Quality Management Plan

U.S. EPA - Region 6

Revision 12 / QTRAK No. 17-538

August 2017

U.S. Environmental Protection Agency
Region 6
1445 Ross Avenue
Dallas, TX 75202-2733

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Quality Management Plan Identification Form

Document Title:

Quality Management Plan for EPA, Region 6

Document Control Number:

QTRAK number to be assigned upon R6 approval

Organization Title and Address:

EPA Region 6
1445 Ross Avenue
Dallas, Texas 75202-2733

Acting Regional Administrator:

Samuel Coleman, P.E.

Regional Quality Assurance Manager and Address:

Donald L. Johnson
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Plan Coverage:

The plan covers all of the monitoring and measurement activities mandated through EPA regulations and memoranda. This includes all internal and external environmental data generated by monitoring activities conducted through Regional program activities, contracts, grants, interagency agreements, and cooperative agreements. The Quality Management Plan primarily covers the activities of the Regional Quality Assurance Manager and the delegation of Quality Assurance responsibilities to the different Divisions and programs at Region 6. Each Division will be responsible for the development and continuous update of its own Quality Management Plan.

Concurrences

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Date: 9/12/17

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Title: Director, Compliance Assurance and Enforcement Division
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Title: Director, Superfund Division
Signature: _____ Date: 9/12/17

Name: James Payne, Jr. Phone: (214) 665-8170
Title: Regional Counsel
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Approval for Implementation

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Title: Acting Deputy Regional Administrator
Signature: _____ Date: 9/12/17

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Title: Acting Regional Administrator
Signature: _____ Date: 9/13/17

Glossary of Acronyms

ANSI	American National Standards Institute
ARA	Assistant Regional Administrator
ASQ	American Society for Quality
CFR	Code of Federal Regulations
CO	Contracting Officer
COR	Contracting Officer Representative
CWPPRA	Coastal Wetlands Planning, Protection and Restoration Act
DQAO	Division Quality Assurance Officer
DQO	Data Quality Objective
EPA	U.S. Environmental Protection Agency
EPAAG	EPA Acquisition Guide
EPAAR	EPA Acquisition Regulation
ERRS	Emergency Response Removal Services
ESAT	Environmental Services Assistance Team
ESB	Environmental Services Branch
FAR	Federal Acquisition Regulations
FR	Funding Recommendation
IGMS	Integrated Grants Management System
IQG	Information Quality Guideline
IRM	Information Resource Management
IT	Information Technology
MSR	Management System Review
OEI	Office of Environmental Information
OPA	Oil Pollution Act
OTOP	Office of Technology Operations and Planning
PE	Performance Evaluation
PT	Proficiency Testing
QA	Quality Assurance
QAM	Quality Assurance Manager
QA MOU	Quality Assurance Memorandum of Understanding
QAPP	Quality Assurance Project Plan
QAARWP	Quality Assurance Annual Report and Work Plan
QAFAP	Quality Assurance Field Activities Procedure
QC	Quality Control
QMP	Quality Management Plan
QSA	Quality System Assessment
QTRAK	Quality Assurance Tracking System
RAC	Remedial Action Contract
RFC	Request for Correction
RFR	Request for Reconsideration
RQAM	Regional Quality Assurance Manager
SOP	Standard Operating Procedure
START	Superfund Technical Assistance and Response Team
TMDL	Total Maximum Daily Load
TSA	Technical System Audit
URL	Uniform Resource Locator

1. MANAGEMENT AND ORGANIZATION

1.1 EPA Mission

The mission of EPA is to protect human health and the environment to the extent outlined by Congress with the tools that are given to it by Congress and the other branches of government. Environmental impacts can be significant statistically, significant to the environment and/or significant to society; EPA only decides whether the first two conditions apply. Other parties, such as Congress, the Executive Branch, the Courts or the public, decide if the last condition applies. A good decision for EPA is one that follows both the spirit and letter of environmental law and regulations, protects the environment and public health, expends the least amount of resources, and is made in a timely manner. Decisions made by EPA **shall**[1] be based on valid scientific assumptions and good **information** because those decisions impact not only the environment but also public health, the regulated community and EPA's credibility.

Appropriate advanced planning is required to make sure that information collected will allow EPA to make a good decision. Good decisions that are made in a timely manner can save time, damage to the environment and/or the public health, lost resources, unnecessary litigation and EPA's credibility. The success of EPA fulfilling its decision-making mission depends on its ability to obtain information about the environment (**data**). The "**quality**" of the information used by EPA and the resources expended to obtain that information should be commensurate with the impact of the decision. The resources used to generate data can be measured with a great deal of **precision**, but the "quality" of data is not easily determined.

1.2 Quality Assurance

Quality Assurance (QA) is an integrated system of management activities (planning, implementation, assessment, reporting, and quality improvement) that focuses on providing confidence in the data or **product** by ensuring that it is of the type and worth needed and expected by the client. To ensure that **decision-makers** in EPA have the information that they need to make proper decisions, EPA Order CIO 2105.0, Policy and Program Requirements for the Mandatory Agency-wide Quality System (May 5, 2000) was issued. This order which requires the establishment of a QA Program at EPA. EPA Order CIO 2105.0 tasked each EPA Regional Administrator to set up a QA Program. This Quality Management Plan (QMP) establishes **policy** and program **requirements** for the conduct of all **work** that generates **environmental data** performed by or for this agency within Region 6.

[1] See Appendix A for the definition of words and phrases that appear in **bold** in the text of this document.

1.3 Quality Management

As a matter of policy, Region 6 is strongly committed to good science and aggressive QA practices. The integrity of our science is a vital component of the Agency's work to fulfill our mission to protect public health and the environment. Indeed, the foundation of our decision making relies on our ability to generate high-quality, irreproachable data from our both our laboratories and from our field activities, as well as work performed by grantees or contractors on our behalf. Region 6 is committed to ensuring that staff are properly trained and provided the necessary resources to maintain an effective quality management program. Doing so will reduce potential vulnerabilities in critical decision making and help protect the Agency's scientific integrity.

1.4 QA Structure

Region 6 utilizes a decentralized QA **organization**, relying on each Division and/or program office to be responsible for its own QA efforts. This was formalized in Region 6 by the QA Memorandum of Understanding (QA MOU) (Appendix B), which supplements this QMP and Division and Branch QMPs in defining Roles and Responsibilities of the **Regional Quality Assurance Manager** (RQAM), Division Quality Assurance Officers (DQAOs), the Environmental Services Branch (ESB) **Quality Assurance (QA) Coordinator** and their respective managers. The Water Division, Compliance Assurance and Enforcement Division, Superfund Division, Management Division, and the Multimedia Division are hereinafter referred to as the Programmatic Divisions in this QMP. The QA Manager in the Management Division shall support the QA needs of the Office of External Affairs, the Office of Environmental Justice, International and Tribal Affairs and the Office of Regional Counsel (hereinafter referred to as Offices).

The QA MOU addresses how each of the Programmatic Divisions funds its DQAO position and contributes to the RQAM's position. Resources for travel of Regional QA Staff are addressed in the QA MOU. Responsibilities of QA Staff support of all areas of the Regional Office are defined in the QA MOU, and as resource availability is a constantly changing situation, allows for the Regional Senior Managers to reallocate responsibilities without requiring a change to this QMP.

Duties assigned to the RQAM, DQAOs and QA Coordinator in this QMP, subordinate QMPs and the QA MOU shall be consistent with EPA Order CIO 2105.0, which states in part in paragraph 7d, "If these personnel have other functions to perform, there shall be no conflict of interest" with their QA duties and responsibilities. The DQAOs should not be assigned direct project management duties, especially if the **project**(s) involves generation of environmental data. If DQAOs are assigned direct project management responsibilities, the supervisor of the DQAO shall prepare a plan that includes a clear statement of who has approval and oversight

authority for the DQAO's technical activities. This plan shall be submitted to the RQAM for approval prior to initiation of any project related activities.

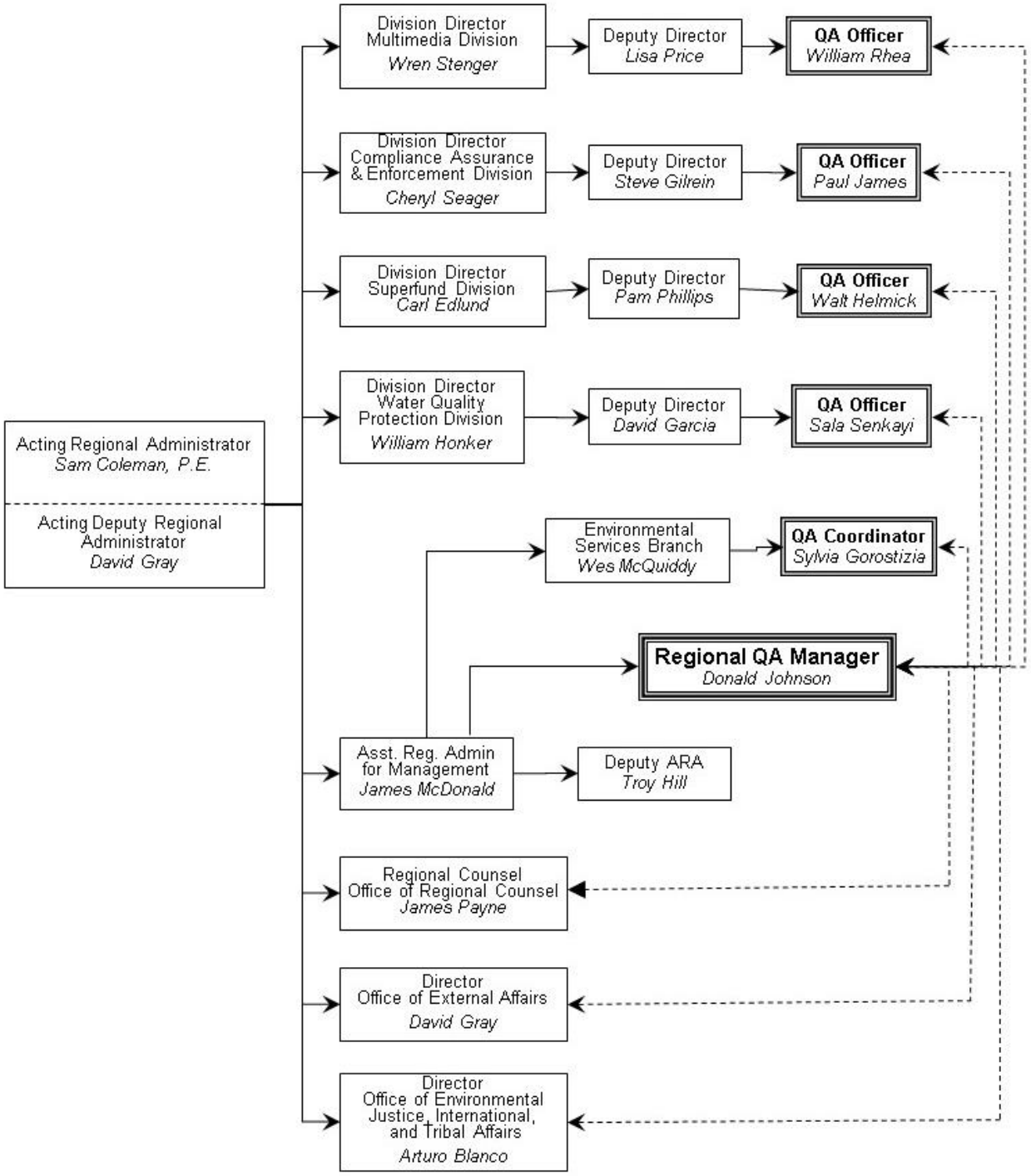
This Region 6 QMP covers the delegation of QA responsibility to the Divisions, the responsibilities of the RQAM (6MD) and his/her oversight of QA in the Divisions and the interactions between the RQAM and the Divisions. Figure 1-1 is an organizational chart that shows the lines of authority in Region 6. The RQAM reports to the Assistant Regional Administrator (ARA) for Management and each DQAO reports to his/her respective Deputy Division or Office Director or Branch Chief, in the case of the ESB QA Coordinator. While the MOU referred to above defines the roles and responsibilities of the RQAM, DQAOs, ESB QA Coordinator and management, it is the responsibility of each DQAO or ESB QA Coordinator to inform the RQAM of any **independence** issues he/she may face within his/her chain of management, and to inform the RQAM of any problems that arise in conducting his/her **assessment** activities. The RQAM is ultimately responsible for assuring the independence of the QA staff of the Region, and shall attempt to assure there is an effective amount of operational independence for all QA staff. Where this independence may be lacking the RQAM will perform assessment and oversight of the affected projects or delegate it to a DQAO in another division, with management approval. This QMP, and through the Management Division QMP and the ESB QMP, defines and further describes the roles and responsibilities of the ESB QA Coordinator. Figure 1 details the Region 6 quality assurance structure as of August 2017.

1.5 Effective Date of QA Documents

This QMP becomes effective on the date signed as **approved** by the Region 6 Administrator or his/her designee and expires 5 years from the date signed, unless a shorter period is specified. Region 6 Divisional QMPs become effective on the date that they are signed as approved by the RQAM and expire 5 years from the date signed, unless a shorter period is specified. QMPs subordinate to and authorized by a Divisional QMP will be reviewed and approved by the **process** defined in that QMP, but not to exceed an expiration date of 5 years. External QMPs submitted to Region 6 for approval become effective when signed as approved by the RQAM, and expire no later than 1 year from the date signed, unless a shorter period is specified. Specific programmatic requirements that are expressed to external customers, such as grantees or contractors, may stipulate a shorter time period, or require submission by a specific time as a condition of a grant or contract. This more specific requirement does not take precedence over the one-year maximum general requirement.

QAPPs, become effective on the date they are signed as approved by the designated approving official in each divisional QMP, and expire 1 year from the date signed, unless otherwise stated in an approved Divisional QMP. The approval period shall be defined in the approval notification.

Figure 1: Quality Assurance Structure – August 2017
Environmental Protection Agency, Region 6



1.6 Scope

As required by Title 2 CFR 1500.11, Title 40 Part 35 and Title 48 CFR Part 46 of the Code of Federal Regulations (CFR), QMPs shall be submitted which cover the activities of the following programs (designated by Region 6 mail code): EPA grants, cooperative agreements, interagency agreements or contracts, and any other entity performing work that generates environmental data funded by or used by the EPA for decision making.

