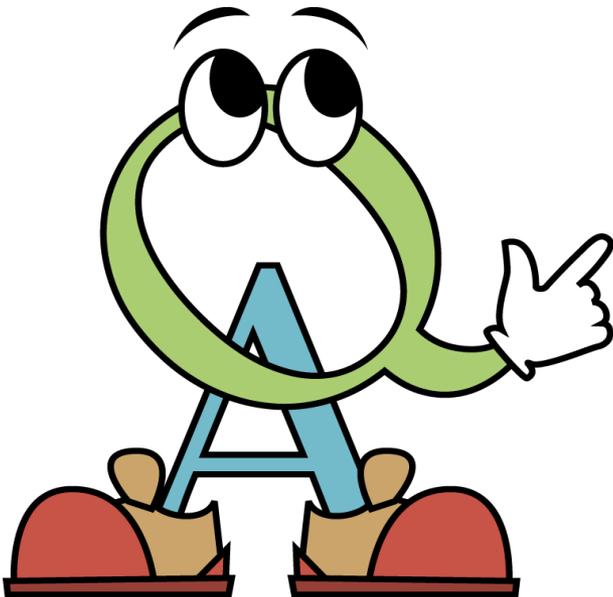


# Delegated QA Approving Officer Training

Introduction to:

Project-level  
QA Document  
Approvals

September 19, 2012



# Objectives

## Describe key areas for Approving QA Documents

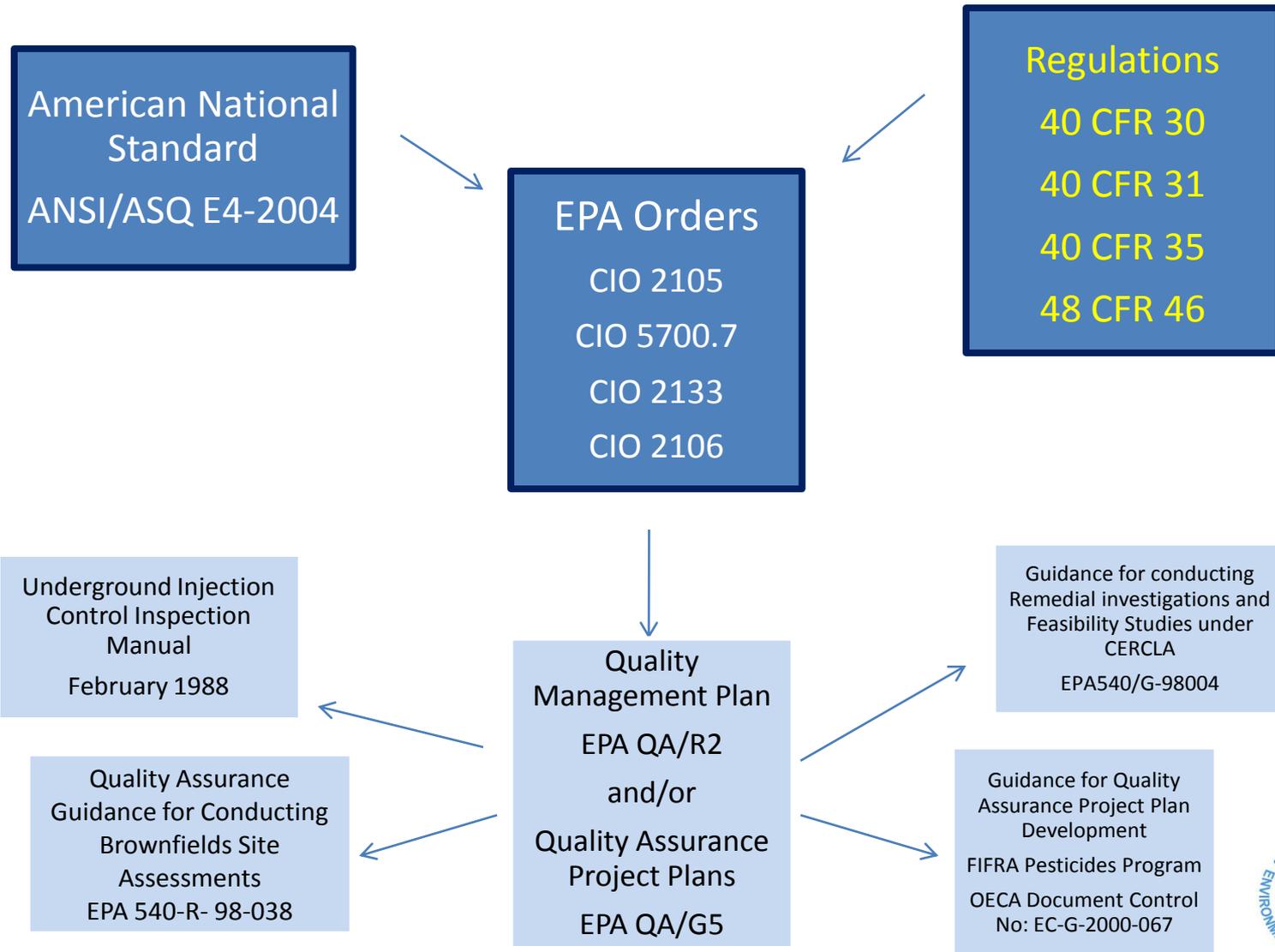
- EPA Regulations for QA Documentation
- Environmental Data Definition
- QA Documents & Approval Hierarchy
- Delegation process
- QAPP content
- Conducting a QAPP review

