US Environmental Protection Agency
Region III: Mid-Atlantic States
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QUALITY MANAGEMENT PLAN

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EPA REGION III QUALITY MANAGEMENT PLAN

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GLOSSARY

A glossary, available on the EPA's website, includes terms commonly used in the context of EPA's Quality System.

http://iaspub.epa.gov/sor_internet/registry/termreg/searchandretrieve/termsandacronyms/search.do

LIST OF ACRONYMS

AA	Accrediting Authorities
ADP	Automated Data Processing
APD	Air Protection Division
CAA	Clean Air Act
CBPO	Chesapeake Bay Program Office
CLP	Contract Laboratory Program
COR	Contracting Officer's Representative
DAI	Data Audit Inspection
DAS	Delivery of Analytical Services
DMRQA	Discharge Monitoring Reports Quality Assurance
DQA	Data Quality Assessment
EAID	Environmental Assessment and Innovation Division
EAS	EPA's Acquisition System
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right to Know Act
FAR	Federal Acquisition Regulations
FIRMR	Federal Information Resources Management Regulations
FOG	Field Operations Group
GIS	Geographic Information Systems
HSCD	Hazardous Site Cleanup Division
IA	Interagency Agreement
IQG	Information Quality Guidelines
IQGO	Information Quality Guidelines Officer
IRM	Information Resources Management
ISB	Information Services Branch
ISO	Information Security Officer
LCD	Land and Chemicals Division
LCM	Laboratory Certification Manual
NARA	National Archives and Records Administration
NELAC	National Environmental Laboratory Accreditation Conference
NELAP	National Environmental Laboratory Accreditation Program
NPDES	National Pollution Discharge Elimination System
OASQA	Office of Analytical Services and Quality Assurance
OCGR	Office of Communications and Government Relations
OECEJ	Office of Enforcement, Compliance and Environmental Justice
OEI	Office of Environmental Information
OIRM	Office of Information Resource Management
OPM	Office of Policy and Management
ORC	Office of Regional Counsel
PDR	Pre-dissemination Review
PRP	Potentially Responsible Party
P/T	Proficiency Testing
QA	Quality Assurance
QAARWP	Quality Assurance Annual Report and Work Plan
QAC	Quality Assurance Coordinator
QAO	Quality Assurance Officer
QAPP	Quality Assurance Project Plan

QC	Quality Control
QMP	Quality Management Plan
QAS	Quality Assurance Staff
QSA	Quality System Assessment
RCRA	Resource Conservation and Recovery Act
RFAC	Regional Field Activities Council
RFC	Request for Correction
RFR	Request for Reconsideration
RQAM	Regional Quality Assurance Manager
RQAO	Regional Quality Assurance Officer
RQC	Regional Quality Council
SARA	Superfund Amendments and Reauthorization Act
SAP	Sampling and Analysis Plan
SDWA	Safe Drinking Water Act
SOP	Standard Operating Procedure
TMDL	Total Maximum Daily Load
TSA	Technical Systems Audit
TSCA	Toxic Substances Control Act
WAM	Work Assignment Manager
WPD	Water Protection Division

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SECTION A: QUALITY SYSTEM FOUNDATION

A.1 INTRODUCTION

A.1.a. Mission, Policy and Scope

EPA's overarching mission is to protect human health and the environment. To accomplish this mission, EPA utilizes environmental information from a variety of sources. The Region III Quality Management Plan (QMP) describes the policies, procedures and management systems within the organization that govern quality control activities of environmental information collection and/or use. Activities involving environmental information and/or data that are covered by the Region III Quality System include, but are not limited to:

> ***Environmental information or data*** *is defined as any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA Region III, environmental information also includes data produced from models, and compiled from other sources such as data bases or literature.*

- Characterize and/or evaluate the states and/or conditions of environmental or ecological systems and the health of human populations;
- Characterize and/or evaluate chemical, biological, physical, or radioactive constituents in environmental and ecological systems, and their behavior and associated interfaces in those systems, including exposure assessment, transport, and fate;
- Establish the ambient conditions in air, water, sediments, soil, etc. in terms of physical, chemical, radiological, or biological characteristics;
- Determine and/or categorize radioactive, hazardous, toxic, and mixed wastes in the environment and to establish their relationships with and/or impact on human health and ecological systems;
- Quantify and/or monitor the waste and effluent discharges to the environment from processes and operations (e.g., energy generation, metallurgical processes, chemicals production), during either normal or upset conditions (i.e., operating conditions that cause pollutant or contaminant discharges);
- Develop and/or evaluate environmental technology for waste treatment, storage, remediation, and disposal; pollution prevention; and pollution control and the use of the technology to generate and/or collect data (e.g., treatability and pilot studies);
- Map environmental processes and conditions, and/or human health risk data, etc. (e.g., geographic information system);
- Support enforcement and/or compliance monitoring efforts;
- Develop or evaluate methods for use in the collection, analysis, and use of environmental data;

- Develop, evaluate and/or use models to characterize environmental processes or conditions; and
- Develop, revise, compare, or otherwise use information technology and management systems that impact the environmental data quality (e.g., electronic databases with environmental information including data entry, handling, transmission and analysis and laboratory information management systems);

The primary goal of the Region's quality system is to ensure that all environmentally-related data activities performed by or for the Region will result in the production of data that is of adequate quality to support specific decisions or actions. In order for this data to be used with a high degree of certainty by the intended user, its quality must be known and documented. This goal will be achieved by ensuring that appropriate resources are made available and proper procedures followed throughout each environmental project's planning, implementation and evaluation phase.

Region III Quality Policy

It is Region III policy that all environmental data and information collected and/or used in the process of decision-making are of known and documented quality, suitable for its intended use, with all aspects of collection and analysis thoroughly documented; such documentation being verifiable and defensible. This policy applies to all data collected under environmental operations and environmental technology activities performed directly by or for the Region. This includes all Federal, State, Tribal and local partners under interagency and financial assistance agreements; contractors funded by EPA; regulated entities and potentially responsible parties.

The Regional Administrator, Senior Leadership and managers ensure that adequate resources (intramural and extramural money, travel and training funds, and personnel) are allocated to achieve the Region's quality policy.

This QMP establishes the foundation for implementing an effective quality system within EPA Region III. The QMP applies to all Region III programs, activities, grants, contracts and interagency agreements that collect and/or evaluate environmental data which is used to make decisions or support actions related to our defined mission and responsibilities. Listed below are specific examples of environmental programs, grants and activities within each Division or Office which are covered by the Region III Quality System.

A.1.b. Programs Covered by the Region III Quality System

A.1.b.1. Air Protection Division

Clean Air Act
Ambient air quality data (monitoring by states via 105 grants)
Ambient air monitoring - per 40 CFR Part 58
CAA compliance inspections
Emissions inventory data (by states as per 40 CFR Part 51)
I/M program statistics (reports by states under 105 grants)

Stack testing (by company, state or EPA)
State Indoor Radon Grants (SIRG)

A.1.b.2. Chesapeake Bay Program Office
Baywide SAV Aerial Survey Program
Mainstem and Tidal Tributary Monitoring Programs
Non-tidal Monitoring Program

A.1.b.3. Environmental Assessment and Innovation Division
Coastal Aerial Survey Program
Coastal waters sampling
Decision Support or MIRA
Dredging
Environmental planning / environmental indicator development
Fish tissue surveys
Geospatial analysis
Green Infrastructure
Human Health Assessments
Laboratory analyses
Laboratory assessments (CLP, Regional contract laboratories, NPDES laboratory assessments of State and regulated laboratories, Superfund PRP laboratories, State drinking water laboratories)
Modeling
NEPA
Ocean Disposal Program
Wetland enforcement and grants

A.1.b.4. Hazardous Site Cleanup Division
CERCLA and the Superfund Amendments and Reauthorization Act of 1986 (SARA)
Regional Oil Program pursuant to the Oil Pollution Act (OPA) of 1990
SARA Title III Chemical Emergency Preparedness and Prevention (CEPP) program.

A.1.b.5. Land and Chemicals Division
Asbestos
Asbestos enforcement
Asbestos hazard in schools (AHERA)
Asbestos Hazard Abatement Act (ASHAA)
Asbestos enforcement grants
CAA - NESHAPS

FIFRA
Pesticide cooperative agreement grants
Pesticide environmental stewardship grants

RCRA
Corrective action
Delisting

RCRA compliance and enforcement
RCRA Subtitle C grants
RCRA Subtitle I grants

TSCA
PCB enforcement
TSCA 404(g) lead grants
Other TSCA lead grants

A.1.b.6. Office of Enforcement, Compliance and Environmental Justice
Compliance inspections (media specific and multi-media)
Facility inspections that support RCRA (Subtitle C and I, NPDES, pretreatment, TSCA/PCB, EPCRA/TRI reporting and asbestos
Sample collection

A.1.b.7. Water Protection Division
Safe Drinking Water Act
Comprehensive State Ground Water Protection Program
Public Water System Supervision Program
Sole Source Aquifer Program
Source Water Protection Program
Underground Injection Control Program
Wellhead Protection Program

Clean Water Act
Ambient water monitoring (routine monitoring performed mostly through the states)
Beaches
Clean Lakes Program
Great Lakes Program
National Estuary Program
National Pollutant Discharge Elimination System (NPDES) Program
Non-point Source (Section 319) Grants Program
Nutrient Criteria Program Water Quality Management Planning (Section 604(b)) Grants Program
State Revolving Fund Program
Targeted Watershed Initiative
Total Maximum Daily Load (TMDL) Program
Water Pollution Control (Surface/Groundwater Programs) (Section 106) Grants Program
Water Quality Management (106) Grants Program
Water Quality Standards Program
Watershed Protection Program

A.1.b.8. Office of Policy and Management
Performance Partnership Agreements and Grants

A.1.b.9. Office of Communications and Government Relations
Environmental Education Grant Program

A.1.b.10. Delegated Programs

The following programs have been delegated to some or all of the Region III Middle Atlantic States - Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia:

Air - Clean Air Act Title I permits, Title V permits, and most of Title III air toxics
National Pollutant Discharge Elimination System (except the District of Columbia)
Pesticides
Pretreatment (except the District of Columbia, Delaware and Pennsylvania)
Public Water Supply (except District of Columbia)
RCRA Subtitle C (hazardous waste)
RCRA Subtitle I (underground storage tanks)
Underground Injection Control (except the District of Columbia and Pennsylvania)

There are no delegations for the Sludge, Oil Pollution Act, Wetlands, Water Quality Standards, or Chlorofluorocarbons (CFCs) programs. The Total Maximum Daily Load (TMDL) program is not an officially delegated program; however, the states have primary responsibility. The Region's quality assurance (QA) responsibilities in relation to these delegated programs are oversight through mid-year program reviews, end of the year program reviews, and approval of QMPs and QAPPs. Program-specific oversight responsibilities are documented in respective Division/Office QMPs.

A.2. REGION III ORGANIZATION STRUCTURE

EPA Region III employs a decentralized approach to quality management. Each Division or Office is responsible for determining the specific environmental programs and activities to which the quality system will apply. Division/Office QA requirements may be more, but not less stringent than those presented in this QMP and are documented in respective Quality Management Plans.

The Region is comprised of five Divisions and six Offices. The program-specific Divisions are the Air Protection Division (APD); Environmental Assessment and Innovation Division (EAID); Hazardous Site Cleanup Division (HSCD); Land and Chemicals Division (LCD) and the Water Protection Division (WPD). The seven Offices are the Chesapeake Bay Program Office (CBPO); Office of Enforcement, Compliance and Environmental Justice (OECEJ); Office of Regional Counsel (ORC); Office of Civil Rights (OCR); Office of Communications and Government Relations (OCGR); and the Office of Policy and Management (OPM). A copy of the Region's organization chart can be found in Figure 1.

At this time, the ORC, OCR, and OCGR do not perform or manage environmental data operations and; consequently, do not maintain QMPs. OPM administratively manages (i.e.,

competition, funding, ensuring completion of deliverables) Performance Partnership Grants (PPGs) and discretionary funded grants involving environmental data operations. However, a technical representative is always also assigned to assist in the management of such grants. These grants will adhere to the respective Division/Office QA requirements and those specified in this QMP, as applicable.

A.3. QUALITY SYSTEM ROLES AND RESPONSIBILITIES

In accordance with ***US EPA Quality Policy, CIO Quality Policy 2105.0 (EPA Order 5360.1 A2)***, overall responsibility for the quality assurance program in Region III rests with the **Regional Administrator**. The responsibility for developing and documenting Regional QA policies, procedures and guidance; overseeing the implementation and assessment of the Regional quality system; and providing QA training has been delegated to the Regional Quality Assurance Manager. The **Regional Quality Assurance Manager (RQAM)** is located in the Immediate Office of the Environmental Assessment and Innovation Division (EAID) Director and is independent of direct environmental data operations. On issues relative to the Region's quality system, the RQAM reports to the Senior Management Representative to the **Regional Quality Council (RQC or Council)** and is afforded access to the Regional Administrator / Deputy Regional Administrator, if needed. The mission of the Council is to oversee implementation and ensure the continuous effectiveness of the Region III Quality Management Plan and create an environment where an awareness of quality is the norm. Each Division and Office that collects and/or evaluates environmental data assigns a Quality Assurance Coordinator to the Council (see Table A.1 for a list of current members). The structure and function of the RQC allows each level of the organization to participate in maintaining and improving the Region's Quality System. An organization chart which shows the reporting relationships and functional responsibilities for Region III QA personnel can be found in Figure 2.

