk by removing the comments

https://www.epa.gov/sites/production/files/2016-01/epa_region_8_qa_document_review_crosswalk_jan_2016.docx

Click here and type Title

Element	Acceptable *Yes/No/N*	Page/ Section	Comments
A. Project Management			
A1. Title and Approval Sheet			
a. Contains project title			
b. Date and revision number line (for when needed)			
c. Indicates organization's name			
d. Date and signature line for organization's project manager			
e. Date and signature line for organization's QA manager			
f. Other date and signatures lines, as needed			
A2. Table of Contents			
a. Lists QA Project Plan information sections			
b. Document control information indicated			
A3. Distribution List			
Includes all individuals who are to receive a copy of the QA Project Plan and identifies their organization			
A4. Project/Task Organization			
a. Identifies key individuals involved in all major aspects of the project, including contractors			
b. Discusses their responsibilities			
c. Project QA Manager position indicates independence from unit generating data			
d. Identifies individual responsible for maintaining the official, approved QA Project Plan			
e. Organizational chart shows lines of authority and reporting responsibilities			
A5. Problem Definition/Background			
a. States decision(s) to be made, actions to be taken, or outcomes expected from the information to be obtained			
b. Clearly explains the reason (site background or historical context) for initiating this project			
c. Identifies regulatory information, applicable criteria, action limits, etc. necessary to the project			
A6. Project/Task Description			

Documenting Changes on a Crosswalk

Element	Acceptable *Yes/No/NA*	Page/ Section	Comments
A. Project Management			
A1. Title and Approval Sheet			
a. Contains project title		2/A1	
b. Date and revision number line (for when needed)		2/A1	
c. Indicates organization's name		2/A1	
d. Date and signature line for organization's project manager			
e. Date and signature line for organization's QA manager		2/A1	
f. Other date and signatures lines, as needed		2/A1	Changed EPA PO from Jennifer Wintersteen to Diana Hammer
A2. Table of Contents			
a. Lists QA Project Plan information sections		3-4/A2	
b. Document control information indicated		Through-out	
A3. Distribution List			
Includes all individuals who are to receive a copy of the QA Project Plan and identifies their organization		6/A3	Changed EPA PO from Jennifer Wintersteen to Diana Hammer
A4. Project/Task Organization			
a. Identifies key individuals involved in all major aspects of the project, including contractors		7-8/A4	
b. Discusses their responsibilities			
c. Project QA Manager position indicates independence from unit generating data		8/A4	
d. Identifies individual responsible for maintaining the official, approved QA Project Plan		18/A9	

Example memo for QAPP annual reviews

The [*Tribe Name*] conducted an annual review of the [*QAPP Title*] on [*date*]; it was previously approved by EPA on [*date*]. We have identified the following key changes/updates to the QAPP, workplan, and program for the current year:

- Change
- Change
- Change

These changes have been documented in a Region 8 QA Document review crosswalk, which is attached. In addition, all other changes to the QAPP, workplan, or Program of lesser importance (such as editorial changes) are also be documented in the crosswalk. In consultation with the EPA QA Manager or Region 8 DAO (see EPA QA/R-5), these changes:

_____ include one or more substantive changes. A new or revised QAPP will be prepared and submitted to EPA for a full review, or

_____ do not include any substantive changes. The QAPP will be updated. The following documentation is provided to document these changes to the QAPP (*mark at least one*):

- ☐ Change pages to the QAPP are attached
- ☐ A QAPP Addendum is attached
- ☐ A complete, updated QAPP that contains these changes is provided. We acknowledge that this is not a QAPP revision. The updated QAPP clearly includes a statement "**Updated on [*date*] for [*operating period*]**" on the cover.

A new (unsigned) signature page is attached showing the QAPP title and new operating period. As applicable, the signature lines have been updated. The Tribe will begin the signature process once EPA has accepted this review documentation.

Once approved, the new signature page and any change pages or addendum will be attached to the original QAPP. Notification and copies of this information will be provided to the individuals on the Distribution List and otherwise as needed (e.g., to the field sampling team).

Attachments:

1. R8 QA Document Review Crosswalk
2. New (unsigned) signature page
3. QAPP update pages as indicated above

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Region 8 QA Web Page

https://www.epa.gov/quality/managing-quality-environmental-data-epa-region-8