## Describe some QA Requirements for Contracts/Grants

- QARFs (contracts)
- IGMS (grants)



# Quality Assurance is a **Regulatory** Program





## EPA Order on Quality Systems:

CIO 2105.0\* (formerly 5360.1) (approved 5/5/2000)

CIO 2105P\* (formerly 5360 A1) (approved 5/5/2000)

This ***Order establishes policy for a mandatory*** Quality System for all environmental programs (CWA, CAA, RCRA, SDWA, etc.)

The Order establishes that environmental data obtained or collected by the Region or delegated State, Local and Tribal Governments are of sufficient quantity and adequate quality for their intended use and are used consistent with such intentions.

*These documents can be found at the QA website (<http://www.epa.gov/region8/qa/>).*



# *You are required by regulation to comply with*

- Order 5700.7\*** Environmental Results under EPA Assistance Agreement
- 40 CFR 30\*** Requires the grantee to develop and implement quality  
**40 CFR 31\*** assurance practices to produce data of adequate quality to  
**40 CFR 35\*** meet project objectives
- 48 CFR Part 46\*** **Contract quality requirements, i.e.,** Attention to organization,  
planning, work instructions, documentation control, and advanced  
metrology

*\*These and other QA related regulations may be found at the QA website (<http://www.epa.gov/region8/qa/>)*



# Environmental Data

Any measurement or information that describes environmental processes, location, or condition; ecological or health effects and consequences, or the performance of environmental technology.<sup>1</sup>

Environmental data include any information collected directly from measurements or obtained from any other sources (i.e., existing/secondary data) such as those compiled from data bases, data reports, literature, surveys, or produced from models.<sup>2</sup>

<sup>1</sup> universal definition; as defined in ANSI/ASQ E4-2004

<sup>2</sup> EPA Quality Manual for Environmental Programs (CIO 2105-P-01-0)