All individuals in the Region who are directly or indirectly involved with environmental data operations have some responsibility for ensuring data quality.

Table A.1. Regional Quality Council Membership

Division/Office or Responsibility	Representative Alternate Rep	Phone	Email
Sr. Mgmt Representative	Walter Wilkie	(215) 814-2150	wilkie.walter@epa.gov
Regional QA Manager	Terry Simpson	(410) 305-2739	simpson.terry@epa.gov
APD	Amy Johansen	(215) 814-2156	johansen.amy@epa.gov
CBPO	Rich Batiuk Mary Ellen Ley	(410) 267-5731 (410) 267-5750	batiuk.richard@epa.gov mley@chesapeakebay.net
EAID	Kristopher DeNardi	(215) 814-2834	denardi.kristopher@epa.gov
HSCD	Jeff Tuttle	(215) 814-3236	tuttle.jeffrey@epa.gov
LCD	Mike Cramer	(215) 814-3446	cramer.mike@epa.gov

Division/Office or Responsibility	Representative Alternate Rep	Phone	Email
OECEJ	Jose Jimenez	(215) 814-2148	jimenez.jose@epa.gov
OPM	Norman Rodriguez	(215) 814-5274	rodriguez.norman@epa.gov
WPD	Bill Richardson	(215) 814-5675	richardson.william@epa.gov
IQG Officer	John Graves	(215) 814-5710	graves.john@epa.gov
FOG Co-Coordinators	Erin Sullivan Jeanna Henry	(215) 814-5564 (215) 814-2820	sullivan.erin@epa.gov henry.jeannar@epa.gov

A.3.a. Regional Administrator and Senior Leadership

The Regional Administrator (RA), Deputy Regional Administrator (DRA), Assistant Regional Administrator (ARA) and Senior Managers (Division Directors/Office Directors and Deputy Directors) have overall responsibility for the Regional QA Program as described in *CIO Quality Policy 2105.0 (EPA Order 5360.1 A2)*. Specifically, the RA, DRA, ARA and Senior Managers are responsible for ensuring that:

- All Regional components and programs comply fully with the requirements of *CIO Quality Policy 2105.0 (EPA Order 5360.1 A2)*;
- Quality program management is an identified activity with associated resources adequate to accomplish its program goals and is implemented as prescribed in the Region III QMP;
- QMPs covering Division or Office environmental data operations are developed, updated and effectively implemented;
- All environmental data operations are covered by the appropriate documentation (i.e., Quality Assurance Project Plans, Sampling and Analysis Plans, Standard Operating Procedures, etc.);
- All environmental data operations implemented through extramural agreements comply fully with applicable QA/QC requirements;
- Training in the fundamental concepts and practices of quality management is available for state, local, and tribal governments performing environmental data operations for EPA;
- Internal quality assessments are performed to ensure that programs comply with QA requirements. Deficiencies highlighted in the assessments are appropriately addressed;
- Agency policy and guidance are applied in identifying work products subject to peer review, determining the type and timing of such review, and documenting the process and outcome of each peer review;
- Each Division or Office which collects, evaluates and/or uses environmental data is represented on the Regional Quality Council by a Quality Assurance Coordinator; and
- Disputes regarding quality system requirements, QA/QC procedures, assessments or corrective actions are resolved.

A.3.b. Program Managers

Program Managers may be Associate Directors, Branch Chiefs, or Team Leaders and are the stewards of environmental data in Region III. EPA staff involved with environmental data operations performed under financial assistance agreements, contracts, and extramural non-supported measurement are responsible for incorporating QA requirements into grant conditions; contracts; and voluntary, consensual or unilateral enforcement agreements, decrees and orders. Program Managers have technical expertise in a specific program area (e.g., TMDL, permits, enforcement, etc.) and serve as the focal lead for a specific environmental program. In this role, they must ensure that:

- All intramural and extramural projects within their program that involve environmental data operations are performed in accordance with the Regional and Divisional QMPs and an approved Quality Assurance Project Plan (QAPP);
- Resources required to implement Program QA requirements are identified and provided;
- Adequate procedures are in place to address QA requirements in all applicable program operations, including those delegated to state agencies;
- All environmental data operations are covered by the appropriate documentation (i.e., Quality Assurance Project Plans, Sampling and Analysis Plans, Standard Operating Procedures, etc.);
- Operations needing Standard Operating Procedures (SOPs) to conduct day-to-day activities are prepared, updated, approved, withdrawn, and archived.
- Internal quality assessments are performed to ensure that programs comply with QA requirements. Deficiencies highlighted in the assessments are appropriately addressed;
- Agency policy and guidance are applied in identifying work products subject to peer review, determining the type and timing of such review, and documenting the process and outcome of each peer review;
- Performance Agreements for supervisors, team leaders, and appropriate staff contain performance measures that are commensurate with their assigned quality management responsibilities;
- The Division or Office cooperates with QA reviews or audits and submits requested information in a timely manner;
- Appropriate corrective action recommended by audit findings is implemented;
- QA concerns with the Division/Office QA Coordinator and/or RQAM are discussed;
- Disputes regarding quality system requirements, QA/QC procedures, assessments or corrective actions are resolved;
- QA training needs for his/her specific environmental program are identified and reported to the QA Coordinator; and
- Pre-dissemination review for an information product will be planned and implemented at the start of each applicable project.

A.3.c. Project Managers / Project Officers

> *For the purposes of this document, the terms Project Manager and/or Project Officer include any of the following: Contractor Officer Representative, Work Assignment Manager, Site Assessment Manager, Remedial Project Manager, or On-Scene Coordinator.*

Project Managers (PMs), Project Officers (POs), Contracting Officer Representatives (CORs), Work Assignment Managers (WAMs), Site Assessment Managers (SAMs), Remedial Project Managers (RPMs), and On-Scene Coordinators (OSCs) are assigned responsibility for specific projects supported by EPA through contracts, cooperative agreements, grants or interagency agreements (IAs). Since POs may not be closely familiar with QA procedures, they are encouraged to work with their Divisional/Office QA Coordinator to ensure that QA requirements are addressed.

The specific responsibilities of Project Managers/Project Officers are to ensure that:

- All extramural projects which generate and/or compile environmentally related data, adhere to QA requirements found in Agency, Regional and Divisional policy and/or QMPs;
- All grant and IA recipients or contractors conducting projects which involve environmental data operations submit a QMP, which documents their quality system, as appropriate. If applicable, the QMP must be submitted to the EPA Project Manager / Project Officer at least 45 days prior to the initiation of environmental data operations per the *Region III Quality Assurance Requirements for Grants and Cooperative Agreements,* November 7, 2000 (Appendix A) and Section B.3.b of this QMP;
- All grant and IA recipients or contractors conducting a project which involves environmental data operations have an approved QAPP prior to initiating any data generation, compilation and/or use per the *Region III Quality Assurance Requirements for Grants and Cooperative Agreements,* November 7, 2000 (Appendix A) and Section B.3.b of this QMP;
- For contracts, the Region III Quality Assurance Review Form for Contract Actions (Appendix B) is completed, and approved in writing by the RQAM (or designee) and Project Officer (see Section E.2 for a description of specific procedures);
- For grants and assistance agreements, the funding recommendation form in the Integrated Grants Management System (IGMS) is completed to indicate whether QA requirements apply;
- Data from environmental programs delegated to state and local governments are of sufficient quantity and adequate quality for their intended use and are used consistent with such intentions;
- Agency policy and guidance are applied in identifying work products subject to peer review, determining the type and timing of such review, and documenting the process and outcome of each peer review;
- Determine whether an information product will be disseminated and ensure that a pre-dissemination review is completed; and
- Plan for dissemination of the information at the start of the project.

A.3.d. Regional Quality Council

The Regional Quality Council (RQC) oversees the Region III Quality System and ensures the effective implementation of practices and policies defined by the Region III Quality Management Plan. The RQC consists of a Senior Management Representative, RQAM, and a QA Coordinator from each Division or Office conducting environmental data operations. The primary responsibilities of the RQC are to:

- Review and update the Region's QMP;
- Develop & oversee implementation of Regional QA policies and procedures;
- Develop QA training and Quality System Assessment plans for the Region;
- Review and implement quality system assessment recommendations;
- Establish QA priorities for each new fiscal year; and
- Resolve disputes regarding quality system requirements, QA/QC procedures, assessments or corrective actions.

A.3.e. Senior Management Representative to the Regional Quality Council

The Senior Management Representative to the RQC serves as a liaison between the Senior Managers and the RQC. Specifically, the Senior Management Representative:

- Provides Senior Managers with periodic updates on the status of the Region's Quality System;
- Provides the RQC with periodic updates from the Senior Managers about issues that impact the Region's Quality System; and
- Resolves disputes regarding quality system requirements, QA/QC procedures, assessments or corrective actions.

A.3.f. Regional Quality Assurance Manager

The Regional Quality Assurance Manager (RQAM) has been delegated primary responsibility for the oversight of the Region III Quality System. Specifically, the RQAM is responsible for:

- Facilitating the development of the Region's QMP and preparing updates to the approved QMP;
- Representing the Region at national quality meetings, such as the RQAM monthly conference call, national QA conferences, etc. Also, serves as primary Regional liaison with the Quality Staff in EPA Headquarters and Region III State QA contacts;
- Providing expert assistance to Regional staff on QA/QC policies, requirements, and procedures applicable to procurement, financial assistance and technical activities/services;
- Reviewing and approving QMPs submitted by Region III Divisions and Offices and by holders of extramural agreements;
- Performing periodic assessments of Regional organizations conducting environmental data operations to determine the conformance of their mandatory quality systems to their approved QMPs and the effectiveness of their implementation;

- Coordinating and submitting the Annual QA Report and Workplan to Senior Regional Managers and the Office of Environmental Information (OEI) Quality staff;
- Authorizing organizations (i.e., states and local governments) to review and approve QAPPs;
- Providing, scheduling and/or notifying Regional staff of QA training and briefings;
- Distributing Agency QA guidance documents, policies, and procedures;
- Initiating and/or revising Regional QA policy & procedures;
- Facilitating the discussion of disputes regarding quality system requirements, QA/QC procedures, assessments and/or corrective actions; and
- Serves as Regional Alternate Test Procedure Coordinator supporting the Clean Water Act (CWA) National Pollutant Discharge and Elimination System (NPDES) and the Safe Drinking Water Act (SDWA) programs.

A.3.g. Information Quality Guidelines Officer

The Information Quality Guidelines (IQG) Officer serves as a Regional coordinator for Information Quality Guidelines activities. The IQG Officer coordinates IQG activities with the RQAM and the Region's Product Review officer. Specific responsibilities are as follows:

- Provide technical assistance to Regional staff on IQG policies, requirements, and procedures;
- Serve as point of contact on IQG procedures;
- Help implement IQG pre-dissemination review procedures in the Region;
- Facilitate communication on IQG policies and procedures within the Region and with HQ Quality Staff; and
- Coordinate responses from Region III information owners to requests for correction and requests for reconsideration with HQ Quality Staff

A.3.h. Quality Assurance Coordinators

Each Division and Office conducting environmental data operations shall have a Quality Assurance Coordinator (QAC). QACs are responsible for coordinating the implementation of the quality system within their Division or Office. The QAC:

- Disseminates QA information to Division or Office staff;
- Conducts QA briefings for Division or Office Directors;
- Participates in RQC meetings;
- Facilitates preparation and/or revision of his/her Division or Office's QMP;
- Helps implement the Division or Office's QMP;
- Helps Project Managers and/or Project Officers resolve data quality issues with contractors and financial assistance recipients;
- Assesses Division or Office's QA-related training needs and arranges the delivery of training;
- Provides assistance to Project Managers/Project Officers with completion of QA Review Forms for acquisitions/contracts/work assignments;
- Reviews and signs QA Review Forms for acquisitions/contracts/work assignments;

- Assists Project Managers/ Project Officers with completion of QA-related questions on the funding recommendation form in IGMS for grants, cooperative agreements, and interagency agreements;
- Tracks the number of projects in progress within his/her Division or Program Office; the number of projects involving environmental data operations; and the title, preparer and date of QAPPs received, reviewed and approved;
- Provides reports on above to RQAM at a frequency to be determined by the RQC (at least annually);
- Consolidates Division or Office's QA information for the QA Annual Report and Work Plan and delivers it to the RQAM; and
- Participates in and/or conducts assessments of Divisional or Office and state QA programs to assure that they adhere to their approved QMPs.

A.3.i. Technical Services Branch

The Technical Services Branch is comprised of the Region III Sample Brokerage and Quality Assurance (QA) Staff. It is organizationally placed in EAID Office of Analytical Services and Quality Assurance (OASQA) and geographically located in Fort Meade, MD. The Branch serves as the focal point for procurement of analytical services for environmental data operations and providing quality assurance support to Divisions and Offices in Region III. The branch's primary quality assurance responsibilities include:

- Evaluating and assessing environmental data for contract compliance;
- Conducting laboratory inspections for the Superfund Contract Laboratory Program (CLP), and other contract laboratories;
- Assisting with environmental project planning;
- Reviewing QAPPs, SAPs, and other QA documentation;
- Assisting the RQAM with review of external Quality Management Plans;
- Providing technical assistance on QA/QC policies, requirements, and procedures applicable to technical activities;
- Participating in assessments of QA and QC activities;
- Working with the RQAM to develop Regional QA policy & guidance documents;
- Oversees the review and certification of drinking water laboratories;
- Administer the SDWA and NPDES Proficiency Testing (P/T) studies;
- Participate in assessments of Regional and State QA programs to assure that they adhere to their approved QMPs; and
- Providing, scheduling and/or notifying Regional staff of QA training courses.