REGIONAL ADMINISTRATORS OFFICE	MAIL-CODE
U.S. Mexico Border 2020	(6RA-DA)
Tribal General Assistance Program	(6RA-DT)
Environmental Justice Small Grant Program	(6RA-DJ)

WATER DIVISION PROGRAMS	MAIL-CODE
Assessment, Listing and TMDL Section	(6WQ-PT)
Beaches Environmental Assessment and Coastal Health Act (BEACH)	(6WQ-AT)
Coastal Wetlands Planning, Protection and Restoration Act (CWPPRA)	(6WQ-AT)
Gulf of Mexico	EPA Region 4
National Estuary Program	(6WQ-AT)
Non-Point Source (319)	(6WQ-AT)
Ocean Dumping	(6WQ-EC)
Pontchartrain Restoration Program	(6WQ-AT)
Public Water Supply Supervision	(6WQ-AP)
Special Appropriation Act Projects	(6WQ-AP)
State Revolving Funds (CW & DW)	(6WQ-AP)
Total Maximum Daily Load (TMDL)	(6WQ-PT)
US/Mexico Border Program	(6WQ-AP)
Urban Waters	(6WQ-AT)
Underground Injection Control	(6WQ-AP)
Water Pollution Control (106, Ground Water)	(6WQ-AT)
Water Quality Management Planning 604(b)	(6WQ-AT)
Water Quality Standards	(6WQ-EW)
Watershed (104)	(6WQ-AT)
Wetland Program Development	(6WQ-AT)
Water Infrastructure for Improvements to the Nation (WIIN) Act (5-yr authorization in 2017 to support Gold King Mine monitoring)	(6WQ-AT)

MULTI MEDIA DIVISION PROGRAMS	MAIL-CODE
Air Emissions Inventory	(6MM-AM)
Air Modeling	(6MM-AM)
Ambient Air Monitoring	(6MM-AA)
Control Agency Resource & Supplementation (105) Air	(6MM-AM)
Pesticides Program Implementation	(6MM-XP)
Radon Action Programs	(6MM-XP)
RCRA Corrective Action	(6MM-RC)
RCRA Facility Assessment	(6MM-RP)
RCRA Federal Facilities	(6MM-RC)
RCRA State and Tribal Oversight	(6MM-RS)
RCRA Strategic Planning and Information Management	(6MM-RS)
Solid Waste Program	(6MM-XU)
State Implementation Plans (Air)	(6MM-AA, 6MM-AB)
Underground Storage Tank Program	(6MM-XU)

MANAGEMENT DIVISION PROGRAMS	MAIL-CODE
Environmental Services Assistance Team (ESAT)	(6MD- HL)
Region 6 Houston Laboratory	(6MD-H)

SUPERFUND DIVISION PROGRAMS	MAIL-CODE
Brownfields	(6SF-V)
Emergency Response Removal Services (ERRS)	(6SF-P, 6SF-V)
Geographic Information Systems	(6SF-V)
Hazardous Spill & Site Response	(6SF-P)
Oil Pollution Act (OPA)	(6SF-V, 6SF-P)
Remedial Action Contract (RAC)	(6SF-V, 6SF-R)
Remedial Activities	(6SF-R)
Response Activities	(6SF-P)
Site Assessment	(6SF-T)
Superfund Cooperative Agreements (Remedial)	(6SF-V, 6SF-R)
Superfund Technical Assistance & Response Team Contract (START)	(6SF-V, 6SF-P, 6SF-T)

COMPLIANCE ASSURANCE AND ENFORCEMENT DIVISION PROGRAMS	MAIL-CODE
Air Enforcement Program	(6EN-A)
Waste Enforcement Program	(6EN-H)
Water Enforcement Program	(6EN-W)

OFFICE OF EXTERNAL AFFAIRS	MAIL-CODE
Environmental Education Program	(6XA)

1.7 QMP Policy

EPA prefers QMPs that adequately cover the most programs as consistently as possible. A single QMP, covering multiple **Quality Assurance Project Plans** (QAPPs), will maximize the consistency of efforts, and minimize the systemic variation in those QAPPs. However, each Region 6 Division, State or State Agency, Municipality, University or Nonprofit Organization, Tribal Grantee and Contractor may develop as many QMPs as they feel are necessary. The QMPs shall follow the **guidance** of Chapter 3 of the EPA Quality Manual for **Environmental Programs** CIO 2105-P-01-0 for EPA organizations, or the current EPA Requirements or Guidance Documents as applicable for non-EPA organizations. Current and approved QMPs shall be on file with the Region 6 RQAM before an application for EPA **financial assistance** is considered complete (See Paragraph 1.11 for additional information).

1.8 QMP Submittal, Review and Extension Procedures

Approval or disapproval and return of a QMP to the submitting grantee or prospective grantee will be accomplished within 30 calendar days by the RQAM and the supporting DQAO. Specific written comments shall be provided when a QMP is disapproved which assist the submitter in creating a workable QMP. In lieu of written comments, at the discretion of the DQAO, verbal or electronic feedback may be provided to the submitter of a QMP if the submitter prefers comments in that manner. If in working with a QMP submitter to revise a non-conforming QMP, the DQAO needs to assure that revised QMPs are submitted in a timely manner to not exceed the 30 calendar day time frame. QMP reviews are normally accomplished by the appropriate or applicable DQAO; however, final approval/disapproval is the sole responsibility of the RQAM.

Review of QMPs submitted by contractors or prospective contractors will be accomplished by the DQAO or QA Coordinator per the instructions of, or as an assistance to, the responsible Contracting Officer (CO) or Contracting Officer's Representative (COR) as described in the EPA Acquisition Guide (EPAAG). This support will be provided by the DQAOs or QA Coordinator, and they are authorized to provide this support by this QMP. Each DQAO or QA Coordinator will follow and accomplish all requirements defined in Chapter 46 of the EPAAG for the RQAM. If any Division QMP defines a QA Review Form that differs from the one that is in Chapter 46 of the EPAAG, that form shall be appended to that Division's QMP, after approval by the RQAM and the OEI Quality Staff.

Once a QMP has been reviewed and approved, its expiration date is set at one year from the date of approval per Section 1.5 of this QMP. A Project Officer, with concurrence of the applicable DQAO, may request that the RQAM extend the expiration date of a previously approved QMP. If the RQAM grants this extension request, the extension shall not exceed a period of 18 months from the date of the initial approval. Extensions beyond 18 months after

initial approval date require the concurrence of the RQAM and a decision by the ARA for Management. Any changes to expiration dates require annotation in the Comments Section of **QTRAK** (Quality Assurance Tracking System) (further described in Section 1.11) regarding details of the extension and revising the expiration date. Regardless of the length of an extension to a QMP, when an updated QMP from the same organization is submitted, the annual approval period for the new QMP shall begin on the date the extended QMP was originally set to expire.

1.9 QMP Reciprocity

If an external organization has a QMP that has been approved by another EPA Organization (i.e. Region, Program Office, ORD Laboratory, etc.) it can be accepted reciprocally by EPA Region 6 as an approved QMP under certain conditions.

Regional QA Staff shall be able to verify the approval period or expiration date of the QMP, and that the EPA organization previously approving the QMP actually did approve it. The decision to accept a QMP under reciprocity requires a recommendation to do so from the applicable programmatic DQAO and approval by the RQAM. The DQAO's recommendation is essential to assure the QMP adequately covers the type of work being performed. DQAO shall make a recommendation regarding the length of the approval period for Region 6 use. The external organization seeking reciprocal approval shall provide an original copy (if available) of the QMP for the files and a QTRAK number shall be assigned for the purpose of **traceability**. The name of the original EPA approver, their organization, date of approval and length of approval shall be obtained and entered into QTRAK. The Region 6 Project Officer will be the Project Officer's name entered into QTRAK. The Project Officer from the original EPA organization that approved the QMP shall be entered in the comments section of QTRAK.

1.10 QAPP Submittal Review and Extension Procedures

In addition to a QMP, Title 2 CFR 1500.11, Title 40 Part 35 and Title 48 CFR Part 46 of the Code of Federal Regulations (CFR) require that all **environmental data operations** performed by or for (with resources supplied by the Agency or for Agency decision making) EPA be described in an approved QAPP or **equivalent document**. Determination of a **document** being equivalent to a QAPP shall be accomplished jointly by the DQAO and the Project Officer. If an approved QMP from the submitting organization exists that defines a process for development of an equivalent document in lieu of a QAPP, no consultation is required. The review and approval of QAPPs, both internal and external, is a responsibility delegated to each Division and is thoroughly described in its Division QMP. The Divisional QMPs will also stipulate the process used to assure that QAPPs are current. Any proposed change in an approved QAPP shall be approved by the same process as the initial approval unless otherwise specified in the Division QMP. QAPPs shall follow the requirements of the Office of Environmental Information's (OEI's)

Quality Staff for QAPPs, designated as EPA Requirements for Quality Assurance Plans, EPA QA/R-5 for external extramural QAPPs and Chapter 5 of the EPA Quality Manual for Environmental Programs, CIO 2105-P-01-0 for internal QAPPs. An approved QAPP is required to be in place prior to the beginning of environmental data operations, except in situations requiring immediate action to protect human health and the environment or operations conducted under police powers. Any entity receiving funds from EPA that does not perform environmental data operations may be exempted from the requirements for a QMP and QAPP, but only by the RQAM. All QAPPs shall be fully implemented, and each Division QMP specifies the process by which implementation will be verified. Oversight of implementation for the Region shall be accomplished during QA **Management System Reviews** (MSR) or Quality System Assessments (QSA) as covered in Section 9 and performed under the direction of the RQAM.

Once a QAPP has been reviewed and approved, its expiration date is set per Section 1.5 of this QMP. Expiration dates of QAPPs may be extended if a valid reason to do so exists and the data from the project would not be impaired. An example of a valid reason for extending a QAPP expiration date would be the temporary non-availability of a key person that writes, reviews or approves the QAPP. Each Divisional QMP will define the process used to assure that QAPP extensions are requested for a specific valid reason and that the approval of the appropriate Division Director or designated QAPP approving authority has been obtained. If the QAPP expiration date is extended, the extension shall not exceed a period of 6 months unless approved by the RQAM. Any changes to expiration dates will require annotation in the Comments Section of QTRAK regarding details of the extension to include addressing the compelling reason an extension is needed and revising the expiration date. These QTRAK changes shall be sent via email from the DQAO to the RQAM and QTRAK coordinator to assure the DQAO approves the extension.

1.11 QAPP and QMP Tracking

All QMPs shall be submitted to the RQAM, or delegated individual, for approval and to receive a tracking number. Region 6 has developed a database called QTRAK for recording, tracking and identifying quality trends, targeting quality assessments and an additional control to detect QA policy non-compliances. QAPPs are not required to be submitted to the RQAM; however, information regarding the QAPPs shall be provided to the RQAM, or delegated individual, in order to receive a tracking number. QMPs and QAPPs are not considered to be approved if they do not have a tracking number, as the tracking number is a required entry on the QA Certification Form that is addressed in Section 1.12. All QMPs and QAPPs, regardless of approval status, shall be tracked to assure timely review, approval or re-submission and to inform internal and external customers of the status of any QA plan at any time. Submission of a QMP or a QAPP to EPA Region 6 from a grantee requires a response, preferably written or at

least electronic, acknowledging receipt and providing the tracking number to the grantee. Responses are the responsibility of the individual at Region 6 that receives the QMP or QAPP.

1.12 QA Certification Form Process for Integrated Grants Management System (IGMS)

The Project Officer has primary responsibility for ensuring QA requirements are satisfied for EPA's financial assistance agreements. The Grants Specialist ensures QA documentation is included in each Funding Recommendation (FR) package. QA roles and responsibilities for both Project Officers and Grants Specialists are described in the Grants Specialist Training and Project Officer Training courses. Additional requirements, or changes to those requirements are defined by the Office of Grants and Debarment; definitions of roles and responsibilities take precedence over this regional document in regard to Grants Training. The DQAO works closely with the appropriate Project Officer to assure all required QA Documentation is present, current and approved prior to release of funds. This responsibility is discharged by a joint QA Certification form (copy at Appendix C) signed by the Project Officer, the DQAO and RQAM. The RQAM will retain a reproduced copy of all signed QA Certification forms for his/her **records** or assure that an electronic copy is part of the permanent IGMS. The DQAO's IGMS approval authority can be exercised by the RQAM in the absence or non-availability of the DQAO. RQAM's IGMS approval authority is retained within the Office of the (ARA) for Management to assure independence of the QA review process. Both the DQAOs and RQAM will strive to assure those designated to perform IGMS QA reviews in their absence or non-availability are aware they will be performing that function. The DQAO and RQAM will attempt to provide prompt responses to Project Officer's IGMS FR, but due to operational necessities of travel and other reasons of non-availability, may take as long as 5 working days to respond to the FR.

1.13 EPA Competency Policy

In August 2014, the ARA issued a memo to all Divisions requiring Regional Staff to assure that Assistance Agreement Holders were in compliance with the EPA Competency Policy. The Competency Policy applies to all Assistance Agreement Holders with awards of $200K or greater during the life of the agreement.

This is accomplished by:

- Project Officers determining the grant is less than $200 K (no action is required);
- Project Officers determining the grant is more than $200 K then actions are required.
    - A statement must be added to the Organizations QA documents, specifically the Work Plans (in addition to the QAPPs or QMP if applicable-see R6 Memo Appendix C).

- Utilize the R6 Checklist for the Implementation of the FEM Policy for Competency for Grants and Cooperative Agreements (Appendix C) to determine implementation with the Agreement Holder.
- All Funding Recommendations must contain the following statement in the terms and conditions of the Cooperative Agreement and the QA Certification Form (see Appendix C) must be filled in appropriately:
  - In accordance with Agency Policy Directive Number FEM-2012-02, Policy to Assure the Competency of Organizations Generating Environmental Measurement Data under Agency-Funded Assistance Agreements, Recipient agrees, by entering into this agreement, that it has demonstrated competency prior to award, or alternatively, where a pre-award demonstration of competency is not practicable, Recipient agrees to demonstrate competency prior to carrying out any activities under the award involving the generation or use of environmental data.
  - Recipient shall maintain competency for the duration of the project period of this agreement.
  - A copy of the Policy is available online at http://www.epa.gov/fem/pdfs/competency-policy-aaia-new.pdf or a copy may also be requested by contacting the EPA project officer for this award.

1.14 RQAM

The Region 6 QA Manager and his/her support staff (Division QA Officers) will be responsible for the following QA activities (see Section 9 for explanation of these functions).

1.14.1 Review and approval of all QMPs and coordination of QMP reviews

1.14.2 Maintenance of the QMP and QAPP tracking system (QTRAK)

1.14.3 Oversight of EPA funded data generation through MSRs or QSAs

1.14.4 Training and **certification** of individuals designated to write, review and/or approve QMPs or QAPPs or to process IGMS awards

1.14.5 Technical assistance to the program offices, States, Municipalities, Nonprofit Organization and Tribal grantees on the preparation of QMPs and QAPPs

1.14.6 Developing and providing courses that train EPA, State, Municipal, Nonprofit Organization and Tribal grantee staff in QA topics

1.14.7 Providing QA specific technical assistance to our customers both at and outside EPA

1.14.8 Providing technical assistance to our customers in the planning of projects that generate or use environmental data

1.14.9 Providing technical assistance to our customers in the development of environmental laws, rules and regulations

1.14.10 Review and approve exemptions for QA plan requirements for Grants, Cooperative Agreements and Interagency Agreements that do not involve Environmental Data

1.14.11 Review and approve QA certifications for Grants, Cooperative Agreements and Interagency Agreements that involve Environmental Data

1.14.12 Maintenance of a file system that contains an original copy, or electronic equivalent of an original copy of all the current Region 6 QMPs

1.14.13 Development and implementation of Regional QA policy

1.14.14 Approval of QAPP expiration date extensions and notification to RQAM of such actions

1.15 Delegation of QAPP Approval Authority to Non-EPA Organizations

The delegation of QAPP approval authority to non-EPA organizations shall be accomplished on a case-by-case basis, with input from the RQAM, the DQAO and managers of the applicable programmatic Division.