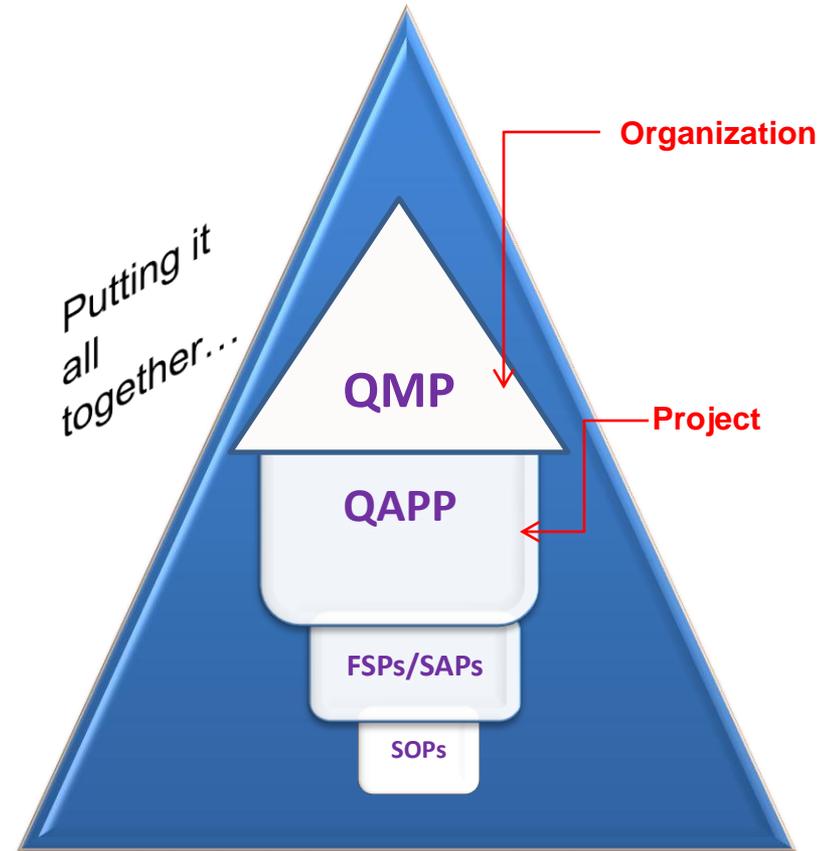


- The **Quality Management Plan (QMP)** describes processes and procedures at the organizational level, management and staff functional responsibilities and line of authority. Include all QMP elements (QA/R-2).
- The **Quality Assurance Project Plan (QAPP)** is the document that details the who, what, when, where, why and how of the project objectives (data quality objectives). Include all QAPP elements (QA/R-5 and QA/G-5).
- The **Field Sampling Plan (FSP)** provides the field sampling details for the sampling event(s).
- The **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).

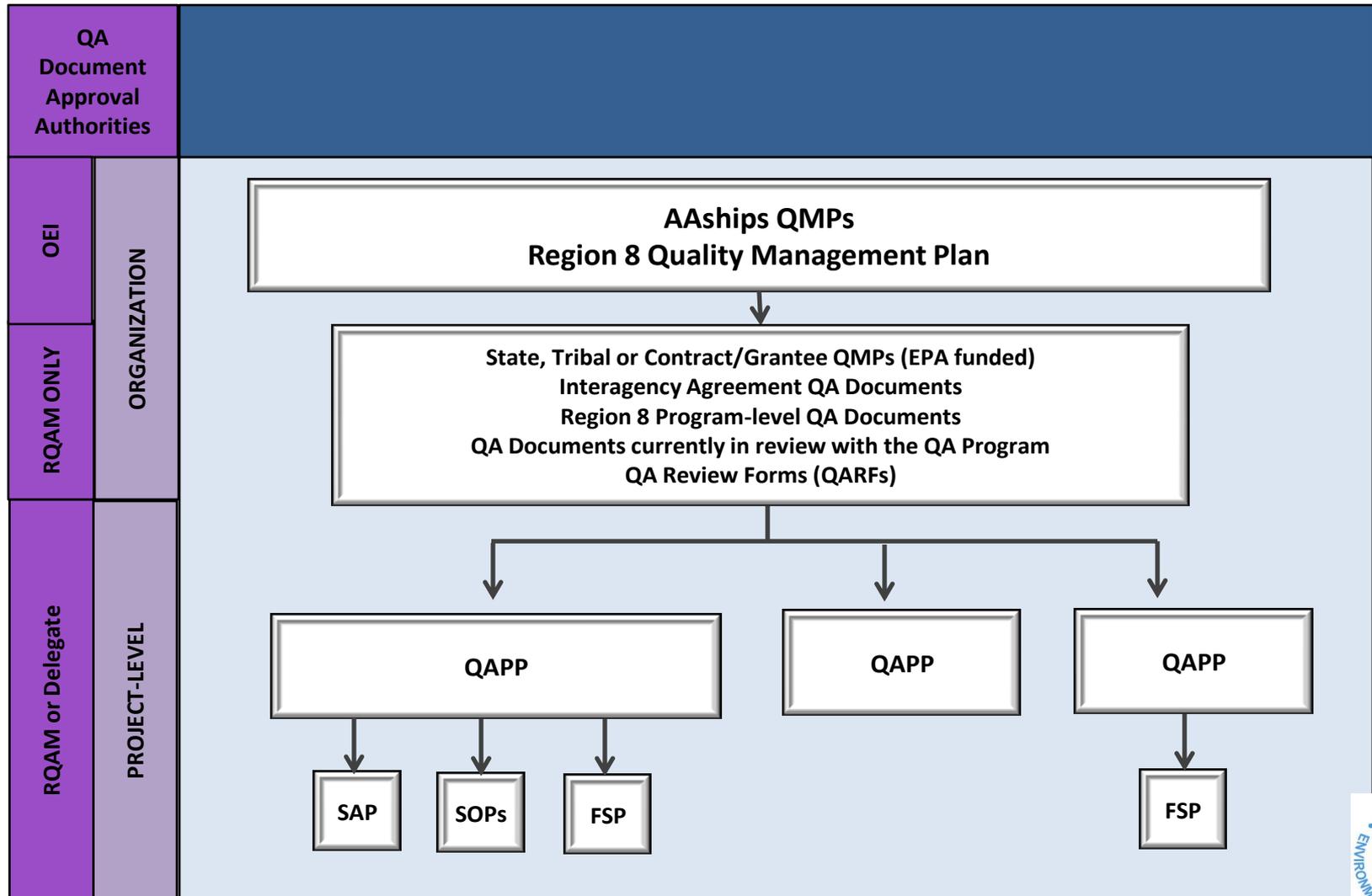
**Note:**

- FSPs, SAPs, and SOPs are subsets of a QAPP
- FSPs and SAPs may be addendums to a previously approved QAPP  
**or**  
a stand alone document, if all QAPP elements are included (QA/R-5 and QA/G-5)

