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**

- **American National Standard**
  ANSI/ASQ E4-2004

- **EPA Orders**
  - CIO 2105
  - CIO 5700.7
  - CIO 2133
  - CIO 2106

- **Regulations**
  - 40 CFR 30
  - 40 CFR 31
  - 40 CFR 35
  - 48 CFR 46

- **Underground Injection Control Inspection Manual**
  February 1988

- **Quality Assurance Guidance for Conducting Brownfields Site Assessments**
  EPA 540-R-98-038

- **Guidance for conducting Remedial investigations and Feasibility Studies under CERCLA**
  EPA540/G-98004

- **Quality Management Plan**
  - EPA QA/R2
  - and/or
  - Quality Assurance Project Plans
  - EPA QA/G5

- **Guidance for Quality Assurance Project Plan Development**
  - FIFRA Pesticides Program
  - OECA Document Control No: EC-G-2000-067

Intro to Delegated QA Approving Officer Training for QA Document Approval Authority—9/19/2012
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 assurance practices to produce data of adequate quality to meet project objectives

40 CFR 31* 40 CFR 35*

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.¹

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.²

¹ universal definition; as defined in ANSI/ASQ E4-2004
² 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 Approval Authority Hierarchy

- **QA Document Approval Authorities**
  - **OEI**
  - **RQAM ONLY**
  - **RQAM or Delegate**

**AAships QMPs**
Region 8 Quality Management Plan

State, Tribal or Contract/Grantee QMPs (EPA funded)
Interagency Agreement QA Documents
Region 8 Program-level QA Documents
QA Documents currently in review with the QA Program
QA Review Forms (QARFs)

- **QAPP**
  - **SAP**
  - **SOPs**
  - **FSP**

- **QAPP**

- **QAPP**
  - **FSP**

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Intro to Delegated QA Approving Officer Training for QA Document Approval Authority—9/19/2012
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.
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;


- 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
Before Award of Contract

Responsibilities & Tracking

Prepare Procurement Initiation (PIN) or Purchase Request (PR) Package
Contract-level SOW & QARF
Prepared by COR/PO

Contract-level SOW & QARF
Reviewed by RQAM

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

Yes

Document QA Requirements for the PIN or PR Package
Prepared by PO/COR & Conurred by RQAM

QARF
signed by RQAM

Finalize Contract-level SOW & QARF, Submit with PIN or PR Package
Prepared by PO/COR & Delivered to AMU

No

QARF signed by RQAM

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
After Award of Contract

Responsibilities & Tracking

**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*?

- **Yes**
  - 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

- **No**
  
  - QARF
    signed by RQAM

**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

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How is a QARF Processed?

- A QARF shall be prepared by the COR\(^1\) 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

- 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
Region 8 QA Training Initiative
QUALITY SYSTEM – QA ROLES
in the
Grant Approval/Administration Process

Grant Application Received And FR Form Initiated

FR (question B.5) states Data/Info Collection in Workplan?

Yes
No

Grant Approved

PO acknowledges grant condition

QAPP Approved (QA and Program Signatures obtained)

Program/Tribal Manager provides demonstration
Grants Program Condition met

Notify PO of Grant Condition

Notify QA for Technical Assistance

Grants Places Condition on Grant (i.e., 60 to 90 day Review Period)

Yes
No

Grants Program condition not met

Notify Grants Program application Not Approved

Grants Program Notify Applicant to submit approvable QAPP

Grant Issued. No Further QA Review

Grants Provide Grantee List to QA

QA will evaluate all grants categorized as “No Data”

Grant Process Path Flow

Coordination with QA

Communication Requirement for PO and PM/TM

Intro to Delegated QA Approving Officer Training for QA Document Approval Authority—9/19/2012
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*
- 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/qa/)
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/jqs-docs/g5-final.pdf


• Region 8 QAPP Checklist is based on QA/R5 for QAPP development. http://www.epa.gov/region8/qa/Generic_QAPP_Checklist.pdf


* 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

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

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

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