1.15.1 QA Criteria - In order to be considered for QAPP approval delegation, an organization shall have had an approved QMP in place for at least 5 years prior to the proposed date of delegation. The delegation request shall indicate the measures the organization proposes to implement to assure their internal QA system produces and effectively reviews QAPPs and what oversight or assessment activities will be accomplished to verify adequacy of these measures during the life of the delegation. The QA Manager of the requesting organization shall concur with the delegation request.

1.15.2 QSA - In order to be considered for QAPP approval delegation, an organization shall have a QSA conducted of the organization by the EPA with participation by the independent QA element of the requesting organization. If either the EPA or the requesting organization has conducted a QSA or equivalent assessment within the past year, their participation is optional, provided that the results were deemed acceptable by the QA Managers of both organizations. The QSA

shall verify that the requesting organization's quality system is in **conformance** with its own approved QMP and with EPA Order CIO 2105.0 and that the quality practices of the organization are suitably and effectively implemented. This assessment shall be led by the RQAM, or his designee, with assistance from the applicable Programmatic Division.

1.15.3 Programmatic Criteria - In order to be considered for QAPP approval delegation, an organization shall have demonstrated a past history of producing and internally reviewing QAPPs that assures a high level of technical competency is in place prior to the proposed date of delegation. Any limitations or exceptions to the proposed QAPP approval delegation shall be developed and coordinated among all affected programmatic managers and the DQAO. Managers responsible for QAPP review shall assure this competency exists by review of previously submitted QAPPs.

1.15.4 Decision Criteria - In order to be delegated QAPP approval authority, joint concurrence by the RQAM, DQAO and Programmatic Division Management of the delegation proposal is required.

1.15.5 Delegation Process - Non-EPA organizations shall request the delegation of QAPP approval authority from the Regional QA Manager. The RQAM will notify the DQAO of the programmatic Division, who will coordinate the Programmatic Criteria assessment with appropriate Division Management. If the delegation is deemed acceptable by the RQAM, DQAO and programmatic Division management, the RQAM will respond to the requesting organization, relaying any limitations or exceptions and requiring that the process be defined acceptably in the organization's QMP. The correspondence giving the approval shall be coordinated through the DQAO and Deputy Division Director of the programmatic office and other areas designated by any involved in the concurrence process. The correspondence to the requesting organization may grant approval of the delegation and be used by the requesting organization as an interim change to their QMP, until the next routine revision.

1.16 Information Quality Guidelines

EPA's **Information Quality Guidelines** (IQGs) contain EPA's policy and procedural guidance for ensuring and maximizing the quality of information the Agency disseminates. They are interrelated to the Regional Quality System for assuring the quality of EPA's data products and information. "Information" generally includes any communication or representation of knowledge or position/policy such as facts or data in any medium or form. This includes "preliminary" information that EPA has endorsed or adopted and also conclusions or facts

drawn from or based upon other existing information. This QMP incorporates by reference all definitions, principles, policies and **procedures** found in EPA's IQGs (http://www.epa.gov/quality/informationguidelines).

1.16.1 Implementation Policy and Procedures

Region 6 will comply fully with EPA's IQGs and where needed will establish policies and procedures for complying with these guidelines. Emphasis will be on using existing Regional processes and procedures wherever possible to comply with the requirements of the IQGs. The review process is intended to ensure the quality of the Region's **information disseminations** and is incorporated into the QAPP review processes of each Divisional QMP. The Region 6 IQG Coordinator assumes responsibility for coordination of the IQG process in Region 6 with the OEI. The IQG Coordinator is supported by the Office of Regional Counsel and the applicable Division's staff with responsibility for the particular programmatic area(s) involved in any IQG Requests for Correction (RFC) and/or Requests for Reconsideration (RFR).

1.16.2 Request for Correction (RFC)

The IQGs allow for affected persons to request correction of information if that information does not comply with EPA or OMB IQGs. The OEI will receive these RFCs and forward them to the Region 6 IQG Coordinator when the information in question belongs to or involves Region 6. Upon receipt of the RFC from the OEI, the IQG Coordinator will notify the Office of Regional Counsel and the responsible Programmatic Division(s).

1.16.3 Request for Reconsideration (RFR)

The IQGs allow for affected persons to request a reconsideration of EPA's decision on a RFC of information if they are dissatisfied with the decision. The OEI will receive these RFRs and forward them to the Region 6 IQG Coordinator when the information in question belongs to or involves Region 6. Upon receipt of the RFR from the OEI, the IQG Coordinator will notify the Office of Regional Counsel and the responsible Programmatic Division(s).

1.17 Pre-dissemination Reviews

EPA's IQGs also addresses Pre-Dissemination Reviews. For data related projects performed by or for Region 6 that require a QAPP, the process of QAPP approval, as defined in each Divisional QMP, will address the Pre-dissemination review process. Information acquired without a QAPP developed by or for Region 6 shall undergo Pre-Dissemination Review prior to dissemination. More information concerning Pre-Dissemination Review can be found at: http://intranet.epa.gov/quality/informationguidelines/pdf/pdr-guidelines.pdf

2. QUALITY SYSTEM COMPONENTS

The Region 6 quality system utilizes a decentralized QA organization. It relies on a RQAM, Divisional QAOs and trained and knowledgeable individuals in the various Divisions and Program Offices to accomplish the QA functions.

In a decentralized quality system each level of the organization has a responsibility to provide products and services of the quality needed and specified by its customers. Effective oversight of the quality process becomes the responsibility of the customer to assure quality is received from his/her **suppliers**.

The RQAM assumes the lead role for preparation of the Region 6 QMP and its periodic updates. This is accomplished through formal meetings of the Region 6 **QA Forum** (see section 10) and the RQAM and their joint assessment of all elements of the QMP.

2.1 Division QA Functions

Each Region 6 Division and Office Director or designee(s) shall be responsible for the following QA activities within his/her respective Division or Office in accordance with the Region 6 divisional QMPs, QA MOU and Position Descriptions (see Section 9 for explanation of these functions):

2.1.1 Development and consistent implementation of the necessary QMPs for Division operations involving environmental data operations, including the Division's internal and external (both grants or cooperative agreements and contracted) projects;

2.1.2 Review and approval of QAPPs for which an approved QMP exists;

2.1.3 Providing assistance to the RQAM in the review of external QMPs;

2.1.4 Concurrence and submission to the RQAM requests for QMP and/or QAPP exemptions;

2.1.5 Determining the validity of the QMP/QAPP Tracking System Data Base (QTRAK) for the Division or Office;

2.1.6 Providing routine technical guidance to customers on development of QMPs and QAPPs;

2.1.7 Referring applicable technical guidance requests from customers to the RQAM;

2.1.8 Maintenance or oversight of a file system that contains an original copy, or electronic equivalent of an original copy of all his/her organization’s valid QAPPs;

2.1.9 Participation as a Team Member in MSRs or QSAs, and Technical System Assessments (TSAs) and other **audit**/review functions as described in Section 9;

2.1.10 Provide assistance to Project Officers as described in Chapter 46 of the EPAAG and participate as a member of the Technical Evaluation Panel as directed by the COR or CO;

2.1.11 Assistance in determining QA needs of his/her respective Division and any State, Municipality, University, Nonprofit Organization or Tribal grantee or cooperative agreement holder under the Division's purview;

2.1.12 Implementation of Regional QA policy at the Division or Office Level;

2.1.13 Serves as a member of the Regional QA Forum; and

2.1.14 Approval of QAPP expiration date extensions and notification to RQAM of such actions.

2.2 Data Quality Objective (DQO) Process

The Data Quality Objective (DQO) Process is an essential tool to be used in planning all environmental data operations. DQOs shall be developed following all applicable OEI Quality Staff guidance, as defined in the current Guidance on Systematic Planning using the Data Quality Objectives Process, (EPA QA/G-4). All QMPs shall require that DQOs or equivalent **systematic planning process** be an essential element of all QAPPs, and contain a mechanism for assuring compliance. This is applicable to activities delegated to State, Municipal, University, Nonprofit Organization, Tribal grantee, cooperative agreement holder or conducted by a contractor. For all enforcement related projects, the appropriate legal counsel shall be involved in the DQO development process to assure that evidentiary needs are met. The purpose of any systematic planning process is to apply the **graded approach** to attempt to assure that the level of controls applied to proposed work is assessed according to the intended use of the results and the degree of confidence needed in the quality of the results.

2.3 QAPPs

EPA Order CIO 2105.0 requires that every project involving an environmental data operation or the use of **secondary data** (**historical data**) shall have a written QAPP approved prior to initiation of environmental data operations.

A QAPP presents, in specific terms, the policies, organization, objectives, functional activities, QA, and **quality control** (QC) activities designed to achieve the data quality objectives (DQO's) of a particular project or continuing operation. The typical **characteristics** of a good QAPP are:

- requirements for management and technical audits and a process for correction of deficiencies,
- requirements for documenting sampling **design**, sampling procedures and data Analysis, and
- the definition of specific QA and QC activities.

OEI's Quality Staff is responsible for guidance on format and areas of coverage for QAPPs. QMPs at the Division level, and lower if utilized, will delineate specific approval and concurrence requirements that comply with this QMP and Chapter 5 of the EPA Quality Manual for Environmental Programs, CIO 2105-P-01-0. In addition, all contracts have to meet the QA requirements of the EPA Acquisition Regulation (EPAAR), which is outlined in 48 CFR 46. The RQAM does not use any contract services to perform QA related activities, although Division QMPs address contract services within each Division in its QMP.

Each QAPP must cite the specific QMP and its effective date. No QAPP can be approved without an approved QMP, as the QMP is essential for defining the criteria of a QAPP. Implementation of QAPPs shall be evaluated by each respective Division and the RQAM will maintain oversight through MSRs, QSAs, Audits and other means, as specifically defined in each Divisional QMP.

2.4 Internal (In-House) Projects

The RQAM shall provide guidance in the development of QMPs and QAPPs during the planning phase of each monitoring **activity**. All Region 6 QMPs and QAPPs shall adhere to the **standards** outlined by the EPA Quality Manual for Environmental Programs, CIO 2105-P-01-0, Chapters 3 and 5 respectively. The Regional QA Staff shall evaluate the implementation of these plans through the Regional RQAM audit program or during MSRs or QSAs.

2.5 External Projects - Grants, Contracts and Cooperative Agreements

This category includes those projects conducted under Agency financial assistance programs, such as grants, cooperative agreements, interagency agreements, contracts, etc. This QMP does not discuss the QA requirements for any projects because the RQAM does not perform environmental data operations or have any contracted services. QA requirements for the different types of projects and contracted services are described in Title 2 CFR 1500.11, Title 40 Part 35 and Title 48 CFR Part 46 EPAAG and EPA Order 1900.2. The QA functions required by these documents are delegated to each Division. The Division QMPs describe the implementation process. The QAPPs required of awardees or contractors shall be developed consistent with EPA guidance and regulations and the respective Division QMP.

2.6 EPA Quality Assurance Field Activities Procedure

To ensure consistency in managing field practices and to reduce potential vulnerabilities, the Office of Environmental Information adopted the EPA Quality Assurance Field Activities Procedure (QAFAP, CIO 2105-P-02-0) which creates a sustainable quality management system for field work at EPA.

The EPA QAFAP is based on best practices for data collection as determined by EPA field groups, EPA quality requirements and concepts of management systems established by the International Organization for Standardization (ISO) including ISO 17020. They are intended to apply to any field activities such as sampling, measurements, and observations used by EPA for any purpose, such as sampling, measurements, and observations used by EPA for any purpose, such as routine ambient monitoring, research, clean-ups, risk management, studying new/revised regulations, screening, compliance monitoring, and enforcement.

The EPA QAFAP provides the foundation for ensuring the quality of the data generated by EPA and used for decision making. If the data quality is compromised at any point from collection to reporting, costly mistakes could occur and undermine the Agency's sound science foundation. Therefore, it is of the greatest importance that all data within the Agency be generated using consistent processes.

The QAFAP establishes the requirements for a quality management system to support field activities for the Agency. The basis of the QAFAP is CIO 2105.0 and Agency QMPs as required under CIO 2105-P-01-0 and EPA/QA R2. As CIO 2105.0 applies to all programs that collect, evaluate and use environmental data for EPA, the QAFAP was developed specifically for implementing field activities under CIO 2105.0. The QAFAP is relevant and beneficial to all Agency organizations that collect environmental data, regardless of the data's intended use. Implementing the QAFAP will reduce potential vulnerabilities and will increase EPA's ability to make reliable, cost effective, and defensible decisions.

Region 6 has fully implemented the QAFAP and established **standard operating procedures** (SOPs) to address each of the required elements of the QAFAP. Region 6 SOPs are available at: http://region6a.epa.gov/intranet/misc/r6qafap.html.

In addition to infrastructure developments such as tracking systems and processes/procedures, aspects of the QAFAP will be incorporated into the Region 6's quality system documentation (Region 6 QMP, Division or Branch Level QMPs, Division, Branch and Section Level SOPs) and all applicable project-level quality planning documentation which involve field environmental data operations.

The following summarizes the ten (10) required elements of the QAFAP:

1. Personnel and Training. Personnel responsible for field activities will have appropriate records documenting qualifications, education, training, experience and competency for carrying out requirements of field activities.

2. Document Control. Field groups will maintain a system for the control of all documents relating to their activities, including the preparation, review, approval, issuance, revision, revocation, and archiving of documents. Controlled documents (policies, SOPs, SOP compendiums, guidance blank template forms, and checklists) are generated internally for each organization and describe how work will be conducted.

3. Records Management. Field groups will maintain a records management system to suit their particular circumstances and to comply with applicable federal, EPA, and regional records management regulations and retention schedules.

4. Sampling and Environmental Data Management. Environmental data includes samples, measurements, and documentation, such as field notes and instrument charts. Field groups will establish and maintain procedures for the identification, transportation, handling, protection, storage and retention of samples and other potential evidence during field studies in accordance with Federal criteria for various types of evidence.

5. Field Documentation. Field groups will establish and maintain procedures to document all field activities to ensure the credibility of all observational, measurement, photographic and sample collection information.

6. Field Equipment. Field groups will establish and maintain procedures for field equipment to ensure all equipment is properly identified, maintained, and calibrated.

7. Field Inspections and Investigations. Field groups will establish and maintain procedures for planning field investigations and **inspections**, taking into consideration all applicable EPA and program-specific requirements.

8. Reports. Field groups will establish and maintain a procedure describing minimum standards for the preparation of a written report to summarize results of field activities and compliance inspections.

9. Internal Audits. Field groups will establish procedures to conduct internal audits to verify that their operations comply with these guidelines. The personnel performing the audits will be qualified and independent from the functions being audited whenever possible.

10. Corrective Actions. Field groups will establish and maintain a procedure for addressing **findings** from internal audits through corrective actions whenever nonconformities with these guidelines are identified.