## QA Document Types



# QA Document Approval Authority Hierarchy



# R8 QA Document Approval Authorities

- **R8 QA Manager (RQAM) retains authority for approving:**
  - Federal, State, Tribal QMPs
  - QMPs developed by contractors and grantees using EPA funds
  - Interagency Agreement QA Documents
  - QA Documents prepared by EPA personnel (*i.e.*, not prepared by contractors or grantees)
  - QA Documents for EPA-lead sampling events not involving grant or contract support for field sampling
  - QA Documents currently in review with the R8 QA Program
  - All QA Review Forms (QARFs)

## ***Special Consideration:***

For enforcement actions such as administrative orders, consent decrees, etc., QA Document approval authority may differ from guidelines presented here. Refer to the individual Order for information about EPA's QA document approval authority.

# R8 QA Document Approval Authorities

➤ **Delegated Authority may be awarded to approve project-level QA Documents that are prepared by grantees or contractors:**

- QAPPs, FSPs, SAPs
- Candidate FSPs and/or SAPs must accompany a *previously* approved QAPP **OR** must include *all* elements of a QAPP.
- If you are unsure of how best to organize your QA Document, we invite you to contact the QA Program early in development. We can advise you!



## To become eligible, a candidate Delegated QA Approving Officer (DAO) must:

- Complete the Introductory Delegated QA Approving Officer Training for Project-level QA Document Approval ✓
- Obtain first line supervisor concurrence to receive DAO status;
- Send the RQAM an email requesting delegated authority for project-level QA document approval & indicate your supervisor's concurrence (cc your supervisor);
- Receive notice of DAO status from the RQAM; and
- Agree to abide by DAO Agreement Statements for review, reporting and oversight activities.

**Authority to approve project-level QA documents begins the date of the RQAM's email awarding delegation.**



## ➤ DAO Agreement Statements:

- Ensure appropriate EPA-approved project-level QA document(s) are in place prior to collection, generation or use of environmental data, except under circumstances requiring Emergency Response immediate actions to protect human health and the environment;
- Review the project-level QA documents using the Region 8 QA Document Review Crosswalk. (<http://www.epa.gov/region8/qa/reference.html>);
- Maintain independence. Review only those project-level QA documents that were not prepared by the DAO;
- For project-level QA documents that are deemed approvable by the DAO:
  - sign and date the QA documents
  - include all attachments and the completed signature page
  - create an electronic file (PDF) of the entire document



## ➤ **DAO Agreement Statements (Cont'd):**

- For emergency response actions excepted from having EPA-approved project-level QA document(s) in place prior to collection, generation or use of environmental data, provide a copy of required documentation to the RQAM;
- Track all QA documents that are reviewed and/or approved (excel table);
- Maintain a file of all reviewed and/or approved QA documents and their companion Crosswalks;
- Report project-level QA document review and approval status to the RQAM (periodic QA Information requests);
- Provide information as requested by the RQAM to support periodic quality systems audits (QSAs) of the project-level QA document reviews and approvals; and
- Complete annual refresher training for Delegated QA Approving Officers.

# What is a QA Review Form (QARF)?

## ➤ Document that summarizes QA requirements for any contract action

- Example QA Requirements: QMPs, Technical Evaluation Criteria/Panel, QAPPs, QA Oversight, Peer Review, Technical Systems Audits, facility audits, etc.

## ➤ Region 8 QA Manager (RQAM) requires QARFs in accordance with the Contracts Management Manual (CMM) for all:

- Contracts managed in Region 8; AND
- Region 8 Buy-ins to other EPA contract mechanisms (e.g., managed by: HQ, other Regions, ORD, etc.)



# When is a QARF Required?

➤ A QARF is required for every SOW:

➤ QARF is required for **new contracts**, as part of the:

- Procurement Initiation (PIN) Package (over \$150K) or
- Purchase Request (PR) Package (Simplified Acquisition)

➤ A QARF is required for **existing contracts** to accompany any Post-Award Individual TO/WA/DO SOW.