A.3.j. OASQA and Freshwater Biology Team Quality Assurance Officers

The OASQA Laboratory and Freshwater Biology Team (FBT) Quality Assurance Officers (QAO) are responsible for the design and management of OASQA's and the FBT's quality systems. Specific responsibilities are detailed in the current version of their respective Quality Manuals locally available here: I:\OASQA Quality System.

A.3.k. Field Operations Group Coordinator(s)

The Field Operations Group (FOG) Coordinator(s) is(are) responsible for ensuring the Region implements and maintains a Field Activities Management System in compliance with the Agency's Field Operations Guidelines. Specific responsibilities include:

- Coordinating with the RQAM to ensure accurate Field Activities Management System language is included in the Region III QMP;
- Coordinating with the RQAM to report on training, audits, corrective actions and changes in the Field Activities Management System in the annual QA Report and Work Plan (QAARWP);
- Reviewing and approving SOPs relating to field activities;
- Ensuring training is provided for all Regional field activity staff;
- Managing an internal audit program;
- Coordinating and managing any external audits (including developing a corrective action plan and ensuring implementation of corrective actions);
- Maintaining a master list of corrective actions resulting from any internal or external audits;
- Maintaining and distributing all Field Activities Management System documents (e.g., policies and procedures) for the Region;
- Reporting on the performance of the Field Activities Management System to Regional Senior Managers;
- Overseeing internal competency evaluation and proficiency testing requirements;
- Communicating with Region III management and staff regarding applicable document development, control, distribution, review and revision;
- Maintaining a master list of active and archived procedural documents (e.g., Standard Operating Procedures (SOPs));
- Ensuring the most recent version of field activity documents are on the Regional LAN, Intranet/Internet, and/or OneDrive/SharePoint site;
- Assigning effective dates for Field Activities Management System documents;
- Assigning document control numbers;
- Archiving obsolete and retired documents;
- Tracking the review status of documents and notifying management and staff of documents requiring review and/or revision;
- Maintaining records associated with the Field Activities Management System;
- Participating on national program meetings and teleconferences to represent regional needs; and
- Providing expert technical assistance and guidance to Region III managers and staff on everything field-related

A.4. COMMUNICATION

This QMP will be distributed to all individuals responsible for implementing the policies and procedures found in this document. Several mechanisms will be used to distribute QA information. On a regular basis, the RQAM will keep the EAID Director, Senior Management Representative, RQC and senior managers apprised of QA issues that impact the Region's quality system. In addition, new QA developments, policies, and procedures will be distributed to all Division and Offices and posted on the Region III Quality Assurance internet

site, as applicable. The Region III QMP will be posted on the Region's internet site and/or shared directories of the Region's Local Area Network, as applicable. When the Region III QMP is revised, the new version will be posted and older versions archived. Organizational QMPs and project-specific QAPPs will be posted on the Region's internet/intranet site, as applicable.

The RQC, as the primary cross-Divisional group for addressing QA topics that impact the entire Region, meets quarterly to discuss and resolve issues about QMP implementation and its impact on data quality. The RQC also discusses ways to improve the Region's Quality System. Communication of an Agency-wide nature, takes place among the RQAM, the OASQA QA Staff, other RQAMs and Headquarters during monthly teleconferences.

A.5. DISPUTE RESOLUTION

In order to resolve disputes related to quality assurance, the Region will strive to resolve the issue at the lowest administrative level practicable. The dispute resolution process shall begin when either disagreeing party declares an issue to be irresolvable and sends written correspondence to the other party defining the disputed issue, and presenting supporting arguments for the first party's position on the issue. All parties shall make every effort to resolve disputes through discussion and negotiation. Should agreement not be reached at this level, the issue will be directed to the Divisional QAC. If the issue is not resolved, it will be directed to the RQAM. If necessary, the RQAM will work to resolve the problem with the Senior Management Representative to the RQC and ultimately the RA/DRA. The resolving officials will document the resolution and provide it to the disputing parties.

A.6. RESOURCES FOR THE REGION III QUALITY SYSTEM

The level of QA resources needed for an environmental program or project is determined by the relevant Regional program. Since an assigned national program element for QA does not exist, most resources needed for QA are taken from a variety of program elements which utilize QA functions and services. Each Division or Office Director shall ensure that there are adequate resources to successfully implement QA requirements for their environmental programs.

A.7. PRINCIPAL COMPONENTS OF THE QUALITY SYSTEM

The Region III Quality System consists of the people, functions, tools and procedures used to ensure that data of known quality and sufficient quantity is generated for Regional data users and decision makers. Successful implementation of the Region III Quality System requires a consistent and graded approach for QA practices commensurate with the intended use of the data. A variety of tools and procedures are employed for planning, implementing and evaluating the Region's Quality System. Managers and staff members are informed of the availability and use of these tools through their Divisional QACs.

The principal components of the Region III's Quality System exist at the program- and project-level. A list of these components is provided below:

Program-level	Project-level

Quality Management Plans	Data Quality Objectives
Laboratory Quality Manuals	Quality Assurance Project Plans
Quality Assurance Annual Report and Work Plan	Standard Operating Procedures
Quality Systems Assessments	Technical System Audits
Training Plans	Proficiency Testing Samples
Information Quality Guidelines	Data Quality Assessments
Quality Management Plan Status Reports	Pre-dissemination Reviews
Newly Awarded Grants Reports	Assessment Factors
Field Operations Group Guidelines	Standard Operating Procedures
Field and Laboratory Competency Policies	Peer Review

A.8. QUALITY MANAGEMENT PLANS

A.8.a. Region III Quality Management Plan

The Region III QMP complies with the requirements found in the *EPA Quality Manual*, CIO Procedure 2105-P-01.0 (EPA Order 5360 A1), May 5, 2000 and *Policy and Program Requirements for the Mandatory Agency-wide Quality System, CIO Quality Policy 2105.0 (EPA Order 5360.1 A2)*, May 5, 2000. This document serves as the "umbrella" document for all Regional programs and describes the quality system in terms of organizational structures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and evaluating activities conducted.

The Region III QMP contains the policies and procedures being implemented to ensure that environmental data generated, collected, compiled, analyzed, and/or utilized by and for the Region are of adequate quality for its intended use.

The QMP is developed by the RQAM with assistance from the Regional Quality Council and the OASQA QA Staff and is intended to be used by all Regional staff. This QMP shall be reviewed and approved by all Division and Office Directors and the Regional Administrator. Final approval of the Region III QMP shall be granted by the Director of the EPA Office of Environmental Information (OEI) Quality Staff. The approval is valid for up to five years; however, pursuant to *CIO Quality Policy 2105.0 (EPA Order 5360.1 A2)*, updates or revisions to the QMP are required as a result of organizational and/or Regional policy/process changes, or findings from quality system assessments. The Region III QMP shall be reviewed for such changes and updated, as necessary, on an annual basis.

A.8.b. Division/Office Quality Management Plans

Each Region III Division and Office that conducts environmental data operations shall develop and maintain its own QMP. This QMP shall describe the organization's QA management policies, objectives, and internal procedures. These documents shall be consistent

with the requirements found in the most recent version of the *CIO Procedure 2105-P-01.0 (EPA Quality Manual 5360A)* and *CIO Quality Policy 2105.0 (EPA Order 5360.1 A2)*. Division and Office QMP requirements may be more, but not less, stringent than those presented in the Region III QMP. All Division/Office's QMPs require approval by Division/Office management and the RQAM, or designee.

The most recent version of the Region III QMP Checklist (Appendix C) may be used to review these QMPs. Approval of the Division/Office QMP is valid for a period up to five years and is subject to review and revision by the Quality Assurance Coordinator annually. Minor organizational and/or policy changes shall be documented in the Division/Office QA Annual Report and Work Plan. When there are substantial organizational or policy changes that impact a Division or Program's quality system, the Division/Office QMP shall be updated and resubmitted to the RQAM for review and approval.

Table A.2 Region III Division/Office Quality Management Plans

Regional Programs (Divisions)	Approval Status	Date Approval Ends/Revised Due[(a)]
Air Protection Division	Approved	03/15/2019
Chesapeake Bay Program	Approved	12/31/2015
Environmental Assessment & Innovation Division	Approved	3/31/2017
EAID - OASQA Lab Quality Manual	Approved	3/25/2017
Hazardous Site Cleanup Division	Tentatively Approved	
Land and Chemicals Division	Approved	8/1/2016
Office of Enforcement, Compliance and Environmental Justice	Under development	10/1/2015
Water Protection Division	Approved, awaiting signatures	10/31/2019
Region 3	Approved	09/21/2020

A.8.c. Quality Management Plans for Extramural Projects

> ***Region III Policy***
>
> *Recipients of Region III financial assistance (i.e., grants, cooperative agreements, contracts and interagency agreements) that involve the generation, collection, compilation and/or use of environmental data must develop and implement QA policies and practices that are sufficient to produce data of adequate quality to meet program objectives.*

Likewise, financial assistance recipients' quality policies and practices shall be documented in a QMP, or equivalent document, in accordance with the most recent version of *EPA Requirements for Quality Management Plans*, EPA QA/R-2, March 2001. Should there be multiple programs involved in a grant, cooperative agreement, IA or contract, the recipient may submit a single QMP covering all of the programs in the grant, cooperative agreement, IA or contract or a separate QMP for each program receiving such funds, per the *Region III Quality Assurance Requirements for Grants and Cooperative Agreements*, November 7, 2000

(Appendix A).

The recipient's QMP shall be approved internally by its Quality Assurance Manager, or equivalent and the organization's senior management. Financial assistance recipients at all levels, must submit their QMP or combined QMP/QAPP to the EPA Project Officer/Project Manager at least 45 days prior to the initiation of environmental data operations, per the *Region III Quality Assurance Requirements for Grants and Cooperative Agreements*, November 7, 2000 (Appendix A). The QMP or combined QMP/QAPP shall be forwarded to the RQAM, or designee, for review. The most recent version of the Region III QMP Review Checklist (Appendix C) may be used to facilitate the review. When applicable, the Region III QACs will be asked to facilitate the QMPs' review by conducting a review of the technical activities and programs documented in QMPs for extramural organizations being funded by their Division or Office. The QMP or combined QMP/QAPP must be approved by the RQAM prior to the conduct of environmental data operations. EPA approval is valid up to five years. The recipient shall review its QMP annually and report minor organizational and/or policy changes in its annual report to the Agency, as applicable. When there are substantial organizational and/or policy changes that impact the recipient's quality system, the recipient shall update and resubmit its QMP to the RQAM for review and approval.

For smaller or single program/project organizations there may be situations when a single document is more applicable. By applying a graded approach to these situations, the RQAM and/or Division/Office QACs may identify more appropriate quality system documentation required from the organization receiving financial assistance. Each situation will be determined on a case-by-case basis by the RQAM and/or Division/Office QAC, as applicable. In general, organizations receiving financial assistance may be granted an exception or modification to the QMP requirement if they meet criteria which may include, but not be limited to, the following:

- small grants as defined by the EPA *Small Grants Guidance*;
- one-time, short-term, and special projects or projects of limited scope; and
- organizations generating, collecting, compiling and/or using environmental data for public education purposes.

Upon receipt of a QMP or combined QMP/QAPP, the RQAM shall update the Region III QMP Status Report. This report contains the name of the organization that submitted the QMP, the receipt date, the review status and the approval status. The QMP approval shall be formally documented in a letter to the financial assistance recipient, a memorandum to the Project Manager/Officer, and/or both. The status of a QMP may be:

Approved:	The Quality Management Plan adheres to requirements found in *EPA Requirements for Quality Management Plan*, EPA QA/R-2. QMP is valid for five years from date of approval.
Conditional:	The cursory review of this document indicates that the grantee has documented the basic components of a quality system. However, minor revisions to the grantee's QMP are required to ensure conformance to *EPA Requirements for Quality Management Plans*, EPA QA/R-2. Conditional approval allows grantees to perform

activities that include the generation and/or use of environmental data while making revisions to finalize their plan.

Resubmit: The Quality Management Plan is in need of significant revision in order to meet the basic components of a quality system. The grantee/contractor is required to ensure conformance to *EPA Requirements for Quality Management Plans*, EPA QA/R-2 prior to performing activities that include the generation and/or use of environmental data.

Expired: The Quality Management Plan on file with EPA Region III is no longer current and needs to be revised and resubmitted for review.

In Progress: The Quality Management Plan has been received by EPA Region III and is undergoing review.

Each month, the updated Region III QMP Status Report shall be posted on the Regions' internet site and distributed to the Region III Division/Office QACs; the Office of Policy and Management (OPM's) Grants and Audit Management Branch; and OPM's Contracts Branch. The Grants and Audit Management Branch and Contracts Branch shall distribute the updated QMP Status Reports to all Region III Project Officers. Region III Project Officers shall use this information to ensure that extramural agreement holders under their purview have fulfilled their EPA QA requirements.