2.7 QA Status Report Requirements - QAPPs

For data collection projects expected or planned to be completed within eighteen months, a single QA status (final) report is required at the conclusion of the project. For projects expected or

planned to continue longer than eighteen months, an interim QA status report is required every twelve months after data collection begins and at the conclusion of the project. These reports shall be submitted to the responsible Region 6 program office staff. The QA report on each project should be a separately identified Status Report (both interim and final) addressing as a minimum the following areas:

- QA management (any changes);
- Status of completion of the QAPP;
- Measures of data quality from the project;
- Significant quality problems, accomplishments, and status of corrective actions;
- Results of QA performance audits;
- Results of QA systems audits;
- Assessment of data quality in terms of precision, **accuracy**, **completeness**, **representativeness** and **comparability**; and
- QA related training.

Each Divisional QMP defines this process specifically.

2.8 Standard Operating Procedures (SOPs)

Standard Operating Procedures (SOPs) may be developed and incorporated into QMPs or QAPPs by reference and/or attachment. Use of SOPs is encouraged both as a **method** to reduce variation and to reduce costs, when a similar method or process is utilized in a number of projects or programs. RQAM SOPs are for internal office use only and are subjected to internal **peer review** and approval by the RQAM. Each SOP will be reviewed periodically and revalidated to indicate continued use. WHERE ARE THESE SOP ARE STORED?

The RQAM maintains copies of program specific EPA SOPs developed by national program offices for reference purposes.

Each Division and external QMP defines the method by which SOPs will be developed, reviewed and approved. At a minimum, all SOPs will be reviewed and updated/revalidated on a periodic

basis. Documentation of annual reviews will, at a minimum, consist of a signature page with final approval by the responsible supervisor.

2.9 Dispute Resolution Process

While recognizing that all Region 6 staff and managers have specific data quality requirements and everyone should work toward a common goal, there are times when differences of opinion do arise that can create conflict between the various organizational elements. If there are issues that do arise regarding the fulfillment of quality system requirements of this QMP, EPA Policy or the Codes of Federal Regulation then the applicable process discussed below will be followed to resolve the issue.

2.9.1 Interdivisional Dispute Resolution Process

If there are data quality related issues between the DQAO of a Programmatic Division and an organizational element of another Division, the RQAM shall be notified by the involved DQAO(s) of the issue. If the issue is over interpretation of Regional QA policy, the RQAM shall resolve the issue. If the issue is not within the purview of the RQAM to resolve, then the RQAM, in conjunction with appropriate managers from the involved Divisions, shall work together to resolve the issue. If the matter cannot be satisfactorily resolved at this level, the RQAM shall involve the ARA for Management, who will seek resolution from his/her peers. Failing to reach resolution at this level, the ARA for Management shall seek resolution from the Regional Administrator or Deputy Regional Administrator.

2.9.2 Intra-Divisional Dispute Resolution Process - Programmatic Division

If there are data quality related issues between the DQAO of a Programmatic Division and an organizational element of his/her own division the Regional QA Manager shall be notified by the involved QA Officer of the issue. If the issue is over interpretation of Regional QA policy, the RQAM shall resolve the issue. If the issue is not within the purview of the RQAM to resolve, then the RQAM, in conjunction with appropriate managers from the involved organizational elements, shall work together to resolve the issue. If the matter cannot be satisfactorily resolved at this level, the appropriate Division Director shall resolve the issue with the concurrence of the RQAM. If concurrence is not granted, the RQAM shall involve the ARA for Management, who will seek resolution from his/her peers. Failing to reach resolution at this level, the ARA for Management shall seek resolution from the Regional Administrator or Deputy Regional Administrator.

2.9.3 Intra-Divisional Dispute Resolution Process - Management Division

If there are data quality related issues between the RQAM and an organizational element of the Management Division, the ARA for Management shall select a neutral arbitrator to attempt to allow the involved parties to resolve the issue. If the matter cannot be satisfactorily resolved at this level, the ARA for Management shall recuse him/her self and seek resolution from the Regional Administrator or Deputy Regional Administrator.

3. PERSONNEL QUALIFICATIONS AND TRAINING

3.1 QA Staff Qualifications

The RQAM and each DQAO shall fulfill the educational, work experience and training requirements for their positions, as outlined by the Office of Personnel Management in their position descriptions. The RQAM and each DQAO will attend meetings and take courses that enhance their knowledge of QA, the technical aspects of the programs they consult and environmental analytical methodology, as time and funds permit.

3.2 QA Training and Certification

The following courses will be offered by Region 6:

- Quality Project and Program Management
- Quality Systems Assessment Workshop
- QA Refresher
- QA for Managers
- ANSI/ASQ E-4 for Quality Systems for Environmental Data & Technology Programs
- **Technical Systems Audit**
- QAFAP Internal Auditing Course

The Quality Project and Program Management course is intended for those who are involved with any aspect of the QA program, either at EPA, or a State, Municipal, University, Nonprofit Organization or Tribal Organization. It is primarily for those who write, review or approve QMPs and/or QAPPs. The Quality Systems Assessment Workshop course is intended for those who have need of knowledge regarding the planning or conducting of an MSR or QSA, either as an assessment team member or a member of an organization that will undergo an assessment. QA Refresher course is a recap of the Region's QA policies and procedures and is intended for Region 6 staff members who have not taken the basic QA course within the previous three years. Prior to 2011 there were three courses that together were considered equivalent to the Quality Project and Program Management course. Titles of those courses were: Orientation to QA Management; Data Quality Objectives; and QMP/QAPP Seminar.

Courses are primarily for EPA employees, and with adequate need and availability of resources, State, Tribal or other cooperative agreement holder's employees and contractor personnel may also take QA courses. Instruction given by the programs may be substituted for these courses if they are approved by the RQAM. A list of the courses and the dates they will be taught will be forwarded to the Region 6 EPA Institute annually and included in the QAARWP to OEI's Quality Staff. Additional classes will be scheduled if the demand exists.

The Regional QA Staff shall attend Quality Project and Program Management course at the earliest opportunity, as well as other OEI's Quality Staff offered courses (webinars). Region 6 shall present training to meet mission needs, and instructors are to be QA Staff members that have taken the particular course they are to present or be a recognized subject matter expert before they may teach a particular course.

The courses will be reviewed on an annual basis and, in response to course critiques, the necessary improvements will be made to the courses and teaching techniques. In addition to the Basic Project Officer training, each Project Officer that prepares, reviews or approves QMPs and/or QAPPs shall have completed the Quality Project and Program Management course above, prior to reviewing QA planning documents. Project Officers are encouraged to take other courses as they are offered. Individuals that approve QAPPs and sign the QA Certification Form (see Section 1.11), shall be certified by the Region 6 RQAM. Successful completion of the Quality Project and Program Management course will be the initial requirement for certification for individuals in each Division that prepare and/or approve QAPPs and sign the QA Certification Form (see Section 1.11). The certification is good for a period of 3 years and can be extended by the RQAM. Before the certification expires, the individual will receive notification of the pending expiration of his/her certification. To renew this certification for an additional three years, the individual shall successfully complete the QA Refresher Course. All individuals that are writing QMPs or QAPPs shall complete the Quality Project and Program Management course. Exceptions from the above certification requirements may be granted by the RQAM upon presentation of objective evidence of similar and equivalent training or experience in the QA field.

A list of properly trained and certified individuals will be maintained by the RQAM. All of the courses will be offered to the State, Municipal, Nonprofit Organization and Tribal Grantees or cooperative agreement holders, if resources are available. The individuals writing Region 6 Division, Branch, Section or Team QMPs are required to take the Quality Project and Program Management course. Prerequisites are as follows:

- Quality Project and Program Management - No prerequisites, open to anyone;
- Quality Systems Assessment Workshop Course - Prerequisite - Completion of the Quality Project and Program Management Course or permission of instructor;
- QA Refresher Course - Prerequisite - Completion of the Quality Project and Program Management Course;
- QA for Managers Course - No prerequisites, open to anyone;
- ANSI/ASQ E-4 for Quality Systems for Environmental Data & Technology Programs Course - No prerequisites, open to anyone;
- Technical Systems Audit Course - No prerequisites, open to anyone; and
- QAFAP Internal Auditing Course - No prerequisites, open to anyone.

These courses were designed and have been used to earn continuing education credits or units. These continuing education credits are used to satisfy the training requirements for professional certifications and requirements for CO and COR.

4. PROCUREMENT OF ITEMS AND SERVICES

The goal of Region 6 is to provide goods or services that comply with predetermined levels of quality and meet the needs and expectations of the customer. A suitable method for accurately translating the customer's needs and expectations to the supplier is a contractual document or a grant or cooperative agreement document that clearly states those needs and expectations to both customer and supplier.

4.1 Applicability

These requirements apply only to those Region 6 procurement actions (as opposed to those originating at EPA Headquarters or other non-Region 6 elements) or suppliers who provide services or **items** that directly affect the quality of results or products (e.g., analytical laboratory services, sample collection or sampling plan preparation) for environmental programs.

4.2 QA Requirements

All Divisions and programs that utilize contracted services or products that eventually yield environmental data will specify or require the description of the QA requirements in a QMP by the provider or prospective provider of the services or products.

This shall be accomplished by meeting the administrative and QA requirements as defined in the current versions of:

- the Federal Acquisition Regulations (FAR), Part 13
- the EPAAG that can be accessed at its website URL of https://oamintra.epa.gov/node/521/

The QMP(s) will be reviewed as described in Sections 1.7 and 1.8.

5. DOCUMENTS AND RECORDS

All QAPPs submitted to Region 6 for approval will be reviewed by the program office administering the work and will be approved or disapproved as stipulated in section 2.3 of this QMP and the applicable Division QMP. All EPA Region 6 field personnel shall follow procedures presented in the EPA Region 6 QAFAP *Standard Operating Procedure (SOP) for Field Documentation* (Number: R6PROC-005-R0, December 1, 2015) when creating, handling, and managing field documentation. All EPA Region 6's Field Activities Quality System Procedures are available at the URL http://region6a.epa.gov/intranet/misc/r6qafap.html.

For documents related to field/inspection activities, EPA Region 6 has implemented Document Control SOP that shall be followed (URL http://region6a.epa.gov/intranet/misc/r6fog/R6SOP-002-R0_Final_Document%20Control_Effective_12-01-2015.pdf).

For records derived from field/inspection activities, EPA Region 6 has implemented Records Management SOP that shall be followed (URL http://region6a.epa.gov/intranet/misc/r6fog/R6SOP-003-R0_Final_Records%20Management_Effective_12-01-2015.pdf).

5.1 Documentation and Procedure for Review of Quality Plans

The process used to review quality plans below is provided as specific guidance for QMPs and as general guidance for QAPPs, to be defined specifically in each Divisional QMP.

5.1.1 QMP Review and Approval Process:

- EPA Requirements for Quality Management Plans (EPA QA/R-2) will be used as the standard for reviewing submitted plans from external sources, and Chapter 3 of the EPA Quality Manual for Environmental Programs, CIO 2105-P-01-0, will be used for internal QMPs.
- All QMPs submitted to the Region will be reviewed for final approved or disapproved status by the RQAM or designee, who is the final approval authority for QMPs.
- QMPs received by program office staff shall be expeditiously forwarded to the RQAM to allow for a timely review, along with any appropriate comments.
- Each Divisional QMP specifies the process used for submission and forwarding of QMPs to the RQAM.
- Any QMP that is disapproved by the RQAM will be returned to the submitter for further action along with an explanation for the disapproval (please refer to Section 1.8).

- Approved QMPs will be filed and maintained by the RQAM within QTRAK system.

5.1.2 QAPP Review and Approval Process:

- Each Region 6 Division or Office will review or approve a QAPP will address the review and approval process specifically in its respective Divisional or Office QMP. This document will address only minimum requirements that assure a level of consistency within Region 6.
- The review of external QAPPs will be conducted using EPA Requirements for QAPPs (EPA QA/R-5), current version or replacement document as detailed at the EPA Quality System Document (URL is http://www.epa.gov/quality/qa_docs.html) as a standard and Chapter 5 of the EPA Quality Manual for Environmental Programs, CIO 2105-P-01-0, will be used for internal QAPPs.
- Additional guidance documents regarding QAPPs both in general and for specific types of QAPPs are also available at the URL http://www.epa.gov/quality/qa_docs.html.
- The applicable approved QMP should be used by the QAPP reviewer for the program and organizational process specific guidance.
- Approved QAPPs will be maintained in the project files of the approving programmatic office.
- The RQAM and each DQAO will have unrestricted access to all QAPPs. No QAPP can be approved until the applicable QMP has been finally approved.
- Each QAPP shall cite the QMP that it falls under either in the QAPP or within the QTRAK system
  (URL is http://b0606gdapk004.aa.ad.epa.gov/apex/f?p=qtrak)
- The reviewer will assure that the preparer of the QAPP has addressed all appropriate programmatic and legal requirements for the generation and management of the data and information.
- These requirements include, but are not limited to, the generation, use, and management of sensitive information (including Confidential Business Information and the Freedom of Information Act).
- The Records Management Policy and Guidance (see Sec. 5.3, Records Maintenance) shall be followed to determine these requirements.
- The reviewer will also assure that the QAPP contains appropriate requirements for records management and field documentation.

Field documentation (including chain of custody) will also adhere to the EPA Region 6 QAFAP *Standard Operating Procedure (SOP) for Field Documentation* (Number: R6PROC-005-R0, December 1, 2015) and the Standard Operating Procedure (SOP) for Records Management

(Number: R6PROC-003-RO, December 1, 2015). Record management of confidential records will be managed and follow custody procedures under the specific program.

5.2. Tracking of Quality Plans

A status record of all QMPs and QAPPs will be maintained on the Region's QTRAK Database (please see Section 6, Use of Computer Hardware and Software). The RQAM and the DQAOs will monitor QTRAK to insure that all QMPs and QAPPs are current. Automatic responses will be sent out from QTRAK notifying DQAOs, Project Officers and reviewers that quality plans will expire within 60 days. Should one of these documents become outdated, the RQAM, the DQAO or the designee shall determine the status of the plan, and initiate appropriate action, in addition inform the appropriate Project Officer of the QTRAK number for QAPPs or applicable QMP upon request. Note: The RQAM is responsible to maintain the Region 6 Divisional QMPs (official current copies) in the Region 6's QAFAP document controlled site: http://region6a.epa.gov/intranet/misc/r6qafap.html

5.3. Record Maintenance

The responsibility for Regional Records Management is within the Management Division in the Enterprise Operation and Support Branch, and this branch is the organizational location of the Regional Records Liaison. All QA documents or copies thereof, which are sent to, generated by and/or sent from the RQAM, DQAOs or QA Coordinator will be filed after action in their working files or in a central file room. The records will be maintained under the supervision of a records clerk. Records Management Policy and Guidance as well as Statutes and Laws, can be found at the EPA Records website by using the URL http://www.epa.gov/records/.

With regards to divisional QMPs and QAPPs, status records will be maintained on the Region's QTRAK Database. The RQAM and the DQAOs will monitor QTRAK to insure that all QMPs and QAPPs are current. The RQAM is responsible to maintain the Region 6 Divisional QMPs.