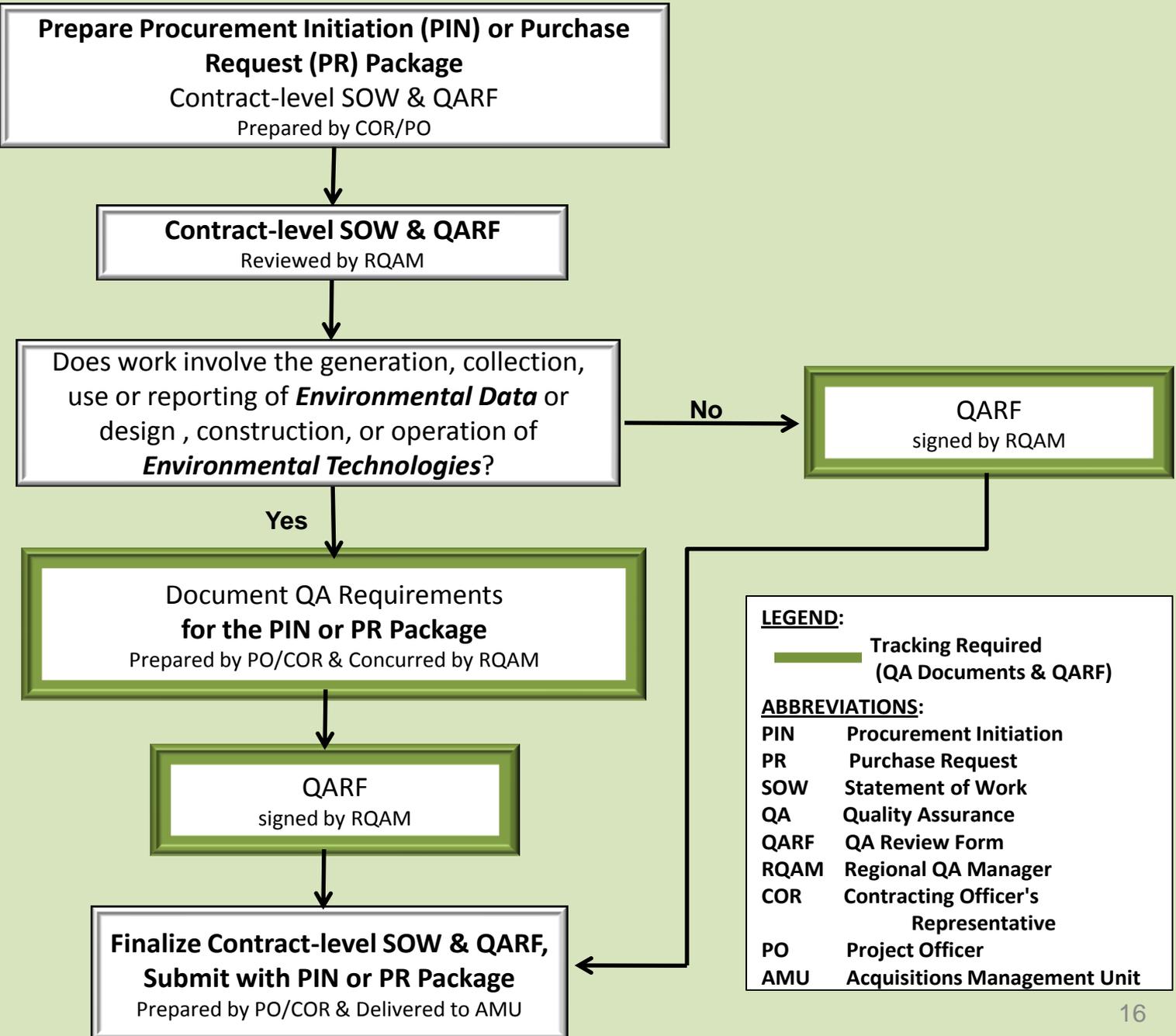
- Attach the Contract-level QARF whenever writing an Individual TO/WA/DO SOW and QARF for that contract



# Responsibilities & Tracking

## Before

## Award of Contract



**LEGEND:**  
 Tracking Required (QA Documents & QARF)

**ABBREVIATIONS:**  
 PIN Procurement Initiation  
 PR Purchase Request  
 SOW Statement of Work  
 QA Quality Assurance  
 QARF QA Review Form  
 RQAM Regional QA Manager  
 COR Contracting Officer's Representative  
 PO Project Officer  
 AMU Acquisitions Management Unit

# Responsibilities & Tracking

After

Award of Contract

**Contract-level Tasks/WAs/Deliveries**  
 Contract-level SOW & QARF  
 and/or  
**Individual TOs/WAs/DOs**  
 Individual TOs/WAs/DOs SOW & QARF  
 Prepared by COR/PO

**COR Meets with RQAM to Discuss which:  
 Individual TOs/WAs/DOs SOW  
 Require QA Documents**

Does work involve the generation, collection, use or reporting of *Environmental Data* or design, construction, or operation of *Environmental Technologies*?