A.8.d. QMP Reciprocity

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

Region III QA Staff must be able to verify the approval period or expiration date of the QMP and confirm approval by the EPA organization. The decision to accept a QMP under reciprocity requires a recommendation from the applicable program QA Coordinator and approval by the RQAM. The QA Coordinator's recommendation is essential to assure the QMP adequately covers the type of work being performed. The external organization seeking reciprocal approval shall provide a signed copy of the QMP for Region III's files. The name of the original EPA approver, their organization, date of approval and length of approval shall be obtained and recorded on the EPA Region III QMP Status Report. The approval period of a reciprocally approved QMP shall not exceed its approval period from the approving EPA organization.

A.9. EPA LABORATORY AND FIELD COMPETENCY

A.9.a. Office of Analytical Services and Quality Assurance

The EAID Office of Analytical Services and Quality Assurance (OASQA) Quality System is based on the requirements of ISO 17025 General Requirements for the Competency of Testing and Calibration Laboratories, and the National Environmental Laboratory Accreditation Program (NELAP) Chapters 2 and 5. Analytical services provided by OASQA are documented in the most recent version of the *OASQA Laboratory Quality Manual*. This manual describes the laboratory's quality system policies and procedures. The Laboratory's Quality System is NELAP accredited by the State of New Jersey Department of Environmental Protection (NJ DEP), an approved Accrediting Body. Each person involved in the laboratory's operations shall be familiar with OASQA's quality system and the technical requirements of the tests being conducted. The *OASQA Laboratory Quality Manual* and Standard Operating Procedures (SOPs) are available on the local share drive I:\OASQA Quality System.

A.9.b. Freshwater Biology Team

The Freshwater Biology Team is located in Wheeling, WV. It provides technical, field and laboratory services in the areas of bio-assessment and bio-criteria by conducting scientific investigations, assessments, surveys and technical assistance. The Team develops bioassessment tools and methods to assess and protect the health of freshwaters; promotes and develops biocriteria; and promotes and provides support for use of freshwater bioassessment in EPA, other Federal agencies, State programs, interstate commissions and universities. They have expertise in biological assessments (macroinvertebrates, fish and fish health, salamanders and mussels), habitat surveys, statistical analyses, biocriteria development, bioassessment method development, GIS tools and toxicity testing and report reviews. The team provides technical expertise and training in bio-assessment evaluations including sample collection methods, taxonomy, data interpretation, and quality control.

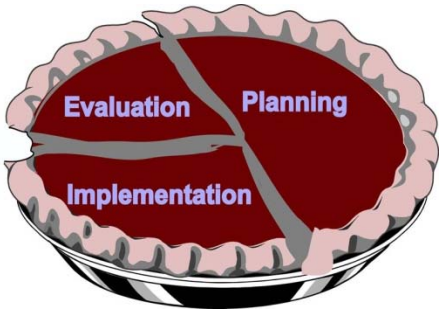
While not accredited, the Freshwater Biology Team maintains a Quality System for its field and laboratory activities. All Team policies and procedures are contained in their *Laboratory Quality Manual* and Standard Operating Procedures (SOPs) which undergo review and/or revision every five and three years, respectively. The Team conducts an annual internal audit against their quality manual and maintains laboratory and field demonstration of capability files on each team member. They complete and update project QA plans, as needed; and address any findings from previous annual internal audit(s).

A.9.c. Field Competency

The FOG Guidelines require that EPA field personnel be evaluated using real or simulated samples or situations (e.g., inspections) to determine if they have acquired the required skills and knowledge to independently analyze or otherwise characterize a sample or process or to independently perform work in a specific area.

The competency of EPA field personnel will be re-evaluated periodically (e.g., at least once every four years, or directly prior to embarking on a field activity/task that is infrequently performed). Region III's proficiency and competency testing program will be documented in a Personnel and Training SOP that is currently under development. The Personnel and Training SOP will describe, among other things, the Region's process for formally evaluating the ability of field staff to perform assigned tasks.

SECTION B: PLANNING



The Quality System PIE

The acronym **PIE** is used to describe Region III's Quality System components. "**P**" stands for **planning**; "**I**" for **implementation**; and "**E**" for **evaluation**. Planning is described here, in Section B. Implementation is described in Section C and Evaluation in Section D.

A major goal of Region III's Quality System is to promote effective planning for the collection, analysis and processing of environmental information and/or data. Quality planning must occur at three levels to ensure that such data meets Regional programmatic and quality goals: Region-Wide, Program-Specific and Project Level.

B.1. REGION-WIDE PLANNING

B.1.a. Internal Strategic Planning

The EPA five-year Strategic Plan is the foundation for all programmatic priorities and environmental operations. Annual national programmatic guidance is then developed each year which outlines the goals and milestones that support the objectives contained in the Strategic Plan. The EPA annual budget supports the goals and milestones contained in the annual guidance and is linked by code to the objectives outlined in the strategic plan. National programs coordinate and negotiate with all regions in development of the guidance and budget on the work to be performed in any one year. Region III senior management, supervisors and staff work with our state partners to provide input to the national goals that reflect regional priorities. Once the annual guidance and budget are finalized, action plans are developed by divisions and offices that specify performance commitments and the environmental data operations that will occur and the corresponding requirements for QA and QC procedures.

B.1.b. External Data Coordination

Region III also coordinates environmental data operations with numerous government agencies, academic and private organizations. Close coordination and planning is essential to ensure that data are of sufficient quality to support the intended uses and can also be shared with other organizations. The Region encourages data sharing wherever possible and supports data quality planning to make that possible.

B.2. PROGRAM-SPECIFIC PLANNING

Programs are functional areas of work authorized by statutory reference (e.g., the Air Toxics Program) or by Executive or Agency direction (e.g., the Volunteer Monitoring Program). All Regional environmental data operations conducted in support of these programs are covered by this QMP, though not all require the same level of QA. When initiating a new program or

incorporating major statutory changes, the program shall establish the minimum quality system components required to achieve program compliance.

For many ongoing environmental monitoring programs, the National Offices at EPA Headquarters have established standard QA/QC requirements. These QA/QC requirements may be documented in a generic Program QMP, QAPP or SOP. In these cases, the Region shall defer to these national program documents. Any modifications or deviations from these documents shall be documented.

B.3. PROJECT-LEVEL PLANNING

B.3.a. Systematic Planning Process

Region III Policy

A systematic planning process shall be used for all environmental data operations conducted by or on behalf of Region III.

The systematic planning process is a mechanism for balancing conflicting demands and data quality needs to ensure that environmental data operations will effectively support decision-making. EPA's *Guidance on Systematic Planning Using the Data Quality Objectives Process*, EPA QA/G-4, February 2006 describes one such process but any other systematic planning process may be used as long as it is based on the scientific method and complies with Chapter 3 of CIO Procedure 2105-P-01.0 (*EPA Quality Manual*, 5360 A1).

Elements of a systematic planning approach shall include:

- ✓ Identification and involvement of the Project Manager/Project Officer, sponsoring organization and responsible official, project personnel, stakeholders, scientific experts, etc. (i.e., all customers and suppliers);
- ✓ Description of the project goal, objectives and questions/issues to be addressed;
- ✓ Identification of project schedule, budget, milestones, and any applicable requirements (e.g., regulatory requirements, contractual requirements);
- ✓ Identification of the type of data needed and how the data will be used to support the project's objectives;
- ✓ Determination of the quantity of data needed and specification of the performance criteria for measuring quality;
- ✓ Description of how, when, and where the data will be obtained including existing data and identification of any constraints on data collection;
- ✓ Specification of needed QA and QC activities to assess the quality performance criteria (e.g., QC samples for both the field and laboratory, audits, technical assessments, performance evaluations, etc.);
- ✓ Description of how the acquired data will be analyzed (either in the field or the laboratory), evaluated (i.e., QA review, validation, verification), and assessed against its intended use and the quality performance criteria.

The Project Manager/Project Officer is responsible for ensuring that a systematic planning process is used and documented and that all organizations and/or parties who contribute

to the quality of the environmental project or use the results are identified and participates in the planning process. Guidance and technical support for using a systematic planning process are available from the RQAM and OASQA Quality Staff, upon request.

B.3.b. Quality Assurance Project Plans

> ***Region III Policy***
>
> *All projects and tasks involving environmental data operations that are conducted by or for the Region shall have an approved QAPP in place prior to the start of data generation or use.*

The systematic planning process described above results in the development of a sampling network design, generation of appropriate data quality indicators, selection of measurement and analytical methodologies, standard operating procedures, etc. Region III policy requires that the results of the systematic planning process be documented in a Quality Assurance Project Plan (QAPP) and approved by authorized personnel prior to implementation. The only exception to this requirement shall be for environmental projects that require immediate action to protect human health and the environment or operations conducted under police powers.

The Region has embraced the "graded approach" as defined in Section 2.4.2 of *EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations*, EPA QA/R-5, March 2001. The level of detail found in the QAPP shall be commensurate with the nature of the work being performed and the intended use of the data.

> ***Important Note***
>
> *A QAPP is not just a paper document. It is a dynamic tool to be used in the field by project personnel.*
>
> *If you deviate from the approved QAPP during implementation, figure out the best course of action, reach agreement, document the changes, attach them to the QAPP, and distribute the changes to everyone involved in the project!!*

The QAPP shall be prepared in accordance with *EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations*, EPA QA/R-5, March 2001. EPA's Office of Solid Waste and Emergency Response (OSWER) has issued OSWER Directive 9272.0-17, stating that the *Uniform Federal Policy for Quality Assurance Project Plans* (UFP-QAPP), EPA-505-B-04-900A, March 2005 is designated for use in Federal facility projects where environmental data are collected (e.g., CERCLA, RCRA, Brownfields). EPA Region III subscribes to this policy and strongly encourages the use of the UFP-QAPP for Federal facility and other hazardous waste projects. QAPP requirements apply to all environmental data operations conducted by Regional staff or through grants, cooperative agreements, contracts, Interagency Agreements and compliance orders.

Project Managers/Project Officers shall ensure that QAPPs are developed and approved for all projects under their authority. The decision to

approve or reject a QAPP is based on the Project Manager/Project Officer's technical expertise and comments received from Regional QA experts.

The title(s) of the individual(s) responsible for the review of QAPPs shall be documented in all Division/Office QMPs. All individuals' assigned responsibility for QAPP reviews shall be knowledgeable of *EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations*, EPA QA/R-5, March 2001 and/or *Uniform Federal Policy for Quality Assurance Project Plans* (UFP-QAPP), EPA-505-B-04-900A, March 2005 and have completed the Region's required training for Project Managers/Project Officers. These individuals should also have professional knowledge of chemical and biological principles, theories, practices and established methods, statistical techniques commonly used in quality control, data assessments, and data management practices. Extensive knowledge of the principles and practices of quality assurance and the ability to adapt these applications to Agency programs is also required. The *Region III QAPP Preparation Checklist* (Appendix D) developed by the EAID/OASQA QA Staff may be used for this review.

The QAPP approval shall be formally documented in accordance with procedures specified in the approved Division or Office QMP. The status of a QAPP may be:

Approved	The document was found to address the key QA issues satisfactorily.
Conditionally Approved	The document satisfactorily addressed most of the key elements; however, minor deficiencies were noted. Sampling and analysis may begin while these minor deficiencies are being resolved.
Resubmission Required	The document was found to be deficient in describing the key elements. Further clarification of specific issues is required. Modification to specific procedures that may influence data quality should be accomplished prior to approval of the plan and initiation of the data collection activity.

Once all critical issues have been addressed, the Project Manager/Project Officer shall indicate QAPP approval via signature or approval memorandum; ensure it is implemented as written; and include a copy in the project file. For continuous projects, the QAPP must be reviewed annually by the authoring organization. Annual review shall be documented in the organization's annual report to the Regional QA Manager. Additionally, the QAPP must be revised and submitted to EPA for review every three to five years, based upon the original approval date, to ensure that the documented procedures are still accurate. Revisions to the approved QAPP shall be documented in a second or subsequent revision or an addendum. Sometimes the scope of a project can change which may have the potential to affect the quality of the data. If these changes are significant (as determined by the Project Manager/Project Officer) and affect the scope and objectives of the project, data use, or data quality; the revised QAPP or addendum must be reviewed and approved in the same manner as the original QAPP. The Project Manager/Project Officer is responsible for ensuring all appropriate personnel receive a copy of the revised QAPP or addendum once it is approved.

B.3.c. Generic, Master or Program Quality Assurance Project Plans

For multiple projects or sites with the same objective(s) and/or environmental decision(s), a Generic or Program QAPP may be desirable and appropriate. A Generic or Program QAPP shall adhere to the QAPP requirements specified in Section B.3.b. The Generic or Program QAPP shall include the elements which remain constant among the different projects or sites. Most Generic or Program QAPPs will be supported by a site-specific or project-specific plan which addresses the QA elements that are unique to each site or project. The Generic or Program QAPP shall include the procedures being used for the preparation, review, and approval of the site-specific or project-specific plan. If the site-specific or project-specific plan contains analytical and/or sampling procedures that are not found in the Generic or Program QAPP, the site-specific or project-specific plan must be reviewed in accordance with the procedures documented in the appropriate Division/Office QMP and Section B.3.b of this QMP.