Information regarding retention and disposition schedules are also available at the same URL site. The records clerk will take special care to preserve the **integrity** of sensitive records. This special care includes such precautions as locking these in the absence of the records clerk. If sensitive documents are to be used at a workstation, due care will be used there too, in order to maintain the integrity of the data. QMPs shall be maintained by the QA staff in the RQAM's working files while they are current, and upon expiration or replacement shall be transferred to central files.

6. COMPUTER HARDWARE AND SOFTWARE

6.1. Policy

It is a Region 6 QA management objective that data collected, analyzed, processed and/or maintained on all **Information Technology** (IT) systems, in support of environmental studies, be accurate and of sufficient integrity to support effective environmental management.

In order to ensure the effective and efficient use of the Regional IT systems, including hardware and software system design, development, implementation and maintenance, Region 6 will follow the EPA Information Resource Management (IRM) Policy developed by the OEI. These EPA policies can be accessed at its index URL, http://intranet.epa.gov/oei/imitpolicy/index.htm.

6.2 Computer Hardware and Software Requirements

EPA's Office of Environmental Information (OEI) and the National Technology Services Division (NTSD) are responsible for managing the hardware, software and communications components that form the foundation of the Agency's information technology. NTSD has established the hardware and software standards with which the Region must conform. Region 6 managers and staff will observe all hardware and software standards as detailed in the NTSD Directives System at http://basin.rtpnc.epa.gov/ntsd/directives.nsf. This directive system is applicable to the personal computer (PC) platform, local area network and server platforms, open systems platforms, Agency electronic mail service, IBM Compatible Mainframe Platform and Supercomputer Platform.

Specifically, OEI's Information Resource Management Branch (IRMB) will be responsible for assessing significant changes in the Agency's hardware and software policy to determine any impact on the Region. In the event changes are required, management from the Region's Enterprise, Technology & Architecture Section, along with OEI's IRMB, will work with regional management to plan and implement appropriate modifications. When software/hardware changes are necessary, the follow must be followed and upheld with IRM authority/approval:

- All hardware and software shall meet EPA's IRM Hardware and Software Standards of the OEI.
- All software systems shall be developed and designed according to the EPA System and Development Guidance of the OEI.
- All software systems shall be operated and maintained according to EPA Operation and Maintenance Manual from the OEI.
- For integrity of computer-resident data in stand-alone PC systems, the laboratories or offices, which use systems for environmental effects studies, shall follow the EPA Good Automated Laboratory Practices guidelines from the OEI.

Region 6's electronic data are stored in two locations: the region's local area network (LAN), and recently, Microsoft Cloud (e.g. SharePoint and/or OneDrive). The LAN is required to be backed-up incrementally Monday through Thursday, and fully backed-up on Friday evenings. One backup is conducted remotely from the Office of Research and Development computer center and another locally from Region 6's computer center. Backups are stored offsite in a fire-proof media safe, located at Region 6's Addison Facility. The Region 6 LAN data backup procedures are defined in Region 6 LAN (R6LAN) Information System Contingence Plan, (ISCP) dated 08 February 2018, and can be found in the R6 Information Security SharePoint site, under R6INFOSEC Procedures and Plans. Contact the Region 6 Information Security Officer for site access.

6.3 QTRAK

QTRAK is a computer program that contains database information on QMPs and QAPPs for the Program Managers, Project Officers and the QA Staff for tracking, planning and assessment of the status of Regional QMPs and the associated QAPPs (URL is http://b0606gdapk004.aa.ad.epa.gov/apex/f?p=qtrak).

QTRAK has been developed as an Oracle database. The QTRAK database contains a complete listing of the Region 6 QMPs and their associated QAPPs required by the Agency, current status of the plans, name of the State agencies involved, approval date of the plans, names of the Project Officer and the reviewer of the plans. QTRAK is available to all Region 6 personnel for read access only. Data can be entered into the system only by the RQAM or by the QTRAK system administrators.

6.4 Data Management

To take full advantage of the Region's growing technological and data resources, there needs to be an increased emphasis on improving compatibility of data among different systems. For consistent definition of data and to facilitate cross-media use of data, all data produced or collected by the computers shall be managed as specified in the Agency IRM Policy Manual. The Agency is in the process of developing Agency-wide **data standards**, in the Agency Catalog of Data Policies and Standards. This catalog will summarize Federal data policies and standards which are the definitive list of data standards that Agency personnel and contractors shall meet when developing **information systems**.

Region 6's electronic files are stored in two locations: the region's local area network (LAN) and Microsoft Cloud (e.g. SharePoint and/or OneDrive). The LAN is required to be backed-up incrementally Monday through Thursday, and fully backed-up starting on Friday evenings. One backup is conducted remotely from the Office of Research and Development computer center

and another locally from Region 6's computer center. Backups are stored offsite in a fire-proof media safe, located at Region 6's Addison Facility.

Region 6 generates field and laboratory data from sampling and measurement activities. The data that is in electronic format shall be stored in various controlled systems, centered on the programs they were generated in (e.g. Superfund Database Management System(SDMS), Laboratory Information Management System(LIMS)). Field Programs without database management system, shall burn the unaltered data/images to a write-only CD/DVD and stored in the Region 6 Records Center after the investigation/action is completed. All metadata with the file shall also be preserved and unaltered during custody, transferring and storing of files. The processes for ensuring this process are described in Region 6 Field Operation Guidelines SOP "R6PROC-004-R0, Management of Sampling and Environmental Data."

6.5 Information Security

It is important that the Region's information resources are protected from potential loss and misuse from a variety of accidental and deliberate causes which can take the form of destruction, disclosure, alteration, delay or undesired manipulation.

For a comprehensive, Region-wide security program to safeguard the Region's information resources, all information resources shall be safeguarded as specified in the Agency's

Interim Agency Network Security Policy

http://intranet.epa.gov/oei/imitpolicy/qic/ciopolicy/CIO-2150-3.pdf

6.6 Documents

For proper implementation and maintenance of the IT system, the appropriate Divisions shall include in their QMPs:

6.6.1 A written description of the computer system(s) hardware and written operating procedures for routine maintenance operations;

6.6.2 A written document which contains detailed description of the software in use, including the listing of all algorithms or formulas used for data generation, processing and assessment, clear guidelines for data acceptance criteria, criteria for **data validation**/invalidation, data deletion/addition, and data correction; and

6.6.3 SOPs which describe the routine operation, maintenance and testing, to ensure that both the hardware and software is accurately performing the intended functions. These documents shall be readily available in the areas where these procedures will be performed. Published literature or vendor documentation may be used as a supplement to software documentation if properly referenced

therein. All deviations from the operational instructions for data collection systems shall be authorized by the designated responsible person. Changes in any part of the operating procedures shall be properly authorized, reviewed and accepted in writing by the designated responsible person. The SOPs can be found in the R6 Information Security SharePoint site, under R6INFOSEC Procedures and Plans.

6.7 Personnel

Personnel involved in computer data collection systems, hardware and software shall:

6.7.1 have adequate education, training and experience to perform the assigned system functions;

6.7.2 have a current summary of their training, experience and job description, including information relevant to system design and operation maintained at the facility; and

6.7.3 be of sufficient number for timely and proper conduct of the study, including timely and proper operation of the automated data collection system(s).

7. PLANNING

Due to the fact that Region 6 has a decentralized QA system, the RQAM is not involved in the QAPP/DQO planning process or **data quality assessment**, except in the capacity of training, MSRs, QSAs and other assessments. The planning process used for projects involving **environmental measurement** are outlined in the Region 6 Division QMPs, which adhere to the requirements of Chapter 3 of the EPA Quality Manual for Environmental Programs, CIO 2105-P-01-0. The RQAM utilizes a work plan showing planned actions on a fiscal year basis as his/her primary planning document (discussed further in paragraph 8.3).

For the collection of environmental information and data, Region 6 endorses the use of **Data Quality Objectives (DQOs)** as the primary systematic planning tool. DQOs and the **Data Quality Objectives Process** are described in in the manual *Guidance on Systematic Planning using the Data Quality Objectives Process (QA/G4), EPA/240/B-06/001, February 2006*. The DQO process has been a very effective tool when used with the **graded approach**.

The seven steps of the DQO process allows the project planner to focus on the goals of the project and the quality needed to achieve those goals. This process includes the identification of the project schedule and milestones that are used to ensure that the schedule is met. The needed resources are identified with a focus on the limitations that resources impose on projects. Also, the process will identify how, when, and where the data will be obtained. Data can be obtained as part of this project (primary data) or can come from existing sources (**secondary data**). The project planner can then identify any constraints on data collection and limitations on the use of the data.

The primary aim of any systematic planning process (including the DQO process) is the identification of the type, quantity, and quality of the data to be collected that will support the objectives of the project. Once the type and quantity of the data are determined, the project planner can specify the performance criteria needed for measuring the quality. These performance criteria are used to identify the specific QA and QC activities that will be used to access the quality performance criteria. These QA and QC activities include such activities as **data verification** and **validation** and the limitations on project specific **data quality indicators**.

The DQO process will also guide the planner in the determination of how the acquired data will be analyzed, evaluated, and assessed against the intended use of the data and the quality performance criteria.

7.1 Routine Planning Process

During the 4th quarter of each fiscal year, the QA Forum (please see section 10) shall make recommendations to the RQAM based on its customer feedback. Since the QA Forum will meet

with the RQAM on an as needed basis, to provide timely customer feedback, these customer needs will be obtained routinely.

7.2 Urgent Customer Needs

On a short-term basis, if the QA Forum or any customer becomes aware of urgent QA needs not previously planned for, they will recommend to the ARA for Management that this urgent need be addressed.

7.3 Resource Allocation

The resources necessary to implement the QA program are described in the QA MOU (Appendix B) that is initiated by the ARA for Management and negotiated with the other Divisions and Offices of Region 6.

8. IMPLEMENTATION OF WORK PROCESSES

This plan exists to ensure environmental data are of known and acceptable quality. To achieve that end, this QMP documents the delegation of the QA responsibilities to the individual Divisions and Offices of Region 6.

8.1 Division QMP

Each Division's QMP addresses the process for implementing environmental data operations according to the approved planning documents. The Division's QMP describes:

- appropriate procedures to ensure that work is performed according to plan;
- the level of management oversight and inspection to be provided that will be commensurate with the importance of the particular project and the intended use of the project results; and
- how procedures for appropriate routine, standardized, special, or critical operations are developed and implemented, including the policies and procedures that address, but are not limited to:
  - identification of operations needing procedures;
  - preparation of procedures, including form content and applicability; and
  - review and approval of procedures.

8.2 Tracking of Implementation

All of these activities will be tracked by the RQAM and reported to Region 6 senior management. Significant slippage of milestones or inability to accomplish planned activities will be addressed in the QA Forum's update to the RQAM.

8.3 Quality Assurance Annual Report and Work Plan

The Quality Assurance Annual Report and Work Plan (QAARWP) has two parts, the annual report of accomplishments for the previous fiscal year and the proposed work plan for the new fiscal year. The OEI will supply the format for the QAARWP each year, normally in the last quarter of the fiscal year, to all EPA Organizations. The preparation and submission process is generally defined in Chapter 4 of the EPA Quality Manual for Environmental Programs, CIO 2105-P-01-0 located at http://www.epa.gov/QUALITY/qaarwps.html. This report and plan will be developed by each Division and Office, collaboratively by the RQAM, DQAOs and the QA Forum.

9. ASSESSMENT AND RESPONSE

In order to ensure that QA plans are being implemented and are adequate for their intended purpose, technical and managerial assessments at both the program level and the project level are necessary. These assessments represent a mechanism of oversight for QA activities used by the Regional Office. The assessment of environmental data operations are generally conducted by contractors, the Regional laboratory or are delegated to State, Tribal and local government authorities. The assessments of these entities are accomplished if essential funding for travel is available.

The OEI's Quality Staff has defined in EPA Quality Manual for Environmental Programs CIO 2105-P-01-0 seven types of tools that are used in assessing the quality of an organization's programs:

- MSRs or QSAs,
- surveillance,
- audits,
- **performance evaluations** (PE) or proficiency tests (PT),
- peer reviews and technical reviews,
- readiness reviews, and
- data quality assessments and other types of data quality reviews.

These assessments should be performed on the Regional Office and on field groups providing environmental data to the Regional Office, i.e., on State, Tribal, local and contracted entities.

The RQAM or designee will review plans for assessments or use of assessment tools in the Regional offices or laboratory. The purpose of this review is to ensure that personnel conducting the assessments are adequately trained and have experience in doing the work being assessed. Also, the RQAM will ensure that personnel conducting the assessments have no direct involvement in the work being assessed and have no real or perceived conflicts of interest. All personnel involved these assessments shall conduct themselves so as to provide independent and objective reviews of the programs being assessed. Any personnel not meeting these requirements will be replaced on the assessment teams.

The RQAM or designee will also ensure that personnel conducting assessments have sufficient authority to access to managers and staff of the programs being assessed. This authority will include access to all necessary documents and records. The RQAM will also ensure that these personnel have the necessary permissions or clearances to access restricted information needed in the assessment.

Disputes can occur during assessments and associated responses. These disputes can include issues caused by restricted access to information and records. When these disputes arise the

lead for the assessment will refer the issue to the RQAM for resolution. If the issue cannot be resolved by the RQAM or if RQAM is part of the dispute, the dispute is referred to ARA for Management. The ARA for Management has the option of resolving the issue, referring the issue to Regional senior management, or referring the issue to an independent third party. For assessments limited to Region 6 (internal assessments) decisions made by the ARA for Management, or decisions made by Regional senior management or independent parties, will be considered final. If the assessment is being conducted by organizations or individuals external to Region 6, the ARA for Management can determine the appropriate course of action to resolve the dispute.

9.1 MSR or QSA

A MSR or QSA is an independent assessment of management, the management process and structure established by a group to carry out QA responsibilities (the EPA's MSR and QSA processes are defined in Guidance on Assessing Quality Systems EPA QA/G-3). The MSR or QSA includes: review of the adequacy, use and effectiveness of guidance provided by Headquarters to the Regions as well as guidance provided to the States, Tribal Grantees, or municipalities, and contractors; the process for preparing important QA documentation; relationship among participants in the program activity under review; the knowledge base of the Regional, State, Tribal, or local government and contractor staff about QA/QC processes and responsibilities; QA process implementation by States, Tribal Grantees, municipalities and contractors; and Regional and State oversight of QA activities, etc.

Specific QA elements addressed in an MSR or QSA include, for example:

- Assessment of the effectiveness of the Quality System or **Quality Management**;
- Procedures for developing Data Quality Objectives (DQOs) and assessing the results (Data Quality Assessments);
- Procedures for developing and approving QAPPs and the quality of existing QAPP guidance;
- Procedures for developing and approving QMPs;
- Procedures and schedules for conducting audits;
- Tracking system for assuring that the QA program is operating and that corrective actions disclosed by audits have been taken;
- Providing a definite level of financial resources and personnel devoted to implementing the QA program;
- The degree of management support;
- Responsibilities and authorities of the various line managers and the QA Officer for carrying out the QA program; and
- Use of Quality Indicators to monitor Quality Improvement.