**QARF**  
 signed by RQAM

Document QA Requirements for:  
**Individual TO/WA/DO SOW**  
 Prepared by COR/PO & Concurred by RQAM

**QARF**  
 signed by RQAM

**Finalize & Submit Contract-level &  
 TO/WA/DO SOWs & QARFs**  
 Prepared by COR/PO & Delivered to AMU

**LEGEND:**  
 Tracking Required (QA Documents & QARF)

**ABBREVIATIONS:**  
 TO Task Order  
 WA Work Assignment  
 DO Delivery Order  
 SOW Statement of Work  
 QA Quality Assurance  
 QARF QA Review Form  
 RQAM Regional QA Manager  
 COR Contracting Officer's Representative  
 PO Project Officer  
 AMU Acquisitions Management Unit

# How is a QARF Processed?

- A QARF shall be prepared by the COR<sup>1</sup> and reviewed with the Region 8 QA Manager (RQAM)
- A blank QARF is available on the QA Program website: (<http://www.epa.gov/region8/qa/>)
- The QARF may only be approved by the RQAM
- QARFs must be signed and routed with the SOW for RQAM signature in hardcopy form.

*1. Contracts Management Manual; Policy, QA Review Form Requirements, Section 46.1.5.1*



# QA Documentation for Grants: IGMS

## B.5 Quality Assurance

<b>B.5. Quality Assurance: Does this program or project include generation of environmental data, or use of existing environmental data?</b>	
	<b>B.5.a. Are the proposed measurement activities covered by an existing or draft Quality Management Plan (QMP), or Quality Assurance Project Plan (QAPP)?</b>
	<b>B.5.b. Are the QA Plans or QA documents required for this assistance award approved?</b>

- The project officer (PO), working with the project manager, must ensure that Question B.5 is appropriately addressed.
- Electronic tracking system

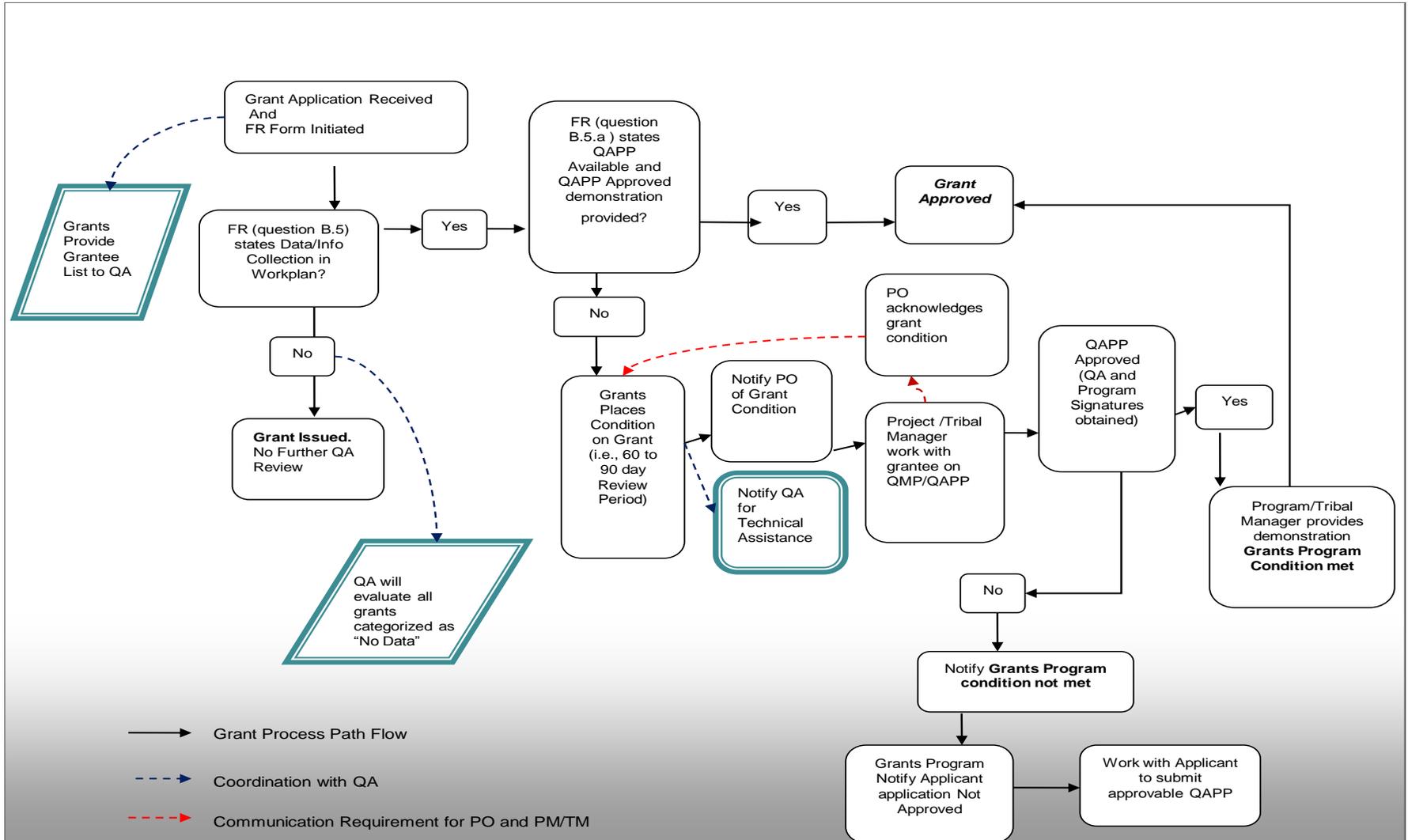
[http://intranet.epa.gov/OGD/course\\_library/manager/0.1-09-INFO-FR.html](http://intranet.epa.gov/OGD/course_library/manager/0.1-09-INFO-FR.html)