The appropriateness of a Generic or Program QAPP is determined on case-by-case basis by the Project Manager/Project Officer in cooperation with the RQAM, RQAO, QAC or QA Staff. The Project Manager/Project Officer shall ensure that the approved Generic or Program QAPP is reviewed annually for changes to organization, policy, and/or procedures and updated every three to five years. Any minor changes can be appended to the original document. Substantial changes require that the document be resubmitted to EPA for review and approval.

B.3.d. 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 QA Coordinator and managers of the applicable programmatic division/office.

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 must indicate the measures the organization proposes to implement to assure their internal Quality 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 must concur with the delegation request.

A delegated approval organization shall have a Quality System Assessment (QSA) conducted of the organization by EPA with participation by the organization's QA manager (or equivalent). 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 must verify that the requesting organization's quality system is in conformance with its own approved QMP and with *CIO Quality Policy 2105.0 (EPA Order 5360.1 A2)* and that the quality practices of the organization are suitably and effectively implemented. This assessment shall be led by the RQAM, or designee, with assistance from the applicable programmatic division/office.

A delegated approval 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 Program/Project Managers and the QA Coordinator. Program/Project Managers responsible for QAPP review shall assure this competency exists by review of previously submitted QAPPs.

Non-EPA organizations shall request the delegation of QAPP approval authority from the Regional QA Manager. The RQAM will notify the QA Coordinator of the programmatic division/office, who will coordinate the assessment with appropriate Program/Project Managers. If the delegation is deemed acceptable by the RQAM, QA Coordinator and Program/Project Managers, 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 RQAM. 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.

B.3.e. Secondary Use of Environmental Information or Data

Secondary use data is defined as data that is collected for other purposes or from other sources, such as literature, industry surveys, compilations from computerized databases and the results from computerized or mathematical models of environmental processes and conditions.

Prior to its use, environmental data collected from secondary sources shall be evaluated to ensure a level of quality that is commensurate with its intended use(s). The Project Manager/Project Officer is responsible for ensuring that such data collection is addressed in a project-specific QAPP, if applicable. The project QAPP shall:

- √ Identify the types of data needed for project implementation or decision making;
- √ Describe the intended use of the data;
- √ Define the acceptance criteria for the use of data (see B.4.a. for characteristics that should be considered);
- √ Specify any limitations on the use of the data;
- √ Identify the individual(s) responsible for evaluating and qualifying the data.

For those projects which involve the compilation and use of environmental data from secondary sources exclusively (i.e., there are no direct environmental data generation performed to accomplish the project), a project-specific QAPP is still required. Per the graded approach, the level of detail for this QAPP will differ from that for a direct environmental data generation project. Assistance with determining the appropriate elements for a QAPP for projects involving secondary use data are available on the Region III QA Website. The Project Manager/Project Officer is responsible for ensuring a QAPP is prepared for these types of environmental data projects.

B.4. INFORMATION QUALITY GUIDELINES

The *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the EPA*, 260R-02-008, December 2002, or more commonly known as the IQGs, contain EPA's policy and procedural guidance for ensuring and maximizing the quality of information the Agency disseminates and complements EPA's Quality System for assuring the quality of EPA's products and information. This QMP incorporates by reference all definitions, principles, policies, and procedures found in EPA's IQGs.

"Information" generally includes any communication or representation of knowledge, position or policy such as facts or data, in any medium, or form. This includes "preliminary" information endorsed or adopted by EPA, and also conclusions or facts drawn from or based upon other existing information.

The Region will ensure that EPA disseminated information products are presented in an accurate, clear, complete and unbiased manner. The Region will also ensure that the integrity of EPA Region III web sites will be protected from unauthorized access or revision.

B.4.a. Assessment Factors

Following promulgation of the Data Quality Act of 2001 and the issuance of EPA's Information Quality Guidelines in October 2002, the EPA Science Policy Council developed guidance entitled *Assessment Factors, EPA 100/B-03/001, June 2003*. The intent of the guidance is to enhance the transparency of EPA's quality expectations for information that is voluntarily submitted, gathered, generated, or used by EPA to evaluate the quality and relevance of scientific and technical information regardless of its source. The five assessment factors are applied to data that come into the Agency from outside sources or existing data that the EPA wishes to use on a secondary project (i.e., B.3.e. above). The five assessment factors are:

1. Soundness - *Based on valid reasoning. The information is founded on thorough knowledge or experience; and marked by showing common sense and good judgment.*
2. Applicability and Utility - *The extent to which the information is relevant and useful for the Agency's intended use.*
3. Clarity and Completeness - *Having all necessary and normal parts.*
4. Uncertainty and Variability - *Uncertainty refers to the inability to know for sure and is often due to incomplete data. Variability is the amount of fluctuation; having no fixed quantitative value.*
5. Evaluation and Review - *Evaluation is the act of examining and determining the value. Review is the consideration, inspection, or reexamination of a subject or thing.*

Region III organizations are expected to develop and use a Quality Assurance Project Plan (QAPP), or an equivalent form of documentation, to document the procedures used in the review and analysis of existing scientific and technical information. The QAPP, or its equivalent, shall include a description of the type and quality of information needed for a specific decision or use, it shall establish the acceptance criteria or quality determinations against which

the information will be evaluated, and it shall document the review and analysis process for the five assessment factors (i.e., B.3.e above). Finally, the QAPP shall describe how the outcomes (or results) of the review and analysis process will be documented and reported. The graded approach also applies to documentation.

While the assessment factors are not a regulation, do not create any legal rights, or impose requirements on EPA or the information-gathering public, the assessment factors do summarize commonly used principles underlying EPA guidelines, policies, and practices.

B.4.b. Implementation Policy and Procedures

In accordance with EPA's IQGs, Region III has established policies and procedures for complying with these guidelines (Appendix E) with emphasis on using existing Regional processes or procedures wherever possible. The Region III Information Quality Guidelines Officer works with communications and web coordinators in each division when an information product is proposed to be disseminated.

B.4.c. Requests for Correction

The IQGs allow for affected persons to request correction of information if that information does not comply with EPA or Office of Management and Budget (OMB) Information Quality Guidelines. The Office of Environmental Information (OEI) Quality Staff will receive the requests for correction (RFC) and forward them to the Region III IQG Officer when the information in question belongs to or involves Region III. The IQG Officer will then work with the OEI Quality Staff and the information owner to formulate a response. A schematic for the RFC process is attached as Figure 4.

B.4.d. Requests for Reconsideration

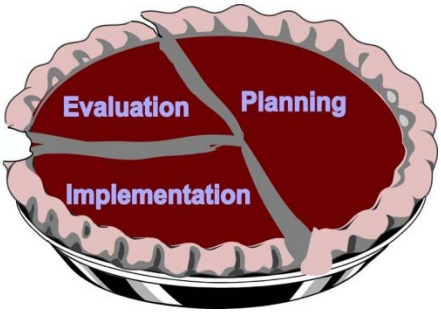
Affected persons may appeal EPA responses to RFC's under a formal Request for Reconsideration (RFR). When an RFR is received for a Region III product, the IQG Officer will work with the information owner and the OEI Quality Staff on the response. This process is depicted in Figure 5.

B.4.e. Pre-Dissemination Review

The review process is intended to ensure the quality of products the Region disseminates. Pre-dissemination review should begin at the planning stage for information products. Region III programs may use one or more review processes to satisfy pre-dissemination review as specified by EPA's Pre-dissemination Review Guidelines. Region III programs may also use the *EPA Region III Information Quality Guidelines Pre-Dissemination Review* document which is included as Appendix E. This document contains the Region's checklist for pre-dissemination of information.

SECTION C: IMPLEMENTATION OF WORK PROCESSES

The implementation of the procedures specified in this section shall ensure that all environmental data operations being conducted within the Region conform to the requirements found in this QMP, *CIO Quality Policy 2105.0 (EPA Order 5360.1 A2)* and *CIO Procedure 2105-P-01.0 (EPA Quality Manual, 5360 A1)*. These procedures are currently being implemented at the program and project level.



The Quality System PIE

C.1. PROGRAM IMPLEMENTATION

C.1.a. Regional Quality Management Plan

Annually, the Region III Quality Management Plan (QMP) shall be reviewed by the Regional Quality Council (RQC) to ensure that the documented QA policies and procedures are current and accurate. The Region III QMP shall also be reviewed whenever there is a major reorganization or there are significant policy and/or procedural changes that impact the Region's Quality System. In addition, every five years, based upon the original approval date, the Region III QMP will undergo a more in-depth review. If revisions are required, the RQC shall revise the QMP and distribute it to Senior Managers for review and approval. After the QMP has been approved by the Regional Administrator, it shall be delivered to the Director of the OEI Quality Staff for review and approval. Upon final approval, a copy of the QMP will be filed with each Regional Division/Office via the Region III intranet and/or shared directories on the Regional local area network and to external organizations through the Region III internet site. An e-mail announcement about the newly approved Region III QMP shall be sent to all staff from the RQAM.

C.1.b. Division/Office Quality Management Plans

Similarly, each Division or Office QA Coordinator shall review his/her organization's QMP. Minor changes to the QMP will be documented in the Division/Office's annual report. Significant policy and/or procedural changes require revision to the QMP and submission to the RQAM for approval. After the Division/Office QMP has been approved, the QA Coordinator shall distribute the newly revised Division/Office QMP to managers and supervisors. Older versions of Division/Office QMPs shall be removed from circulation.

C.1.c. Quality Management Plans for Extramural Agreement Holders

The Region is responsible for ensuring that its contractors, grantees, and other partners have and implement Quality Systems of their own that will be sufficient to ensure that their environmental data operations fulfill the Region's needs.

For larger organizations, this means that they must develop and implement Quality Management Plans of their own, demonstrating their organization's commitment to quality,

describing their organizational roles and responsibilities, and their internal systematic planning process. The RQAM, in consultation with the QA Coordinators and Project Officers, will determine which organizations shall be required to submit QMPs. The Region's policy is that all submitted QMPs must conform to *EPA Requirements for Quality Management Plans,* EPA QA/R-2, March 2001. Approved QMPs for extramural projects shall be updated every five years, or whenever there are major organizational changes that impact the documented quality system. Extramural agreement holders are required to review their QMP annually and report the outcome of the review in their annual report. If revisions are required, the revised QMP shall be resubmitted to EPA Region III for review and approval in accordance with the procedures specified in Section A.8.c. The QMP Status Report is used to document the approval status of QMPs for extramural projects.

C.1.d. Quality Assurance Annual Report and Work Plan

Annually, the Region shall submit a Quality Assurance Annual Report and Work Plan (QAARWP) to the Director of the OEI Quality Staff. The QA report will summarize the QA-related resources, training, accomplishments (i.e., innovative practices, technical assessments, QMP revisions, QA guidance, technical assistance, etc.) and quality system assessments/audits that have been conducted in the previous fiscal year. The QAARWP will also include a list of QA activities planned for the upcoming fiscal year. Each Division or Office that is a part of the Region's Quality System shall provide its information to be compiled into a Region-wide report. The QAARWP will be prepared according to Chapter 4 of the most current version of the *CIO Procedure 2105-P-01.0 (EPA Quality Manual, 5360 A1)* by the RQAM with cooperation from the QA Coordinators and OASQA Quality Staff. The QAARWP will also be used to identify minor changes or updates to Region III's QMP. The QAARWP will be distributed to the RQC for concurrence. Prior to its distribution to the Director of the EPA OEI Quality Staff, the report shall be reviewed and approved by the Regional Administrator or his/her designee.

C.2. PROJECT IMPLEMENTATION

C.2.a. Quality Assurance Project Plans

Once final approval has been received, the Project Managers/Project Officers shall ensure that all project personnel have a copy of the newly approved QAPP. The Project Manager/Project Officer shall also ensure that obsolete versions of the QAPP are removed from work areas. Verification of the changes to the QAPP shall be determined during a project's technical system audit. The approved QAPP must be implemented as prescribed; however, the QAPP may be modified and/or amended at any time to ensure project objectives are met. Modifications and/or amendments to the QAPP must follow the appropriate submission and approval procedures outlined in Section B of this QMP.

C.2.b. Standard Operating Procedures

A Standard Operating Procedure is a set of written instructions that document a routine or repetitive activity that shall be followed.

The use of Standard Operating Procedures (SOPs) serves as a mechanism to ensure comparability across programs and individual environmental data operations. SOP use is encouraged as a means of ensuring that routine or repetitive activities, processes or procedures are performed consistently within acceptable timeframes and with acceptable quality. SOPs can describe both technical and administrative operational elements. SOPs will thoroughly describe steps and techniques, and will be sufficiently clear to be understood by a person with knowledge in the general concept of the procedure or process without interpretation or assumption. Any limitation on the use or applicability of a specific SOP will be documented in the SOP itself.

The need for an SOP for a specific activity or operation can be identified by any staff member in the Region, and can be written by any Regional staff member who is knowledgeable of the activity, equipment, procedure, or process to be addressed. However, Program Managers responsible for the routine use of the specific procedure in conducting day-to-day activities are responsible for updating, approving, withdrawing, and archiving SOPs. It is the responsibility of the individual users of an SOP to follow the procedures contained in the SOP or to document any deviations. Deviations to current procedures must be justified and documented. Program Managers are responsible for ensuring that SOPs are implemented appropriately and deviations are documented. Program Managers can use a variety of mechanisms to accomplish this, including direct oversight of work being performed, comparability of work products between staff, and results of assessments. Outdated SOPs are withdrawn from work areas and archived when no longer relevant.