Typically, an Assessment Team will be comprised of a Team Leader and one or more members from the Regional QA Staff. The team may be augmented from time to time with members drawn from a variety of possible sources, such as Program Divisions, ESB, Headquarters, other Regional Offices, State offices, Tribal organizations and ORD Laboratories. Selection and composition will depend upon the domain and scope of the assessment. However, each team member will be fully qualified in the area he is to assess. If a contractor is part of any of the assessment activities as discussed in the QMP, then any review and assessment of the contractor or the contractor's work products will be conducted in coordination with the agency's CO and any COR.

The schedule for conducting MSRs or QSAs will be developed with the concurrence of the manager whose program is to be reviewed and is then included in the annual QA work plan. If necessary, MSRs or QSAs can be conducted on an unannounced basis. The RQAM is to schedule MSRs or QSAs so that each Division or Program will be reviewed at least every 5 years. More frequent reviews and follow-up reviews will be conducted if findings were significant or corrective actions were ineffective.

Members of an MSR or QSA Team will be selected by the RQAM, or designee, from the QA Staff members, other Region 6 programmatic staff and state/tribal staff. All members of an MSR or QSA Team shall have completed the Quality Systems Assessment Workshop course conducted by either OEI's Quality Staff or the Region 6 QA Staff.

The Team Leader shall discuss the initial impressions and all preliminary findings from the MSR or QSA with the reviewed managers. This briefing will allow for closure of the objectives set forth in the entrance briefing. Following the MSR or QSA, the Team Leader, in conjunction with Team Members, will prepare a written report, which will be submitted, to the reviewed manager through the appropriate Division Directors. The reviewed manager will prepare a written statement of corrective actions to each of the findings and will return this response to the RQAM within the time specified in the findings report.

Upon receipt of response, the MSR or QSA Team Leader will evaluate corrective actions for adequacy and for timeliness of implementation. If deemed inadequate, the Region 6 QA Manager will be notified to initiate appropriate action.

9.2 Routine Surveillance and Assessment Process of Funding Recommendations

The primary assessment activity performed by the RQAM and DQAOs is the continual **surveillance** of the Regional, Divisional and external Quality Systems as a routine part of review of financial award documents. Each action initiated to transfer funds to a recipient is reviewed to assure the integrity of the internal and external organization's Quality System.

The process of reviewing all grants, cooperative agreements or interagency agreements in the IGMS requires the Project Officer to initiate and attach a locally developed QA Certification form (copy at Appendix C) to each of the FR documents. This QA Certification notes the approval status of the prospective recipient's QMP and approval status of the applicable existing QAPP(s). If the approval period of the QMP or QAPP is expired, the DQAO and RQAM are to disapprove the FR thus halting the possible award of funds. In the event the QMP or QAPP has less than 30 days remaining before expiration and no updated document has been received, the FR shall be disapproved. If a revised document has been received and is still under review, the FR may be approved at the discretion of the DQAO and RQAM.

If a QAPP or QAPPs will be deliverables under the grant or cooperative agreement funding, a QAPP Deliverable QTRAK number will be requested by the Project Officer and included in the appropriate place on the QA Certification form. In the event a Region 6 organizational element has an electronic tracking system for deliverables that includes QAPPs, the requirement to obtain QTRAK numbers for QAPP Deliverables is waived by approval of the DQAO and RQAM. This is done to assure the effectiveness of a recipient's QA System.

The FR contains the questions a Project Officer shall respond to regarding a grantee's QA documentation status, applicable requirements, and whether or not Geospatial Information is part of the grant. This also assures that the various programmatic areas of the Regional Office have effective QA Systems. Initial approval is by the Division QA Officer, with final approval by the RQAM, assuring that particular elements of the Regional QA System are correctly working. These assessments can and occasionally do preclude the award of grant monies assures the grantee, EPA Project Officer and supporting QA staff have all done their parts to assure effectively implement their Quality Systems.

9.3 QA Technical Systems Audit (TSA)

The RQAM does not conduct TSAs. Field TSAs are conducted by the Program Division and the work processes covered in their respective QMP. Laboratory TSAs are conducted by the Houston ESB and the detailed work processes are covered in the ESB QMP. TSAs will be planned and conducted in accordance with applicable EPA guidance and/or requirements.

A TSA focuses on the given system for environmental data operations and its associated QC system. The primary purpose is to assess the adequacy of sampling, measurement, analysis, **calibration** and similar procedures used to generate the data. TSAs that deal with sampling and measurements are field TSAs.

9.4. Laboratory Performance Evaluations or Proficiency Testing

The ESB QMP addresses Laboratory **Performance Evaluations** (PE) or **Proficiency Testing** (PT) for the Region.

9.5 Peer and Technical Reviews

Peer review refers to the use of independent technical experts who are not associated with the generation of an Agency product critically evaluating the technical aspect of that product. The output of the peer review process is an independent, objective judgment on the technical merit of the product. Peer review can and should encompass a broad range of issues including, but not limited to, statistical design, data collection, monitoring, research and development, data analysis, risk assessment, technical and regulatory support documents, economic analysis, and **remediation** options. All QA documents such as QMPs and QAPPs submitted to the Region for approval or generated within the Regional program offices will comply with the Regional Administrator's policy (Region 6 Standard Operating Procedures for Peer Review) on peer and **technical review**. The Region 6 peer review coordinator is the Regional Science Liaison located within the immediate office of the Regional Administrator, 6RA. Each of the Region 6 Division QMPs will outline who and/or what position in the Division coordinates peer review. Division QMPs will define the process the Division will use to determine which documents need to undergo a peer review. Division QMPs will describe their peer review system and what that system entails. Further, each document contains a statement that it was (or was not) peer and/or technically reviewed and by whom.

9.6 Readiness Reviews

The RQAM does not perform **readiness reviews**. It is the responsibility of the program office administering the work to ensure that an approved QAPP and an approved QMP are in place. Oversight will be done by RQAM during MSRs or QSAs.

9.7 Data Quality Reviews

An important part of data collection efforts is the subsequent review of the data to determine if the data are usable for their intended purpose. The intended use of the data is determined by the project manager through a systematic planning process, such as the Data Quality Objectives process (section 2.2). The project manager will determine the type, quantity and quality of data needed for the project, then determine the necessary review steps for that data. These review processes are to be described in the QAPPs or equivalent project planning documents.

The Regional Laboratory routinely reviews and validates data generated both in house and by contracted laboratories. Those processes are defined in the ESB QMP. Other Regional staff,

contractors, and grantees may also conduct **data review** activities. These functions are guided by general SOPs and programmatic policies which are designed to permit structured and consistent data review.

All Regional data collection efforts, internal or external, will require that a portion of the resources be committed to performing data reviews, including **data verification**, data validation, and **data usability assessments**/reviews. Each Division QMP describes the methods by which data quality reviews are conducted and utilized.

9.8 QAFAP Internal Audits

Field groups shall periodically conduct internal audits to verify that their operations comply with the EPA Quality Assurance Field Activity Procedure (QAFAP). The personnel performing the audits shall be qualified and independent from the functions being audited, whenever possible. The roles and responsibilities of management and staff for planning, implementing, and reporting of internal audit findings, including the need for corrective actions, are described in the Region 6 Standard Operating Procedure (SOP) for Internal Audits and Corrective Actions (R6PROC-009-R0).

9.9 Internal Corrective Actions

A corrective action shall be initiated to address any nonconformance related to internal audits, or other assessments. Once the need for a corrective action has been identified, anyone within the organization can initiate a corrective action request through the RQAM, or the Field Quality Manager (FQM), if the nonconformance is field related.

After the audit has been completed, the RQAM AND/OR FQM, in consultation with management, shall initiate the following corrective action process to address all nonconformances identified during the audit, as appropriate. Corrective actions shall be commensurate with the magnitude and the risk of the finding. The RQAM and/or FQM, in consultation with affected management, shall designate a Corrective Action Team (CAT) to assess the issues surrounding the nonconformance. The CAT shall investigate the issue and determine the root cause of the problem. A summary of the issue and root cause can be included on the Corrective Action Form (R6FORM-09-R0).

Once the root cause of the problem has been identified, the CAT shall determine how to correct the problem and prevent it from recurring. A summary of the proposed action to resolve the root cause of the nonconformance shall be documented on the Corrective Action Form. The CAT shall present the proposed action to affected management for approval. Upon approval of the proposed action, if any policies or procedures require updating, the RQAM and/or FQM shall assure document updates are conducted in accordance with Region 6 Standard Operating Procedure for Document Control. The RQAM and/or FQM shall notify all affected personnel either verbally or in writing (email or memo) of any changes that result from the corrective action process. Management is responsible for ensuring all

affected personnel are implementing any changes to the field operations management system resulting from the corrective actions. This may be accomplished by direct communication with staff, review of project records, and training. The RQAM and/or FQM shall formally monitor the effectiveness of corrective actions by conducting a follow-up review. The time frame for reviews shall be determined by the RQAM and/or FQM and shall be based on the magnitude and risk of the problem. Multiple follow-ups may be conducted to assure the effectiveness of the corrective action. If the RQAM and/or FQM determines that the corrective action is not effective, based on the magnitude and risk of the problem, the CAT or management may be tasked with re-evaluating the problem and proposing another solution. In some situations, management may need to reassign members of the CAT due to expertise with a specific issue or to bring new perspective to a problem. Once the problem has been adequately addressed, the RQAM and/or FQM shall close-out the corrective action.

10. QUALITY IMPROVEMENT

10.1 RQAM Responsibilities

The process of continuous quality improvement leads to the development of a better and more responsive quality system. Toward that end, the QA Staff will perform the following:

10.1.1 RQAM is responsible for monitoring the QTRAK system for tracking the current status of QMPs and QAPPs.

10.1.2 RQAM will conduct MSRs or QSAs (see Section 9.1) that will require written comments to the findings and where findings were significant, and take appropriate follow-up action.

10.1.3 Region QA Staff will conduct training in the area of the preparation and the review of QAPPs and QMPs and in topics related to QA (See Section 3).

10.1.4 RQAM will hold periodic meetings, at least annually, with divisional program offices on QA related matters of interest.

10.1.5 QA Staff will participate in monthly conference calls with the OEI's Quality Staff, other Headquarters staff, and/or the staffs from the other Regions, when conducted as scheduled.

10.1.6 QA Staff will maintain a close liaison with the various State/Tribal/Municipal QA officers and laboratory staffs.

10.1.7 QA Staff will provide technical assistance to the regulated community.

10.2 QA Forum Responsibilities

To effectively maintain customer alignment of the QA process in Region 6, an advisory group, known as the QA Forum, has been established to accomplish the following tasks:

10.2.1 Solicit feedback from customers continually improve the QA process in Region 6;

10.2.2 Identify areas of the Region 6 QMP that need improvement or revision; and

10.2.3 Provide feedback to RQAM and QA Staff on all aspects of the QA Program.

The QA Forum will meet as needed and provide feedback, in the form of recommendations or findings, to the ARA for Management.

10.3 QA Forum Membership

The Region 6 QA Forum will be an interdivisional organization with one member from each of the following Divisions or Offices plus the DQAOs and the Regional IQG Coordinator:

- Compliance Assurance and Enforcement Division,
- Superfund Division,
- Management Division (Dallas),
- Management Division, Region 6 Houston Laboratory,
- Office of Environmental Justice, International and Tribal Affairs,
- Multimedia Division, and
- Water Division.

Members should be either supervisors or senior technical staff members appointed by the respective Division Director. Members serve at the discretion of the respective Division or Office Director (as applicable). A chairperson for the QA Forum will be elected each January to serve for a one-year term. Election will be by a simple majority of the members. The RQAM, Regional IQG Coordinator and DQAO's are not eligible to be selected as chairperson. A vacant chairperson position will be filled at the next meeting of the QA Forum. The member from the Office of Regional Counsel has the option to attend meetings regularly, or attend meetings where reasonable advance notice has been provided that support on legal matters will be needed.

The RQAM, who serves as the technical advisor to the QA Forum, is responsible for notification to respective Division Directors of a need for a QA Forum member from that Division.

Regular meetings of the QA Forum will occur as determined by RQAM or QA Forum Chairperson. The Houston Laboratory member will normally participate through a conference call.

Appendix A - Terms and Definitions

APPENDIX A
TERMS AND DEFINITION

Accuracy - the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations; a data quality indicator. Examples of QC measures for accuracy include proficiency testing samples, matrix spikes, laboratory control samples (LCSs), and equipment blanks.[6]

Activity - an all-inclusive term describing a specific set of operations or related tasks to be performed, either serially or in parallel (e.g., research and development, field sampling, analytical operations, equipment fabrication), that in total result in a product or service.[2]

Approved - the documented determination that the proposed quality document is suitable for the intended purpose and meets the requirements specified in the applicable Quality Standard.[5]

Assessment - the evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management review, peer review, inspection, or surveillance.[5]

Audit (quality) - a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.[1]

Calibration - comparison of a measurement standard, instrument, or item with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustments.[1]

Certification - the process of testing and evaluation against specifications designed to document, verify, and recognize the competence of a person, organization, or other entity to perform a function or service, usually for a specified time.[6]

Characteristic - any property or attribute of a datum, item, process, or service that is distinct, describable, and/or measurable.[6]

Comparability - the degree to which different methods or data agree or can be represented as similar. Comparability describes the confidence that two data sets can contribute to a common analysis and interpolation. [6]

Completeness - a measure of the amount of valid data obtained from a measurement system compared with the amount that was expected to be obtained under correct, normal conditions.[6]

Conformance - an affirmative indication or judgment that a product or service has met the requirements of the relevant specification, contract, or regulation; also, the state of meeting the requirements. [6]

Data - a collection of facts and estimates from which conclusions may be drawn. [3]

Data Quality Assessment - a statistical and scientific evaluation of the data set to determine the validity and performance of the data collection design and statistical test, and to determine the adequacy of the data set for its intended use. [6]

Data Quality Objectives (DQOs) - qualitative and quantitative statements derived from the DQO process that clarify study objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions. [1]

Data Quality Objectives Process - a systematic planning tool to facilitate the planning of environmental data collection activities. Data quality objectives are the qualitative and quantitative outputs from the DQO Process. See Systematic planning process. [1]

Data Review - the process of examining and/or evaluating data to varying levels of detail and specificity by a variety of personnel who have different responsibilities within the data management process. It includes verification, validation, and usability assessment. [6]

Data Standard - documented consensus-based agreement on the format and definition of common data. [3]

Data Validation - see Validation (Information)

Data Verification - see Verification (Information)

Decision-Maker - project manager, stakeholder, regulator, etc., who has specific interests in the outcome of site-related activities and will use the collected data to make decisions regarding the ultimate disposition of the site or whether to proceed to the next study phase. [6]

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the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality. [3]

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Remediation - the process of reducing the concentration of a contaminant (or contaminants) in air, water, or soil media to a level that poses an acceptable risk to human health. [2]

Representativeness - a measure of the degree to which data accurately and precisely represent a characteristic of a population, a parameter variation at a sampling point, a process condition, or an environmental condition. [6]

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Shall - when used in a sentence, a term denoting a requirement that has to be met. [6]

Standard - an accepted, consensus-based specification which defines systems, processes, methodologies, or practices. It provides a basis for assuring consistent and acceptable minimum levels of quality, performance, safety, and reliability. Standards usually are included in or accompany procedures. [5]

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Systematic planning process - Systematic planning is a process that is based on the scientific method and includes concepts such as objectivity of approach and acceptability of results. Systematic planning is based on a common sense, graded approach to ensure that the level of detail in planning is commensurate with the importance and intended use of the work and the available resources. This framework promotes communication among all organizations and individuals involved in an environmental program. Through a systematic planning process, a team can develop acceptance or performance criteria for the quality of the data collected and for the quality of the decision. [6]

Technical Review - a documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are

independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied. [1]

Technical Systems Audit (TSA) - a thorough, systematic, on-site, qualitative audit of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system. [1]

Traceability - The ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project. [6]

Usability Assessment - the evaluation of data based upon the results of data validation and verification for the decision(s) being made. Reviewers assess whether the process execution and resulting data meet quality objectives based on the criteria given in the QAPP. [5]

Validation (Information) - the confirmation by examination and provision of objective evidence that the particular requirement for which the information is intended are fulfilled; the process of determining whether the specifications were appropriate and that the verified results will meet the data user's needs. [5]

Verification (Information) - the confirmation by examination and provision of objective evidence that validated information fulfills specified requirements; the process of checking whether the information met the project's specifications. [5]

Work - the process of performing a defined task or activity. [2]

Source of definitions:

1. EPA Quality Manual for Environmental Programs, CIO 2105.0-P-1-01, May 5, 2000.
2. American National Standard, Quality Management Systems for Environmental Information and Technology Programs (E-Standard), ANSI/ASQ E4- 2014.
3. EPA Quality Policy, CIO 2106.0, October 20, 2008.
4. EPA Order, Policy and Program Requirements for The Mandatory Agency-Wide Quality System, CIO 2105.0, May 5, 2000.
5. Quality Standard for Environmental Data Collection, Production and Use by EPA Organizations, CIO 2106-S-01 (Draft Final, 2/22/12).
6. Uniform Federal Policy for Quality Assurance Project Plans (UFP QAPP Manual), March 2005.