# Region 8 QA Training Initiative

## QUALITY SYSTEM – QA ROLES

in the  
Grant Approval/Administration Process



# What Is a QAPP?

## Four Main Parts of a QAPP

- A. Project Management
- B. Data Generation and Acquisition
- C. Assessment and Oversight
- D. Data Validation and Usability

### ➤ **QAPPs, FSPs, SAPs are living documents**

- Make changes before activity is conducted
- Make changes directly on document

### ➤ **Annual Review is required**



# Reviewing QA Documents: Project-level QAPPs, FSPs, and SAPs

- Assemble Documentation
- Compare Workplan or SOW with QA Document
- Review the QA Document using the R8 QA Document Review Crosswalk Crosswalk\*
- Send review to grantee/contractor
- Review revised QA Document
- Finalize QA Document
- Approve (sign & date)
- Record/Track Reviews & Approvals

**Region 8 QA Program offers:  
QAPP Review Consultation!!**

See QA Document Review Instructions

\* The R8 Crosswalk and Review Instructions can be found at the QA website (<http://www.epa.gov/region8/ga/>)

Page 1 of 1

EPA Region 8 QA Document Review Crosswalk  
Click here and type Title

**EPA REGION 8 QA DOCUMENT REVIEW CROSSWALK**

<b>QAPP/FSP/SAP for:</b> <i>(check appropriate box)</i>	<b>Entity</b> <i>(grantee, contract, EPA AO, EPA Program, Other)</i>	<b>Regulatory Authority</b>	<input type="checkbox"/> 40 CFR 31 for Grants <input type="checkbox"/> 48 CFR Part 46 for Contracts <input type="checkbox"/> Interagency Agreement <input type="checkbox"/> EPA Administrative Order <input type="checkbox"/> EPA Program Funding <input type="checkbox"/> EPA Program Regulation <input type="checkbox"/> EPA CIO 2105
<input type="checkbox"/> GRANTEE <input type="checkbox"/> CONTRACTOR <input type="checkbox"/> EPA <input type="checkbox"/> Other	Click here and type Entity	and/or	
<b>Document Title</b> <i>(Note: Title will be repeated in Header)</i>	Click here and type Title	<b>Funding Mechanism</b>	
<b>QAPP/FSP/SAP Preparer</b>			
<b>Period of Performance</b> <i>(of QAPP/FSP/SAP)</i>		<b>Date Submitted for Review</b>	
<b>EPA Project Officer</b>		<b>FO Phone #</b>	
<b>EPA Project Manager</b>		<b>PM Phone #</b>	
<b>QA Program Reviewer or Approving Official</b>		<b>Date of Review</b>	