The RQAM, FOG Coordinator(s), QA Coordinators and/or QA Staff may also identify the need for standardized procedures through quality system assessments and technical system audits, which identify areas of inconsistency that would benefit from standardized procedures. When this occurs, the QA personnel recommends the development of SOPs as a corrective action.

The primary guidance document for the preparation of SOPs in Region III is entitled, *"Guidance for the Preparation of Standard Operating Procedure"*, EPA QA/G-6, April 2007. All SOPs shall be reviewed and approved by the manager of the organization within the respective Division/Office originating the SOPs and by the Division/Office QAC or his/her designee. All SOPs will be reviewed every three years or periodically, as specified in the respective Division/Office QMP. Detailed procedures/processes for SOP development, review, approval, revision and withdrawal are further documented in each Division/Office QMP. The RQAM, or designee, shall ensure that the procedures each organization conducting environmental data operations uses to develop, review, approve and implement SOPs are found in its respective QMP.

C.2.c. Inspection and Oversight of Facilities and Work Processes

Compliance inspections occur at active municipal, industrial and/or federally owned facilities. These inspections are primarily focused on making compliance determinations based upon facility representative interviews, facility records and facility documents. However, samples may be collected to help identify whether a potential violation exists.

The vast majority of sampling conducted during compliance inspections would be considered "opportunistic" sampling. These sampling activities are not planned. The inspector makes a decision to collect samples as a result of observations made during the course of the inspection. If sampling is required, samples are collected in accordance with SOPs developed by the Office of Enforcement, Compliance and Environmental Justice (OECEJ) Field Inspection Program. For inspections being conducted to support criminal investigations, the Criminal Investigation Division (CID) investigator in charge of the case manages the sampling activities. CID investigators often rely on the technical expertise of the OECEJ field inspectors to help determine where to sample and how many samples to collect.

OECEJ field personnel rarely conduct sampling in support of the Region III Superfund program. However, when this type of sampling is required, OECEJ field personnel work closely with the Project Manager/Project Officer to ensure that all of the necessary sampling objectives are met. Prior to sampling, OECEJ field personnel familiarize themselves with the site's QAPP and/or Sampling and Analysis Plan (SAP). To the extent practicable, OECEJ field personnel ensure that their sampling activities are consistent with those specified in the site's approved QAPP and/or SAP. Any deviations between OECEJ sampling procedures and those specified in the sites approved QAPP and/or SAP are discussed with the Project Manager/Project Officer.

In addition to compliance related sampling, OECEJ field personnel routinely collect samples to support ambient water quality monitoring projects, such as TMDL and water quality standards investigations. For these types of sampling activities, the Region uses an approved generic SAP developed by the Pennsylvania Department of Environmental Protection (PA DEP) for ambient water quality monitoring projects.

Samples collected for compliance and multi-media inspections are transported to the OASQA Regional Laboratory. Occasionally, samples are shipped to a laboratory that is secured by the Region's Sample Brokerage. Analytical data reports are sent to the OECEJ inspector. The inspector shall be responsible for evaluating the analytical results and submitting a written report to the appropriate Region III Division/Office. The written report shall include the inspector's conclusions regarding the data and its regulatory implication.

C.3. FIELD OPERATIONS

A National Field Operations Group (FOG) exists under EPA's Regional Science and Technology (RS&T) Community and is charged with promoting national consistency among the Agency's field activities. The Agency relies heavily on environmental data to make sound decisions and, thus, has an obligation to ensure that reliable, accurate environmental data of known quality is generated and that the process of generating such data, from planning to implementation to reporting, is traceable and transparent.

C.3.a. FOG Operational Guidelines for Field Activities

The National FOG created consensus standards, the *FOG Operational Guidelines for Field Activities*, March 1, 2013, which are tailored around the requirements of EPA Quality Policy CIO 2105.0, *Policy and Program Requirements for the Mandatory Agency-Wide Quality System* and concepts of management systems established by the International Organization for Standardization (ISO). The Office of Environmental Information Quality Staff have developed the *EPA QA Field Activities Procedure*, CIO 2105-P-02.0, September 23, 2014 to incorporate the FOG Guidelines into the Agency's Quality System. A crosswalk between the FOG Guidelines, QMP requirements, and draft quality standards shows the similarities.

The FOG developed ten (10) operational guidelines for field activities to ensure consistency in managing field practices and to reduce potential vulnerabilities. The ten elements that make up the FOG Guidelines are:

1. Personnel and Training;
2. Document Control;
3. Records Management;
4. Evidence Management;
5. Field Documentation;
6. Field Equipment;
7. Field Inspections and Investigations;
8. Reports;
9. Internal Audits; and
10. Corrective Action.

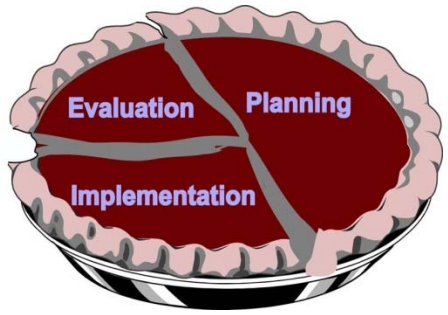
The FOG Guidelines apply to any field sampling, measurements, and observations used by EPA for any purpose, such as ambient monitoring, research, clean-ups, risk management, studying new/revised regulations, screening, compliance monitoring, and enforcement. The guidelines apply to all EPA programs that conduct field activities. These guidelines do not apply to EPA programs carrying out activities with the primary goal of education (e.g., demonstrations, volunteer educational monitoring).

C.3.b. Implementing the FOG Guidelines in Region III

The FOG Guidelines are an important and integral component of Region III's Quality System. A Region III Field Activities Council (RFAC) is evaluating existing regional processes against the FOG Guidelines to identify where the guidelines are satisfied and where work is required to meet the requirements.

Several sub-groups have been formed to develop, implement and assess SOPs for each of the 10 FOG elements. The Region is still working to develop these SOPs. Implementation and assessment will follow as described in the *Field Operations Guidelines Implementation Plan for EPA Region III*, November 14, 2013.

SECTION D: EVALUATION



The Quality System PIE

The Region uses a variety of tools (i.e., quality system audits, technical audits, etc.) to ensure that the procedures documented in this QMP are being implemented. These independent audits, reviews and assessments evaluate the conformance of the Region's Quality System with the procedures described in this QMP.

Annually, the RQC will assess the adequacy of QA resources and the level of expertise necessary to support the various programs in the Region. This assessment will evaluate the Region's environmental program activities to determine if the number and type of QA resources are adequate. The assessment will also evaluate the adequacy of intramural and extramural funding to determine if adequate funding is provided for QA-related activities. The results of this assessment will be documented in the Region's Quality Assurance Annual Report and Work Plan (QAARWP) described earlier. Region III Senior Leadership is responsible for making final decisions about the allocation of QA resources.

*Region III uses the terms **audit, review, assess,** and **evaluate** interchangeably.*

D.1. ASSESSMENT TOOLS

Selection of the appropriate assessment tool depends upon whether a quality system or technical system is being assessed. Technical system assessment tools are also dependent upon the stage of the project being assessed. The following table outlines the types of assessment tools that may be used in Region III.

Quality System Assessments

Level	Appropriate Tool	Comments
Assessment of Quality System	Quality System Assessment (QSA)	Assesses conformance to a documented quality system through collection of information and documented evidence of implementation.

Technical (Project-level) Assessments

Project Stage	Appropriate Tool	Example(s)
Planning	QA Project Plan Review; Site Scoping Meeting and/or Visit	QAPP Review; Peer Review
Sampling	Technical Systems Audit	Field Sampling Audit
Analysis	Technical Systems Audit	Laboratory (Field or Fixed) Audit; Proficiency Testing Sample

Project Stage	Appropriate Tool	Example(s)
Data Evaluation/Assessment	Data Audit	Data Audit Inspection; Data Verification and Validation
Data Usability	Data Quality Assessment	Data Quality Assessment; Usability Report; Peer Review

D.1.a. Reporting and Response

Assessments must, by definition, produce a written report which summarizes the assessment, states the findings, and, for certain types of assessments, provides recommendations for response actions. Without documentation in a final report, a site visit, evaluation, or other review is not considered an assessment.

The objective of the report is to communicate assessment results to the responsible level of management. Efficient communication of results allows management to implement timely, effective response actions so that the quality objectives can be met. Quality System Assessments are typically reported to senior managers of the organization responsible for the work. Assessments of project activities are reported to the EPA Project Manager. The EPA Project Manager may request a review of an audit report by the QA Staff.

Senior managers of the assessed organization are responsible for ensuring that any deficiencies found in Quality System Assessments are appropriately addressed. Project Officers and Project Managers are responsible for ensuring that findings from assessments of project activities are appropriately addressed.

D.1.b. Corrective Action

The principal responsibility for the implementation of corrective action is that of the assessed organization. A written response is provided by the assessed organization for all assessment findings with objective evidence of the effectiveness of the correction, and with specified time frames for those actions in progress or planned for the future.

The authority and responsibility for verifying the timeliness and effectiveness of corrective action resides with the senior management ultimately responsible for the work that was assessed. The responsible senior manager may request the assessors who conducted the assessment to verify the effective implementation of corrective actions. Assessment follow up is documented and reported using the same process as the original assessment

D.1.c. Dispute Resolution

If disputes are encountered as a result of assessments and related responses, the dispute resolution process as defined in Section A.5 of this QMP shall apply.

D.2. QUALITY SYSTEM ASSESSMENTS

Each year, the RQAM and RQC shall evaluate the Region's conformance with the *CIO Quality Policy 2105 (EPA Order 5360.1 A2)* and the *CIO Procedure 2105-P-01.0 (EPA Quality*

Manual, 5360 A1). Each October, the RQAM requests, compiles, and reviews information regarding Regional quality resources and activities, including: 1) quality management resources; 2) QA/QC training; 3) quality system-related accomplishments; and 4) assessments of quality and technical systems. For any area found to need improvement, an action plan is developed and incorporated in the QA Annual Report and Work Plan. The QAAWRP will summarize the findings of each QSA conducted during the previous fiscal year. A summary of corrective actions initiated as a result of these QSAs shall also be included. The RQC shall use these reports to inform decisions on the QA priorities for the following year.

D.2.a. Internal Quality System Assessments

It is the goal of Regional Quality Council to conduct an internal QSA of at least one division/office per year, and complete QSAs on all divisions/offices within a three year cycle. The RQAM and RQC are responsible for regional-level QSAs of each division/office. The RQAM shall be responsible for assembling the assessment team and coordinating activities. At a minimum, the team shall consist of the RQAM (or designee) and at least one member of the RQC. The team may also include a member of the OASQA Quality Assurance Staff and a representative from outside the program being assessed. The audited Division or Office's QA Coordinator shall assist the QSA Team in handling the logistics of the assessment and scheduling interviews.

Upon completion of the assessment, the preliminary results of the regional-level QSA shall be shared with the Division or Office's Senior Leadership during an exit briefing. Approximately 60 days following the QSA, the assessment team shall submit a written draft findings report documenting the results of the QSA to the Division or Office's Senior Management. Findings may include noteworthy accomplishments and/or objective evidence of non-conformance with the organization's quality system. The Division or Office shall review the draft findings report to ensure it accurately describes the QA procedures being implemented by their organization. The Division or Office shall then provide the assessment team with formal comments on the draft findings report. If the QSA team concurs with these comments, the findings report shall be revised and finalized. If concurrence with the formal comments cannot be achieved, dispute resolution specified in Section A.5 shall be used to achieve consensus on the content of the final findings report. The assessment team shall submit the final report to the Division or Office's Senior Management.

Upon receipt of the final findings report, the Division or Office shall prepare a written corrective action plan and submit it to the RQC. The Corrective Action Plan must identify the corrective action, responsible official(s), and the projected completion date for each finding requiring corrective action. Upon acceptance by the RQC, implementation may begin. The Division or Office's QA Coordinator and the RQC shall periodically review the status of the Division or Office Corrective Action Plans.

All members of the assessment teams shall be familiar with the QA requirements found in *CIO Quality Policy 2105.0 (EPA Order 5360.1 A2)* and this QMP. The individuals should also have professional knowledge of chemical and biological principles, theories, practices and established methods. Knowledge of the principles and practices of quality assurance and the ability to adapt these applications to Agency programs is also desired.

Information found in EPA's *Guidance on Assessing Quality Systems*, QA/G-3, March 2003 may be used in the development of the QSA. A standard checklist, developed by the RQAM (Appendix F), is used to help ensure that the appropriate QA requirements are evaluated during the QSA. During the QSA, managers and active participants in the organization's quality system are interviewed. Project files, previous audit reports and corrective action plans are also reviewed.

Likewise, it is the goal of each division/office to conduct a QSA of at least one program element within its division/office per year. More frequent review may be needed if serious deficiencies are detected. The respective division/office QAC and line managers are responsible for the assessments of program elements within the respective division/office. Assessments conducted at the division/office level follow similar procedures as discussed above, depending upon the program element assessed, with one exception. The RQC is not typically involved in the briefing, reporting, or corrective action processes. The RQC may be employed in the event of disputes. Further details on the procedures for planning, conducting, documenting, and reporting QSAs at the division/office level are documented in the QMP of each respective division/office.