Appendix B - Quality Assurance Memorandum of Understanding

Appendix B

Not included in electronic version.

New Version to be added

Appendix C - Quality Assurance Certification Form

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Appendix A - Terms and Definitions

APPENDIX A
TERMS AND DEFINITION

Accuracy - the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations; a data quality indicator. Examples of QC measures for accuracy include proficiency testing samples, matrix spikes, laboratory control samples (LCSs), and equipment blanks.[6]

Activity - an all-inclusive term describing a specific set of operations or related tasks to be performed, either serially or in parallel (e.g., research and development, field sampling, analytical operations, equipment fabrication), that in total result in a product or service.[2]

Approved - the documented determination that the proposed quality document is suitable for the intended purpose and meets the requirements specified in the applicable Quality Standard.[5]

Assessment - the evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management review, peer review, inspection, or surveillance.[5]

Audit (quality) - a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.[1]

Calibration - comparison of a measurement standard, instrument, or item with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustments.[1]

Certification - the process of testing and evaluation against specifications designed to document, verify, and recognize the competence of a person, organization, or other entity to perform a function or service, usually for a specified time.[6]

Characteristic - any property or attribute of a datum, item, process, or service that is distinct, describable, and/or measurable.[6]

Comparability - the degree to which different methods or data agree or can be represented as similar. Comparability describes the confidence that two data sets can contribute to a common analysis and interpolation. [6]

Completeness - a measure of the amount of valid data obtained from a measurement system compared with the amount that was expected to be obtained under correct, normal conditions.[6]

Conformance - an affirmative indication or judgment that a product or service has met the requirements of the relevant specification, contract, or regulation; also, the state of meeting the requirements. [6]

Data - a collection of facts and estimates from which conclusions may be drawn. [3]

Data Quality Assessment - a statistical and scientific evaluation of the data set to determine the validity and performance of the data collection design and statistical test, and to determine the adequacy of the data set for its intended use. [6]

Data Quality Objectives (DQOs) - qualitative and quantitative statements derived from the DQO process that clarify study objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions. [1]

Data Quality Objectives Process - a systematic planning tool to facilitate the planning of environmental data collection activities. Data quality objectives are the qualitative and quantitative outputs from the DQO Process. See Systematic planning process. [1]

Data Review - the process of examining and/or evaluating data to varying levels of detail and specificity by a variety of personnel who have different responsibilities within the data management process. It includes verification, validation, and usability assessment. [6]

Data Standard - documented consensus-based agreement on the format and definition of common data. [3]

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Data Verification - see Verification (Information)

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independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied. [1]

Technical Systems Audit (TSA) - a thorough, systematic, on-site, qualitative audit of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system. [1]

Traceability - The ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project. [6]

Usability Assessment - the evaluation of data based upon the results of data validation and verification for the decision(s) being made. Reviewers assess whether the process execution and resulting data meet quality objectives based on the criteria given in the QAPP. [5]

Validation (Information) - the confirmation by examination and provision of objective evidence that the particular requirement for which the information is intended are fulfilled; the process of determining whether the specifications were appropriate and that the verified results will meet the data user's needs. [5]

Verification (Information) - the confirmation by examination and provision of objective evidence that validated information fulfills specified requirements; the process of checking whether the information met the project's specifications. [5]

Work - the process of performing a defined task or activity. [2]

Source of definitions:

1. EPA Quality Manual for Environmental Programs, CIO 2105.0-P-1-01, May 5, 2000.
2. American National Standard, Quality Management Systems for Environmental Information and Technology Programs (E-Standard), ANSI/ASQ E4- 2014.
3. EPA Quality Policy, CIO 2106.0, October 20, 2008.
4. EPA Order, Policy and Program Requirements for The Mandatory Agency-Wide Quality System, CIO 2105.0, May 5, 2000.
5. Quality Standard for Environmental Data Collection, Production and Use by EPA Organizations, CIO 2106-S-01 (Draft Final, 2/22/12).
6. Uniform Federal Policy for Quality Assurance Project Plans (UFP QAPP Manual), March 2005.

Appendix B - Quality Assurance Memorandum of Understanding

Quality Assurance Memorandum of Understanding

Between The

Region 6 Management Division (6MD)

And The

Region 6 Water Division (6WQ)
Region 6 Multimedia Division (6MM)
Region 6 Superfund Division (6SF)
Region 6 Compliance Assurance & Enforcement Division (6EN)
Office of External Affairs (6XA)
Office of Regional Counsel (6RC)
Office of Environmental Justice, International and Tribal Affairs (6RA-DA)

I. Introduction

It is both a Regulatory requirement and policy of EPA that all environmental programs conducted by or on behalf of EPA shall establish and implement effective Quality Systems. EPA Order CIO 2105.0, "Policy and Program Requirements for the Mandatory Agency-wide Quality System" establishes policy and program requirements for the preparation and implementation of organizational or programmatic management systems pertaining to quality and contains the minimum requirements for the mandatory agency-wide quality system. Specifically, this Order states;

(1) It is EPA policy that all environmental programs performed by EPA or directly for EPA through EPA-funded extramural agreements shall be supported by individual quality systems that comply fully with the Quality systems for environmental data and technology programs, American National Standard ANSI/ASQ E4- 2014; and

(2) Regional Administrators and senior managers shall:

(a) Ensure that all Regional components and programs comply fully with the requirements of this Order.

(b) Ensure that quality management is an identified activity with associated resources adequate to accomplish its program goals and is implemented as prescribed in the organization's approved QMP.

(c) Ensure that all environmental programs implemented through extramural agreements comply fully with applicable QA and QC requirements.

(d) Ensure that the environmental data from environmental programs delegated to State, local, and Tribal governments are of sufficient quantity and adequate quality for their intended use and are used consistently with such intentions.

(e) Ensure that training is available for State, local, and Tribal governments performing environmental programs for EPA in the fundamental concepts and practices of quality management and QA and QC activities that they may be expected by EPA to perform.

(f) Perform periodic assessments of Regional organizations conducting environmental programs to determine the conformance of their mandatory quality systems to their approved QMPs and the effectiveness of their implementation.

(g) Ensure that deficiencies highlighted in the assessments are appropriately addressed.

(h) Identify QA and QC training needs for all levels of management and staff and provide for this training.

The undersigned enter into this Memorandum of Understanding (MOU) to ensure that Regional resources are used effectively to achieve compliance with the QA/QC requirements imposed by EPA Order CIO 2105.0. This MOU documents the respective Divisional and Office relationships for implementing an effective quality system that meets or exceeds Agency and National Standard requirements.

II. Roles and Responsibilities

Region 6 utilizes a decentralized QA organization. Under the Delegation of Authority outlined in the Region's QMP, the Management Division is the focal point in the Region for Quality Systems policy. The Management Division, in conjunction with the Region's QA Forum, is responsible for developing QA/QC requirements and for overseeing the over-all implementation of the Agency-wide Quality System within the Region. The Assistant Regional Administrator for Management (ARA) is designated as the Region's Senior Management Official for Quality. The Regional Quality Assurance Manager (RQAM) is designated to serve as the central management authority for this program. The RQAM is located in the Management Division and individual Division QA Officers (DQAOs) are located in the Water Quality Division, Compliance Assurance and Enforcement Division, Superfund Division, and the Multimedia Division (hereinafter referred to as the Program Divisions in this MOU). The RQAM in the Management Division shall support the QA needs of the Office of External Affairs, the Office of Environmental Justice, Tribal and International Affairs and the Office of Regional Counsel (hereinafter referred to as supported offices). The Management Division, Environmental

Services Branch in Houston has a Quality Assurance Coordinator that reports to the Chief of the Environmental Services Branch. The organizational location of the RQAM, each DQAO and the ESB QA Coordinator shall be such as to satisfy the independence and organizational reporting requirements contained in paragraph 6.a.(1) of EPA Order CIO 2105.0. The Divisional QAOs will receive QA work assignments related to regional QA activities from their respective program office supervisor. A description of the Region's over-all quality system, as well as delegation of QA responsibilities to individual Divisions is contained in the Region 6 QMP. Specifically, section 1.13 addresses the functions/responsibilities of the RQAM; section 2.1 addresses the functions/responsibilities of the DQAOs; and section 10.2 addresses the functions/responsibilities of the Region's QA Forum. Each Divisional QMP describes their individual quality system and specifically details the roles and responsibilities of staff members (DQAO, Project Officers, Project Managers, Task Order Managers, Work Assignment Managers, Remedial Program Managers, On Scene Coordinators, Contracting Officer Representatives, etc.) to assure implementation of its QA System.

To ensure that the Region fully complies with the Agency's mandatory Quality System requirements the Management Division, Program Divisions and the supported offices mutually agree to the following commitments to accomplish specific components of the Region's quality system:

QA Forum

Section 10.2 of the Region's QMP details the roles and responsibilities of the Region's QA Forum. Each Division has two members, and each supported office has one member. One member is the Divisional QAO (and the ESB QA Coordinator) and the other member should be either a supervisor or senior technical staff member who is appointed by and serves at the discretion of their Division or Office Director. The Forum meets as needed. The Management Division agrees to be lead in scheduling the QA Forum meetings and in the taking and publishing of meeting minutes. The Program Divisions agree to support the Forum through their members and to exercise their role in appointing, reappointing, extending or removing their "at large" members as outlined in section 10.2 of the Regional QMP. During the initial meeting of the QA Forum will establish or re-affirm their internal operating rules for that and following meetings. One additional QA Forum member will be the individual designated as the Region's Information Quality Guidelines Officer, regardless of his/her divisional location. Office of Regional Counsel agrees to provide legal support to the QA Forum at meetings where reasonable advance notice has been provided if such support is needed, or can designate an individual to attend meetings regularly.

Quality Assurance Annual Report and Work Plan (QAARWP)

Chapter 4 of the Agency's Quality Manual, CIO 2105-P-01-0, requires that each Agency organization prepare a QAARWP to report progress made during the previous fiscal year in the implementation of its quality system and quality functions planned for the upcoming fiscal year. The call letter for the QAARWP usually is issued in mid-September with submission required (under the Regional Administrator's signature) by the end of October. The Management Division will be the lead in preparing the QAARWP and the Program Divisions and each supported office agree to provide input to the plan through their QA Forum members to the Management Division in a timely manner. Prior to final submission of the QAARWP to the RA for signature, the proposed QAARWP will be submitted to the QA Forum and individual Division Directors for concurrence.

Revision of the Region 6 QMP

Paragraph 3.2.4 of the "EPA Quality Assurance Manual for Environmental Programs CIO 2105-P-01-0" contains the criteria for when the Region's over-all QMP must be revised/updated. The Management Division, through the RQAM, agrees to take the lead in accomplishing these revisions. The Program Divisions and each supported office agree to support the accomplishment of these revisions through their QA Forum members. Any revision will be processed through the QA Forum and each Division Director for concurrence prior to being submitted to the RA for approval.

Revision of Divisional QMPs

Periodically, a Division's QMP will require revision and in accordance with the Regional QMP, the RQAM is required to review and approve each Divisional QMP. The Program Divisions agree to submit their revised QMPs to the RQAM within 90 calendar days after notification of approval, by Headquarters, of the Regional QMP. When a Program Divisions' revised QMP is submitted to the RQAM, the review will be accomplished within the time frame allowed in the Region's QMP. The Management Division's QMP will address the QA policies and processes of the supported offices and will be revised with assistance from each supported office.

Management System Reviews and Quality System Assessments

One of the tools used by the Agency to determine if the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained is the Management System Review (MSR) or Quality System Assessment (QSA). The Management Division and the program office will be responsible for conducting both internal MSRs or QSAs (of each Program Division and each supported office) and external MSRs or QSAs of State, local, and Tribal organizations that receive financial assistance from the Region. Paragraph 9.1 of the Regional QMP outlines the

procedures for conducting MSRs or QSAs as well as the frequency of the reviews. The Management Division with the participation of the program office will schedule, coordinate all activities, assure that the results are reported, and assure that corrective measures (if required) are completed for each MSR. The Program Divisions and each supported office agree to provide qualified MSR or QSA team members (if requested) for internal or external MSRs or QSAs (each team member must have completed the QA training requirements contained in the Regional QMP).

Technical System Audits

Technical System Audits (TSAs) focus on the given system for environmental data operations. The primary purpose is to assess the adequacy of sampling, measurement, analysis, calibration, and similar procedures used to generate data. TSAs that deal with sampling and measurements are field TSAs. Those that deal with a laboratory's operation, capabilities, and the reliability of data produced are laboratory TSAs. At the request of a Program Division, the Management Division, Environmental Services Branch, will schedule and conduct a laboratory TSA, however, audit team members may be requested from a Program Division. Paragraph 9.3 of the Regional QMP delegates the responsibility for conducting field TSAs to the Program Divisions, and the discussion of how field TSAs are planned, implemented, reported, and the accomplishment of corrective action is contained in the individual Divisional QMPs. The RQAM will determine the adequacy of field TSAs when Divisional QMPs are reviewed, and during MSRs and other audits. All parties agree that a Divisional QAO may seek assistance in conducting a field TSA from the RQAM, other Divisional QAOs, or the Regional Laboratory.