<b>Documents to Review:</b> 1. QAPP written by Grantee or EPA must also include for review: Work Plan(WP) / Statement of Work (SOW) / Program Plan (PP) / Research Proposal (RP) 2. QAPP written by Contractor must also include for review: a) Copy of signed QARF for Task Order b) Copy of Task Order SOW c) Made available hard or electronic copy of approved QMP d) If QMP not approved, provide Contract SOW 3. For a Field Sampling Plan (FSP) or Sampling & Analyses Plan (SAP), the Project QAPP must also be provided. <b>QR</b> The FSP or SAP must be clearly identified as a stand-alone QA document and must contain all QAPP required elements (Project Management, Data Generation/Acquisition, Assessment and Oversight, and Data Validation and Usability).	<b>Documents Submitted for QAPP Review:</b> 1. QA Document(s) submitted for review: <table border="1"> <thead> <tr> <th>QA Document</th> <th>Date</th> <th>Document Stand-alone</th> <th>Document with QAPP</th> </tr> </thead> <tbody> <tr> <td>QAPP</td> <td></td> <td>Yes / No</td> <td>Yes / No</td> </tr> <tr> <td>FSP</td> <td></td> <td>Yes / No</td> <td>Yes / No</td> </tr> <tr> <td>SAP</td> <td></td> <td>Yes / No</td> <td>Yes / No</td> </tr> <tr> <td>SOP(s)</td> <td></td> <td>Yes / No</td> <td>Yes / No</td> </tr> </tbody> </table> 2. WP/SOW/TO/PP/RP Date _____ WP/SOW/TO/PP Performance Period _____ 3. QA document consistent with the: WP/SOW/PP for grants? Yes/No _____ SOW/TO for contracts? Yes/No _____ 4. QARF signed by RS QAM Yes/No/NA _____ Funding Mechanism IA / contract / grant / NA Amount _____	QA Document	Date	Document Stand-alone	Document with QAPP	QAPP		Yes / No	Yes / No	FSP		Yes / No	Yes / No	SAP		Yes / No	Yes / No	SOP(s)		Yes / No	Yes / No
QA Document	Date	Document Stand-alone	Document with QAPP																		
QAPP		Yes / No	Yes / No																		
FSP		Yes / No	Yes / No																		
SAP		Yes / No	Yes / No																		
SOP(s)		Yes / No	Yes / No																		

**Summary of Comments** *(highlight significant concerns/issues):*

1. Comment #1
2. Comment #2
3. Comment #3
4. The Click here and type Entity must address the comments in the Summary of Comments, as well as those identified in the Comment section(s) that includes a "Response (date)" and Resolved (date)".

Update # 2 8-2012 QAPP Crosswalk:



# Questions?



# References\*

1. Region 8 QA Document Review Crosswalk
2. Region 8 Instructions for Project-level QA Document Reviews
3. QA Review Form (QARF)

\*These documents and other QA references may be found at the QA website (<http://www.epa.gov/region8/qa/>)



# QA References



## Important Requirement/Guidance/Assistance\*

- QA/G-5 is the guidance on developing Quality Assurance Project Plans that meet EPA specifications.  
<http://www.epa.gov/quality/qs-docs/g5-final.pdf>
- QA/R-5, “EPA Requirements for QA Project Plans”, describes how we plan a project. <http://epa.gov/quality/qs-docs/r5-final.pdf>
- Region 8 QAPP Checklist is based on QA/R5 for QAPP development.  
[http://www.epa.gov/region8/qa/Generic\\_QAPP\\_Checklist.pdf](http://www.epa.gov/region8/qa/Generic_QAPP_Checklist.pdf)
- EPA-505-B-04-900C and DoD: DTIC ADA 426186, Workbook for Uniform Federal Policy for Quality Assurance Project Plans.  
<http://www.epa.gov/swerffrr/documents/qualityassurance.htm>

\* *These documents may be found in the QA website (<http://www.epa.gov/region8/qa/>)*



# Main Parts of the QAPP

## A Elements - Project Management

- A1 Title and Approval Sheet
- A2 Table of Contents
- A3 Distribution List
- A4 Project/Task Organization
- A5 Problem Definition/Background
- A6 Project/Task Description
- A7 Quality Objectives and Criteria
- A8 Special Training/Certification
- A9 Documents and Records

## C Elements - Assessment and Oversight

(activities done to see if project is conducted as per the QAPP)

- C1 Assessments and Response Actions
- C2 Reports to Management

## B Elements - Data Generation and Acquisition

- B1 Sampling Process Design
- B2 Sampling Methods
- B3 Sample Handling and Custody
- B4 Analytical Methods
- B5 Quality Control
- B6 Instrument/Equipment Testing, Inspection, and Maintenance
- B7 Instrument/Equipment Calibration and Frequency
- B8 Inspection/Acceptance of Supplies and Consumables
- B9 Non-direct Measurements
- B10 Data Management

## D Elements - Data Validation and Usability

- D1 Data Review, Verification, and Validation
- D2 Verification and Validation Methods
- D3 Reconciliation with User Requirements