D.2.b. Independent External Assessments

Independent assessments are conducted by the OEI Quality Staff, the Office of Inspector General, the Government Accountability Office, or Headquarters' Office personnel. The frequency of these assessments is determined by the office conducting the QSA. Every three years, the OEI Quality Staff conducts a QSA of the Region's Quality System. The QSA Team usually consists of members from the OEI Quality Staff and at least one person from another Region or EPA Headquarters Office. The scope of their assessment is determined by the OEI QSA Team. The RQAM and RQC shall assist the OEI QSA team by handling the logistics and scheduling interviews.

The findings of the OEI QSA are documented in a Draft Findings Report. After the Region's Senior Management and the OEI QSA Team reach consensus on the accuracy of the observations made in the QSA Draft Findings Report, the Findings Report is finalized. If corrective actions are required, the RQC with input from Senior Managers shall develop the Region's Corrective Action Plan. Milestones will be developed so that progress on corrective actions can be measured. This information will be included in the assessment file, which is maintained by the RQAM, or designee. Region III managers are responsible for ensuring compliance with the approved corrective actions. The RQC will periodically provide Senior Managers with information about the Region's progress on implementation of the Corrective Action Plan.

D.3. TECHNICAL SYSTEMS AUDITS

The goal of the technical systems audit (TSA) is to determine whether environmental data operations and related results comply with the project's QAPP and other planning documents. A TSA compares the implemented activity against the documented (i.e., QAPP, SOP, manual, etc.) activity. TSAs may also be used as an investigative tool when problems are

suspected. It is usually project-specific, and is usually conducted in the field or laboratory.

Grantees with approved QMPs may conduct TSAs of their own environmental data operations. In some instances, Region III is required by regulation to conduct TSAs of certain delegated program activities (e.g., state drinking water analysis laboratories and state ambient air quality monitoring networks). To maximize the efficient use of resources, Region III will often times combine the TSA with mid- and end-of-year program reviews. EPA remedial and field investigation team contractors are required to conduct TSAs of their own environmental data operations.

A technical systems audit is a systematic and objective examination of the facilities, equipment, personnel, training, procedures, record-keeping, data validation, data management and analysis, and reporting aspects of an environmental measurement system.

At a minimum, each QAPP shall include the scope and frequency of TSAs to be conducted during the life of the project. The QAPP shall also include the title(s) of individual(s) responsible for conducting the TSA and the procedures to be used to implement corrective actions. The QAPP reviewer shall ensure that information about TSAs is documented in the QAPP. The Project Manager or Project Officer is responsible for ensuring the specified TSAs are accomplished. The individuals conducting the technical system audit should be knowledgeable of the procedures being audited. These individuals should also have professional knowledge of chemical and biological principles, theories, practices and established methods. Extensive knowledge of the principles and practices of quality assurance and the ability to adapt these applications to Agency programs is also required.

All programs in the Region that employ environmental data operations are subject to a TSA. EPA's *Guidance on Technical Audits and Related Assessments for Environmental Data Operations*, EPA QA/G-7, January 2000 may be used as a resource for planning, conducting, evaluating and documenting technical systems audits and related assessments. The RQAM (or designee) shall ensure that a description of applicable TSAs is included in all QMPs and that all QMPs include the title(s) of the individual(s) responsible for conducting TSAs.

D.4. LABORATORY AUDITS

OASQA staff conduct assessments of laboratories that support the National Pollution Discharge Elimination System (NPDES) program and the Safe Drinking Water Act (SDWA) program. OASQA personnel may also conduct assessments of laboratories being used by some Superfund Potentially Responsible Parties (PRPs). Sample Brokerage personnel conduct assessments of laboratories that participate in the Contract Laboratory Program and the Regional laboratory contract procurement process. OASQA also performs inspections under the National Environmental Laboratory Accreditation Program (NELAP) for the review of Accrediting Bodies (AB).

D.4.a. National Pollutant Discharge Elimination System

OASQA staff conduct laboratory assessments of National Pollutant Discharge Elimination System (NPDES) permittees' and commercial laboratories analyzing compliance samples, as requested by the NPDES program in the Water Protection Division. Inspections are performed in partnership with the State Authority and may be announced or unannounced to the facility. The goals of these assessments are to:

- improve Discharge Monitoring Reports Quality Assurance (DMRQA) performance;
- provide technical assistance to States that have limited expertise in certain analytical methodology;
- improve analytical QA/QC procedures; and
- improve documentation procedures.

During the laboratory assessments, analytical procedures; sampling procedures; equipment; instrumentation; record keeping; documentation; analytical data and Proficiency Testing (P/T) sample results are reviewed. A Data Audit Inspection (DAI) may also be conducted. If routine problems are found in the P/T sample results, a more extensive tracking of P/T sample results will occur until successful performance is achieved. Laboratory assessment reports are completed within 30 days of the assessment and follow-up corrective actions are tracked (corrective action reports are required within 45 days of the assessment through the issuance of a Deficiency Notice). OASQA staff are responsible for tracking resulting corrective actions for NPDES permittee laboratories and commercial laboratories analyzing compliance samples. The procedures employed are described in *NPDES Self-Monitoring Data and Data Inspections DAIs*, EPA-903-R-94-043, Fall 1994.

A DAI consists of recalculating the results from unprocessed instrument results and comparing them to the results reported on the Discharge Monitoring Reports (DMRs).

D.4.b. Safe Drinking Water Act

OASQA performs laboratory inspections of Region III State Laboratories using procedures specified by the Agency's *Manual for the Certification of Laboratories Analyzing Drinking Water: Criteria and Procedures Quality Assurance*, Fifth Edition, EPA 815-R-05-004, January 2005 and the OASQA SOP, *On-site Laboratory Assessments in the Drinking Water Laboratory Certification Program*, R3-QA801.0, September 2001 (or most current version). The procedures for the Data Audit Inspections are similar to those described above. On-site assessments are conducted every three years and corrective actions are tracked and official certification update reports are issued. OASQA QA Staff are responsible for tracking resulting corrective actions. OASQA also performs reviews of the Region III State Safe Drinking Water Act (SDWA) Laboratory Certification Programs as per the laboratory certification manual. Every three years, the assessments and program are reviewed by the Office of Ground Water and Drinking Water through yearly questionnaires and on-site inspection.

D.4.c. Laboratories Used by Potentially Responsible Parties

OASQA personnel may conduct limited inspections of laboratories used by Region III Superfund Potentially Responsible Parties (PRPs). The Region III Hazardous Site and Cleanup Division (HSCD) and/or the Land and Chemicals Division (LCD) selects the PRP laboratories to be inspected, as needed. These laboratory inspections are conducted in accordance with the procedures found in the Standard Operating Procedure for *On-site Inspection of Superfund PRP Monitoring Procedures*, December 2000 (or most current version). The procedures for the Data Audit Inspections are similar to those described above. The PRP laboratory inspections include the review of P/T sample results; the site's QAPP and/or SAP; and the site's third party data validation reports. Prior to distribution of the laboratory inspection findings report to the appropriate HSCD or LCD Project Officer, the report shall be reviewed by the OASQA Quality Assurance Staff. OASQA QA Staff are responsible for tracking the resulting corrective actions for PRP laboratories.

D.4.d. Contract Laboratory Program

The Contract Laboratory Program (CLP) Project Officer conducts annual on-site audits of CLP laboratories located in Region III. These audits are conducted in accordance with procedures found in the applicable CLP Statement of Work. The national Contract Laboratory Program processes the data through an automated data assessment tool called the Electronic Data Exchange and Evaluation System (EXES). EXES is a complete data assessment package that incorporates Contract Compliance Screening (CCS) and data usability reviews to provide EPA Regions with electronic data usability and compliance reports, spreadsheets, and files within 24 to 48 hours from the receipt of data from laboratories. This automated tool facilitates the transfer of analytical data into Regional databases. In addition to the Regional electronic reports, the CLP laboratories are provided with a data assessment report that documents the instances of non-compliance. The CLP Quality Assurance and Technical Support (QATS) contractor performs data evaluation and review services. This three-step review process provides the CLP customer with data of known and documented quality.

When the data package is delivered to the Regional Sample Control Center, the package is subject to an evidentiary review to ensure the documentation for chain-of custody and sample handling procedures are present. It also undergoes a data validation process following the *National Functional Guidelines* (most current version), to further assess the quality and usability of the data.

The above described activities, as well as routine P/T samples, are used to assess a CLP laboratory's overall performance. Corrective actions from these laboratory checks are monitored by the Region III CLP Project Officer. Significant contract non-conformances are forwarded to the National CLP Program Manager and Contracting Officer for appropriate action. This action may include the rejection of data and/or a reduction in payment. Further information on the CLP Quality System can be found here: http://www.epa.gov/superfund/programs/clp/qaqc.htm.

D.4.e. Other Analytical Services

For the analysis of samples using non-CLP methods, the Region acquires commercial

laboratory capability and/or capacity via small purchase orders or regional contracts. Whenever possible, the Region will use accredited or certified laboratories. The use of accredited laboratories, provides the Region with access to information about the laboratory's performance (i.e., Proficiency Testing sample results, on-site audit reports, etc). Prior to contract award, laboratories not accredited, must provide a copy of their quality manual, which should include the laboratory's quality policy; a description of the laboratory facilities; a list of personnel with qualifications; measurement and calibration procedures; procedures for data review and corrective action procedures. For non-routine methods, the laboratory must also submit an initial demonstration of capability and method detection limit study for the non-routine method. OASQA evaluates the above quality documentation to determine the laboratory's competency and capability to conduct the requested analyses, in accordance with the *Policy to Assure Competency of Organizations Generating Environmental Measurement Data Under Agency-Funded Acquisitions*, Agency Policy Directive Number FEM-2011-01, March 28, 2011.

OASQA will conduct on-site audits of the regionally contracted laboratories where the Region has reason to believe data quality is suspect. The procedures identified above and contained in the applicable Statement of Work will be used to conduct these on-site audits. If applicable, the CLP on-site audit checklist may also be used for specific analytical fractions (i.e., volatiles, semi-volatiles, pesticides, metals, cyanide, etc.). The regionally contracted laboratory data is subject to the same evidentiary review and data validation procedures as CLP data. Corrective actions are monitored by the Region III Project Officer. If significant contract non-conformance is found, the Region III Project Officer may recommend rejection of the data and/or reduction in payment.

D.4.f. National Environmental Laboratory Accreditation Program

OASQA participates in inspections under the National Environmental Laboratory Accreditation Program (NELAP) for the review of Accrediting Bodies (AB). The procedures for conducting these inspections are documented in Chapter 6 of the *National Environmental Laboratory Accreditation Conference (NELAC)* standards. The results of the inspections are documented in a checklist. Findings are resolved with the ABs and the final reports are sent to the NELAP Board for final review and approval. The program's procedures, assessments and accreditation are reviewed annually by the NELAP Board as described in Chapter 6 of the NELAC standards.

D.5. PROFICIENCY TESTING SAMPLES

A Proficiency Testing (P/T) sample is used as a quantitative audit of analytical results generated by a measurement system. Whenever possible, the proficiency testing sample shall mimic the matrix of the routine field sample. The concentration of the P/T sample shall be unknown to the analyst. The results of the P/T sample are used to determine if a measurement system's results are within the measurement quality objectives specified by the Program (i.e., Superfund, CLP, Drinking Water, etc.) or found in the QAPP. The procedures being used for the acquisition and evaluation of proficiency testing samples shall be included in the QMP, Laboratory Quality Manual or project QAPP.

D.6. DATA VERIFICATION & VALIDATION

Data verification and data validation are key steps in the assessment phase. Data verification is the process of evaluating the completeness, correctness, and conformance/compliance of a specific data set against the method, procedural, or contractual requirements. The goal of data verification is to ensure and document that the reported results reflect what was actually done. Data verification may be performed by personnel involved with the collection of samples or data, generation of analytical data, and/or by an external data verifier. Some programs may require external data verification upon receipt of data packages to confirm the completeness of the data package and to permit authorization of payment for the work.

Data validation is an analyte- and sample-specific process that extends the evaluation of data beyond verification to determine the analytical quality of a specific data set. The goal of data validation is to evaluate whether the data quality goals established during the planning phase have been achieved. Data validation is typically performed by person(s) independent of the project activity. The appropriate degree of independence will be determined on a program specific basis. At a minimum, the individual(s) conducting the validation should not belong to the same organizational unit with immediate responsibility for producing the data set. Data quality indicators (such as precision, bias, comparability, sensitivity, representativeness, and completeness) are typically used as expressions of the quality of the data.

Personnel performing data verification and validation should have professional knowledge of chemical and biological principles, theories, practices and established methods, statistical techniques commonly used in quality control, data assessments, and data management practices. Extensive knowledge of the principles and practices of quality assurance and familiarity with the project-specific data quality indicators is also necessary. The specific procedures and title(s) of the individual(s) responsible for data verification and validation shall be included in the project's QAPP or SAP. Results of the data verification and validation shall be documented and provided to the Project Manager/Project Officer. EPA's guidance documents *Guidance on Environmental Data Verification and Data Validation*, EPA QA/G-8, November 2002 and *US EPA's Contract Laboratory Program National Functional Guidelines* may be used to conduct the data verification and validation processes.

D.6.a. Tiered Data Review

Region III follows a data evaluation system, in which the level of effort of the review increases with successive levels. The level is appropriate to project DQOs and financial and temporal resource constraints.