Quality Assurance Training

The EPA Order for QA requires the RA to ensure that QA training is provided to Regional Staff as well as for State, local, and Tribal governments performing environmental programs for the Region. The Management Division, with assistance of the Program Divisions, will coordinate and schedule QA training, arrange for facilities, publish training notices, enroll students, and issue training certificates. The Program Divisions agree to provide the services of their respective DQAO as an instructor for QA courses that the DQAO has been previously qualified to teach. If the QA training involves travel funds to accomplish the training the Program Division will fund the travel of their respective DQAO or acceptable alternate from another Division.

Review of QMPs submitted by Financial Assistance Recipients

QMPs submitted to the Region are required to be submitted to the RQAM. Once received, the RQAM will issue a QTRAK number for the QMP, determine which DQAO should be lead for the review and route it to that DQAO. If the QMP is not media specific (i.e., a multimedia or multi programmatic), the RQAM will coordinate with the respective DQAOs and their supervisors to

determine workload before assignment for review. In accordance with the Regional QMP, the RQAM or designee is the final approval authority for QMPs. Each Program Division agrees that (1) its DQAO will perform the review of assigned QMPs within the time frames outlined in the Regional QMP, (2) the DQAO will provide constructive comments if recommending disapproval, and (3) the DQAO will sign the QMP indicating concurrence or otherwise indicate their concurrence if the recommendation is for approval.

Quality Assurance Tracking System (QTRAK)

QTRAK is a computer program that contains database information on QMPs and Quality Assurance Project Plans (QAPPs) for the program managers, project officers, the RQAM and the DQAOs. The Management Division agrees to continue to maintain and upgrade this system and to provide training to the Regional staff as necessary.

Professional Development for Regional QA Personnel

It is imperative that all QA personnel continue to be informed of changes in the Agency's Quality System and/or policies and of developments or changes in National, International or Industry Standards.

QA Outreach to the Regulated Community

In an attempt to keep the QA staffs in the regulated community informed of new requirements or changes in the Agency's QA Program, the Region has, for a number of years, sponsored an annual State/EPA QA Conference in Dallas. The entire QA Staff will take the lead in scheduling and coordinating this conference, if resources allow. Each Program Division agrees to allot time for its DQAO and QA Forum member(s) to assist in planning and assisting with this conference and to provide speakers on an as requested basis.

Travel Funding

This MOU contains commitments by the Management Division for travel funds for the RQAM, and the ESB QA Coordinator to conduct essential centralized QA functions such as external MSRs, QA training and QA professional development. Travel funds necessary to accomplish QA functions delegated to Program Divisions and each supported office by the Regional or a Divisional QMP, such as QA training support, MSR team member support are the responsibility of the individual Program Divisions and each supported Office. If the RQAM or any other QA Staff are requested to provide assistance to a Programmatic Division, supported office or their customers, any travel funds involved are the responsibility of the applicable Program Division.

Equity

In order to accomplish the Regional QA Program goals, each Program Division will provide travel funding for the conduct of QA training and to perform MSRs or QSAs. Each Program

Division will provide staff resources for the conduct of QA training and to perform MSRs or QSAs. The RQAM will attempt to assure the burden of QA related travel funds and the use of Programmatic staff are equitable among the Program Divisions for the entire QA Program.

Acting RQAM

Periodically, it may be necessary to designate an acting RQAM to assure that centralized QA functions are accomplished in a timely manner. The Management Division will consult and coordinate with the Program Divisions before designating an acting RQAM outside of the Division.

Acting DQAO

Periodically, it may be necessary to designate an acting DQAO to assure that Program Division QA functions are accomplished in a timely manner. The Program Division will consult and coordinate with the Management Division before designating an acting Divisional QAO.

III. Reopener, Termination and Effective Date

This agreement is meant to provide the framework within which the Divisions intend to operate. This MOU begins (replace with Date of Revised QMP local approval) and continues until such time as a new MOU is signed. Any party may request revisions to the MOU. In the event of revisions, the portion thereof not altered by the revisions shall remain in full effect.

Approvals, Quality Assurance Memorandum of Understanding

Name: James McDonald
Title: Assistant Regional Administrator for Management
Signature: James McDonald Date: 8/31/17

Name: William K. Honker, P.E.
Title: Director Water Division
Signature: Jamie B Walker for WK Honker Date: 08/24/2017 9/12/17

Name: Wren Stenger
Title: Director Multimedia Division
Signature: _____ Date: 8/31/17

Name: Carl E. Edlund, P.E.
Title: Director Superfund Division
Signature: _____ Date: 8/31/17

Name: Cheryl T. Seager
Title: Director Compliance Assurance and Enforcement Division
Signature: _____ Date: 8/31/2017

Name: David W. Gray
Title: Director Office of External Affairs
Signature: _____ Date: 9/8/17

Name: James Payne, Jr.
Title: Regional Counsel
Signature: _____ Date: 9/6/17

Name: Arturo Blanco
Title: Director Office of Environmental Justice, International and Tribal Affairs
Signature: _____ Date: 8/31/17

Appendix C - Quality Assurance Certification Form and R6 Forum on Environmental Measurements or FEM Competency Policy Checklist/Statements

EPA REGION 6 QUALITY ASSURANCE CERTIFICATION FOR ASSISTANCE AGREEMENTS

Grant/IAG/Contract Number	Recipient
Agreement Description	Amount Budgeted & Agreement Period

QA OFFICER'S AND QA MANAGER'S CERTIFICATION

We, the undersigned, certify that (check each applicable element):

( ) The requirements under this extramural agreement do not include any activities that involve the use of environmentally related measurements and related decisions. Therefore, an exemption is granted from EPA Quality Assurance and FEM Competency Policy Requirements.

( ) An approved Quality Management Plan (QMP) compliant with ANSI/ASQC E-4 and/or EPA QA/R-2 currently exists and is on file with the EPA Region 6 Regional Quality Assurance Manager as identified by QTRAK number _____. ***This block requires completion of below certification and assigned QTRAK number for the QA Project Plan/s under the subject extramural agreement.***

( ) This extramural agreement is an Interagency Agreement (IA) and is exempt from the FEM Competency Policy Requirements.

RECOMMENDATION	**DQAO APPROVAL**	**RQAM APPROVAL**
QA Cert. Project Officer	Divisional QA Officer	Reg. 6 QA Manager
Printed Name	Printed Name	Printed Name
Mail-code, Ext & Date	Mail-code, Ext & Date	Mail-code, Ext & Date

PROJECT OFFICER'S CERTIFICATION

I, the undersigned EPA Project Officer, having completed the EPA Region 6 QA Certification Course requirement and being officially recognized to oversee this/these project/s (check applicable elements):

( ) Certify that each approved Quality Assurance Project Plan (QAPP) is compliant with EPA QA/R-5, is on file with the appropriate program office, and is registered with the Regional QA Manager as identified by QTRAK number(s) _____.

( ) Certify that the Quality Assurance Project Plan(s) (QAPP) is/are required for completion of the referenced assistance agreement and will be developed and submitted as a deliverable under this award and that no activities will be conducted until the QAPP has been received, reviewed and approved. The following QTRAK number is assigned for tracking purposes _____.

(Continues on next page)

( ) ***In accordance with the Competency Policy, as Project Officer I have determined that the recipient meets the requirements for demonstration of competence through ongoing successful past performance to similar statement(s) of work "for this continuing environmental program."***

( ) Grantee has submitted the *R6 Checklist for the Implementation of the FEM Policy for Competency for Grants and Cooperative Agreements* (attached) in accordance with the FEM Competency Policy, documenting that the recipient meets the requirements for demonstration of competence without past performance for programs other than continuing environmental programs. (New grantees and "first and only" submission for tribes and programs that repeat annually but are not considered CEPs. Ex: National Estuary Program)

( ) Grantee has previously submitted the *R6 Checklist for the Implementation of the FEM Policy for Competency for Grants and Cooperative Agreements* in accordance with the FEM Competency Policy, documenting that the recipient meets the requirements for demonstration of competence through ongoing successful past performance to similar statement(s) of work for programs other than the continuing environmental programs.

( ) It has been determined that at the time of award the total maximum value of the assistance agreement does not nor is it presently expected to exceed $200,000 in federal funding over the life of the agreement. Specific grant competency term and condition is not required.

_____

QA Cert. Project Officer

_____

Printed Name

_____

Mail-code, Ext. & Date

R6 CHECKLIST FOR THE IMPLEMENTATION OF THE FEM POLICY FOR COMPETENCY FOR GRANTS AND COOPERATIVE AGREEMENTS

May 2014

This checklist is to be used by the applicant as a guide on the documents that may be considered to address and demonstrate competency. Applicants must have on record justification for each checked box, additionally these documents are required to remain on file. Your records should be preserved for three years from the date of the submission of the final FFR. If any litigation, claim, negotiation, audit, or other action involving the records has been started before expiration of the three-year period, the records must be retained until completion of the action and all issues are resolved. To ensure proper disposition of all your records on this project, please refer to 40 CFR Part 31.42. After the requirements of this regulation are satisfied, you may dispose of these records in accordance with your standard practices.

Please complete Section A (by providing the necessary items if applicable) and/or Section B (by checking the appropriate box), and return to the EPA Project Officer during work-plan negotiation or prior to carrying out any activities involving the generation or use of environmental data under the current or upcoming agreement. One or more of the competency documentation listed on page two can also be included in the organization's Quality Management Plan, Quality Assurance Project Plan and/or Laboratory QA Manual. Additionally, by submitting these items a grantee "warrants, represents, and agrees that it and all its contractors, employees and representatives will comply with all APPLICABLE provisions of 40 CFR Chapter 1, Subchapter B, INCLUDING BUT NOT LIMITED TO the provisions of 40 CFR Parts 31, 32, 34, and 35" as described in EPA Administrative Terms and Conditions.

SECTION A

At a minimum, the following documentation must be provided to U.S. EPA in addition to the completed checklist:

Box	Competency Demonstrations in the Field of Sampling &/or Analyses to be Conducted	Check (√) All That Apply
1.	Current certificate(s) of accreditation/certification for applicable sampling and/or analysis. Usually included in the Laboratory QA Manual or the organization QMP, if available.	

If your organization relies on accreditation/certification to demonstrate its qualifications in the field of sampling or analyses to be conducted (as implied by checking, the above, Box 1), please attach the following minimum documentation as required by the Competency Policy. If this doesn't apply, please proceed to Section B and fill out Boxes 2 through 10.

- A copy of the organization's quality system documentation. It may be called a Quality Management Plan (QMP), a quality manual, or some other name, depending on the organization. It should describe how the organization will plan, implement and assess the effectiveness of its QA/QC operations applied to environmental programs. It should conform to ANSI/ASQ E-4 2004, "Quality Systems for Environmental Data and Technology Programs: Requirements with Guidance for Use," as well as the U.S. EPA Quality documents listed in the answer to FAQ #9 and their referenced guidance. In some cases, analytical laboratories are now following ISO Guide 17025.

- Copies of the dated certificate(s) of accreditation/certification from those accrediting bodies indicating the applicable field(s) of sampling or analysis, and the period for which the accreditation/certification is valid.

- If the accreditation/certification is limited to specific sampling techniques, analytes or laboratory instrumentation, then a complete list of those techniques, analytes or instruments must be provided.

SECTION B

Listed below are other document(s) that may be used to demonstrate competency in addition to QMP/QAPP:

Box	Competency Demonstrations in the Field of Sampling &/or Analyses to be Conducted	Check (√) All That Apply
2.	Results from ongoing participation by the organization in relevant proficiency testing studies, round-robin programs or equivalent. – Applicable to Laboratories	
3.	Documented successful demonstrations of competency with applicable sampling and/or analytical equipment.	
4.	Documented experience with parameters and methods of interest.	
5.	References of past performance (Other similar project grants is acceptable).	
6.	Recent reports of technical and/or quality system assessments/audits of the organization, including associated corrective action plans.	
7.	Documented position descriptions for key personnel detailing major responsibilities and qualifications (e.g., education, training certificates, job experience, and active participation in professional associations. Also discussed in QMP, QAPP and Lab QA Manual).	
8.	Organizational quality documentation, such as a QMP, laboratory QA manuals, field quality manuals that provide descriptions of the organization's quality policies. Such documents should include: all requirements described in EPA Requirements for Quality Management Plans (EPA QA/R-2) http://www.epa.gov/quality/qs-docs/r2-final.pdf .	
9.	Technical/Project Level quality documentation, such as QAPPs, Sampling and Analysis Plans (SAPs) and/or standard operating procedures (SOPs). Such documents should include: auditing practices, descriptions of applicable equipment, method sensitivities, reporting practices, capacity, etc.	
10.	Other – Describe the competency demonstration(s)	

***References**

- FEM website: http://www.epa.gov/fem/lab_comp.htm.
- Policy to Assure the Competency of Organizations Generating Environmental Measurement Data under Agency-Funded Assistance Agreements
- Frequently Asked Questions (FAQs) for Agreements
- DRAFT – Examples of Competency Demonstration for Recipients
- Catalog of Federal Domestic Assistance (CFDA)

Project Manager Name (Please TYPE)

Project Manager Signature / Date

Region 6 has drafted a list of competency demonstrations that may be used by Continuing Environmental Program (CEP) applicants when preparing a statement demonstrating competency.

Competency Demonstration #1 – Documented successful demonstrations of competency with applicable sampling and/or analytical equipment.

> "Competency is demonstrated through the applicant's experience using (manufacturer name/model) water quality monitoring equipment for (number of years) years.

Competency Demonstration #2 - References of past performance (Other similar project grants is acceptable).

> "Competency is demonstrated through the maintenance of quality assurance project plans for data collection activities for water quality monitoring."

Competency Demonstration #3 - Recent reports of technical and/or quality system assessments/audits of the organization, including associated corrective action plans.

> "Competency is demonstrated by the Region 6 Quality Assurance Management Review conducted on (date)."

Competency Demonstration #4 - Documented position descriptions for key personnel detailing major responsibilities and qualifications (e.g., education, training certificates, job experience, and active participation in professional associations. Also discussed in QMP, QAPP and Lab QA Manual).

> "Competency is demonstrated through QA-QC documents that state position descriptions for key personnel detailing major responsibilities and qualifications."

> "Competency is demonstrated through (type of training) training course taken on (date of training). Certificate is available upon request."

Competency Demonstration #5 - Organizational quality documentation, such as a QMP, laboratory QA manuals, field quality manuals that provide descriptions of the organization's quality policies. Such documents should include: all requirements described in EPA Requirements for Quality Management Plans (EPA QA/R-2) http://www.epa.gov/quality/qs-docs/r2-final.pdf .

> "Competency is demonstrated through the Quality Management Plan that provides descriptions of the quality policies, including all requirements described in EPA QA/R-2."

Competency Demonstration #6 - Technical/Project Level quality documentation, such as QAPPs, Sampling and Analysis Plans (SAPs) and/or standard operating procedures (SOPs). Such documents should include: auditing practices, descriptions of applicable equipment, method sensitivities, reporting practices, capacity, etc.

> "Competency is demonstrated through the EPA approval of the Pueblo/Tribe's Quality Assurance Project Plan for GIS/GPS data collection."