Level 1 is a relatively streamlined review of quality control (QC) information. Data review may be limited to reviewing reported QC results against acceptance limits, possibly using a software program, with no review of the raw data. The inherent risk of mischaracterizing data quality must be assumed to be acceptable for project needs.

In Level 2, a full data review is performed, including but not limited to method details, instrument printouts and logs, including calculation checks. Level 2 reviews are intended to

evaluate the legal defensibility of the data. For Superfund projects, Level 2 validation is performed using the *US EPA National Functional Guidelines* for organic and inorganic analyses generated through the Contract Laboratory Program (CLP). The guidance may be found here: http://www.epa.gov/superfund/programs/clp/guidance.htm. Although the guidance is used principally to validate Superfund data, it may be used in other programs.

The following table visually represents Region III validation level nomenclature which is consistent with the National Contract Laboratory Program's *Guidance for Labeling Externally Validated Laboratory Analytical Data for Superfund Use*.

NAME	SUMMARY	SUPERFUND STAGE	
INORGANIC LEVEL 1	QC, false negatives, detection limits	Stage 2B Validation Electronic and Manual	S2BVEM
INORGANIC LEVEL 2	CLP National Functional Guidelines w/R3 Modification (Use of 'B' qualifier)	Stage 4 Validation Electronic and Manual	S4VEM
ORGANIC LEVEL 1	QC, false negatives, detection limits	Stage 3 Validation Electronic and Manual	S3VEM
ORGANIC LEVEL 2	CLP National Functional Guidelines w/R3 Modification (Use of 'B' qualifier)	Stage 4 Validation Electronic and Manual	S4VEM

D.7 DATA QUALITY ASSESSMENT

A Data Quality Assessment (DQA) is the scientific evaluation of data to determine if they meet the planning objectives of the project, and thus are of the right type, quality, and quantity to support their intended use.

The scope of the DQA should be commensurate with the project objectives and intended use of the data. EPA's guidance documents *Data Quality Assessment: A Reviewer's Guide*, EPA QA/G-9R, February 2006 and *Data Quality Assessment: Statistical Methods for Practitioners*, EPA QA/G-9S, February 2006 may be used to conduct the DQA. The specific procedures to be followed for data quality assessments shall be included in the project's QAPP or SAP. The title(s) of the individual(s) responsible for the DQA process shall also be included in the project QAPP or SAP. The results of the DQA should be documented and provided to the Project Manager/Project Officer.

At a minimum, all environmental data shall be reviewed to ensure that the analytical measurement criteria specified in the approved QAPP has been achieved. Data shall be qualified in accordance with the data validation criteria specified in the approved QAPP.

D.8. PEER REVIEW

Peer review is intended to uncover any technical problems or unresolved issues in a preliminary work product through the use of independent experts. This information is then used to revise that draft product so that the final work product will reflect sound technical information and analyses. Peer review is a process for enhancing a scientific or technical work product so that the decision or position taken by the Agency, based on that product, has a sound, credible basis. To be most effective, peer review of a scientific and/or technical work product should be incorporated into the up-front planning of any action based on the work product - this includes obtaining the proper resource commitments and establishing realistic schedules. Peer review takes many different forms depending on the nature of the work product, relevant statutory requirements, and office-specific policies and practices. It is Region III practice that Project Managers/Project Officers, in consultation with their first line supervisors, senior managers and technical staff, will make the decision on whether his/her project should be peer reviewed and what level that peer review will take. When applicable, Region III follows the procedures and guidance found in EPA's *Peer Review Handbook, 3rd Edition*, EPA/100/B-06/002, 2006.

D.9. QUALITY IMPROVEMENT

The quality assurance procedures described in this QMP establish a foundation for ensuring that data of acceptable quality for its intended use will be used to make environmental decisions. One of the goals of the Region III Quality System is to incorporate quality assurance as a critical component of all the work functions within our programs.

All Regional personnel are encouraged to raise issues that impact the quality of data and information being generated and/or used by the Region. Issues should be raised to the designated Division or Office QA Coordinator. If these issues impact more than one Division or

Office, the QA Coordinator will facilitate a discussion of the issue during the scheduled RQC meeting. Based on these discussions, the RQC will make a recommendation to Senior Management about ways to resolve the issue and improve the Region's Quality System. If the issue requires immediate action, it will be forwarded to the Senior Management Representative to the RQC. The Senior Management Representative to the RQC will then determine the appropriate mechanism to resolve the issue. Whenever possible, the RQC will be involved in discussions about issues that impact the Region's Quality System.

SECTION E: INFRASTRUCTURE

E.1. QUALIFICATIONS AND TRAINING

> ***Region III Policy***
>
> *It is Region III's policy to provide the training necessary to ensure that all persons involved in handling environmental data understand the Region's Quality System.*

All Regional personnel involved with environmental data operations shall be required to have the appropriate QA training. It shall be the responsibility of the Directors of all Region III Divisions and Offices to ensure that the individuals in their organizations meet the minimum QA training requirements for their assigned activities. The following sections describe Region III's QA training program and the requirements for Regional personnel involved with environmental data operations.

E.1.a. Region III QA Training Program

The Region is committed to ensuring that all personnel have the necessary skills to effectively accomplish the tasks that have been assigned. To facilitate this process, it is imperative that all individuals involved with environmental data operations obtain information about EPA QA requirements and understand their QA roles and responsibilities.

Each Region III Division or Office shall determine their organization's QA training needs in accordance with the procedures specified in their Division/Office QMP. EPA's *Guidance for Developing a Training Program for Quality Systems*, EPA QA/G-10, December 2000 may be used as a tool for this exercise. Senior Managers must ensure that adequate resources are available to deliver QA training. Annually, the RQC shall review these QA training needs to determine if the training needs for Divisions and Programs are similar. When similar QA training needs have been identified, the RQC shall determine the feasibility of offering a Region-wide QA training course(s). The RQC shall then identify the most cost-effective method(s) to obtain Region-wide QA training.

The implementation of QA requirements for extramural agreements is a critical component of the Region's Quality System. Project Managers/Project Officers/Work Assignment Managers are responsible for assisting major assistance agreement holders obtain necessary QA-related training.

This section describes the recommended core Region-wide QA training courses, the program logistics, associated documentation and requirements. The Region is in the process of rebuilding its QA training program.

E.1.b. Courses

Table E.1 describes the core QA courses that are being developed and offered to Region III personnel and Region III state and local government agencies. More courses may be developed as additional training needs are identified.

Table E.1. Core Quality Assurance Courses

Course Title	Description
Region III Quality System Awareness	A detailed overview of the Agency's quality system requirements and how they are implemented in Region III.
Systematic Planning for Environmental Data Operations	This course shall provide an overview of systematic planning. During this course, participants will learn the elements of a systematic planning approach based on the scientific method.
Quality Assurance Project Plans	This course shall provide an overview of the twenty-four QAPP elements found in QA/R-5 and the UFP-QAPP. During this course, the need for systematic planning and EPA's graded approach to project plan development shall be emphasized. Based on the training needs of the audience, the course may either focus on how to write a QAPP or how to review a QAPP.
Field Operations	Under development
Data Evaluation	This course shall provide an overview of data validation and usability. Participants will acquire knowledge of 1) the importance of data validation; 2) Region III's data validation procedures; and 3) the usability of data against project objectives.
Information Quality Guidelines	Participants will acquire: 1) knowledge of the origin and intent of the 2001 Data Quality Act; 2) information on the implementation of EPA's Information Quality Guidelines (IQGs); 3) insight on managing IQG requests; and 4) appreciation of the impact of the IQGs on enhancing EPA's Quality System.
QA Refresher (On-line – under development)	A briefing on updates/changes to the quality system; required for Region III staff every 2 years to maintain QA proficiency.

E.1.c. Logistics

The Region III QA training program shall be administered through a collaborative effort between the Region's EAID and the RQC. Additional training support for non-routine topics may be provided by the OEI Quality Staff, other Regions, other Federal Agencies, local universities, contractors or professional organizations. When QA training is needed, Program Managers shall forward a training request to their Division or Office QA Coordinator, who is then responsible for bringing it to the attention of the RQAM and RQC.

E.1.d. Documentation of Training

After completion of each QA training course, attendees shall receive a certificate of

completion from the organization providing the training. For this reason, attendance at all courses shall be recorded. At the end of each fiscal year, the RQAM or designee shall provide a summary of the QA training courses that have been offered in the Region in the QA Annual Report and Work Plan. This summary shall include, but is not limited to the courses offered, the number of attendees and a list of all non-EPA participating organizations.

E.1.e. Training Requirements

Table E.2 illustrates the required QA-related training courses by functional role/title.

R3QMP001-09212015

Table E.2. Training Requirements by Functional Role/Title

		Region III Quality System Awareness	Systematic Planning for Environmental Data Operations	Quality Assurance Project Plans	Field Operations (Under development)	Data Evaluation	Quality System Assessments	Information Quality Guidelines	Refresher
Regional Administrator & Senior Leadership		X (briefing only)			X (briefing only)			X (briefing only)	
Program Managers (Associate Directors / Branch Chiefs / Section Chiefs / Team Leaders)		X		X	X	X		X	X
Project Managers / Project Officers / Contracting Officer Representatives / Work Assignment Managers / etc.		X	X	X	X	X		X	X
Regional QA Manager		X	X	X	X	X	X	X	X
Quality Assurance Coordinators		X	X	X	X	X	X	X	X
Field Operations Coordinator		X	X	X	X		X	X	X
Information Quality Guidelines Officer		X						X	X
Technical Services Branch	QA Staff	X	X	X	X	X	X	X	X
	Client Services Staff	X		X	X	X			X
Laboratory Branch		per current Laboratory Quality Manual							

E.2. PROCUREMENT AND FINANCIAL ASSISTANCE

E.2.a. Procurement – Contracts

The Contracts Branch within the Office of Policy and Management is responsible for developing and keeping current Regional purchasing policies and procedures. Quality assurance requirements for contracts are set forth in the *EPA Contracts Management Manual Chapter 46* and the *Federal Acquisition Regulation (FAR) 46.202-4 and 52.246-01*. All procurements originating in Region III must meet established administrative and quality assurance requirements in the latest editions of the:

- *Federal Acquisition Regulations, Part 13*
- *Acquisition Handbook*
- *Contracts Management Manual*

A Contracting Officer's Representative is a collective term to include: Project Manager, Project Officer (Technical & Administrative), Site Assessment Manager, Remedial Project Manager, On-Scene Coordinator and Work Assignment Manager.

In order to assure that contractually procured environmental data operations are scientifically valid, defensible, and of known precision and accuracy, Contract Project Officers, Contracting Officer Representatives, and Contracting Officers are responsible for adhering to EPA's *Guidance for Use of Higher-Level Contract Quality Requirements in Acquisitions*, Chapter 46, EPA Contracts Management Manual, April 7, 2004. Requirements include the QA Review Form, modified for Region III, as shown in Appendix B. The QA Review Form shall be completed and signed by the Project Manager/Project Officer. The Project Manager/Project Officer signature indicates that the agreement clearly describes the item or service needed and that associated technical and quality requirements are defined. The RQAM reviews and signs the QA Review Form to assure that all environmental data operations contractually funded by EPA are in compliance with *CIO Policy 2105.0 (EPA Order 5360.1 A2).* Where QA requirements apply, the Contracting Officer will assure that quality assurance terms and conditions are included in contract statements of work. The quality assurance term and condition requires contractors to document its quality system in a Quality Management Plan and submit quality assurance project plans or appropriate planning documents that meet EPA program-specific project goals and objectives. The EPA Project Manager/Project Officer will assure that the contractor complies with the conditions and deliverables.

Region III Policy

Contracts procured by the Region III Contracts Branch involving environmental data operations shall require submission of a QMP, prepared in accordance with the specifications provided in the most current version of EPA Requirements for Quality Management Plans, QA/R-2, March 2001, along with the proposal.

The QMP documents and describes the quality system implemented by the applicant. The QMP shall be reviewed and approved by the EPA Contracting Officer, the EPA Project Manager/Project Officer, and the RQAM as described in Section A.8.c of this QMP as a condition for award of any contract involving environmental data operations. The

QMP shall be submitted as part of the application.

If the QMP is not submitted as part of the application and EPA decides to award the contract, EPA will include a term and condition in the contract. This term and condition requires the recipient to submit the QMP within a specified time after award of the contract and notifies the recipient that they may not begin work involving environmental data operations until the EPA Contracting Officer informs them that the QMP has been approved.

The contractor shall also be required to submit QAPPs to EPA for review and approval by the EPA Project Manager/Project Officer according to the procedures described in Section B.3.b of this QMP prior to undertaking any work involving environmental data collection or use.

Region III typically employs the use of contract vehicles procured at the headquarters level; however, when a contract originates at the regional level and involves the generation and/or use of environmental data, the RQAM or an individual knowledgeable in QA (e.g., a member of the Quality Assurance Staff or the division/office Quality Assurance Coordinator) may be included as part of the Technical Evaluation Panel (TEP) to evaluate the satisfaction of technical and quality requirements. The TEP develops the evaluation criteria and the Statement of Work for the solicitation and performs the technical evaluation of offers. Ultimately, the Project Manager/Project Officer is responsible for ensuring that procured items and services conform to specifications and needs of the program prior to payment as well as throughout the life of the contract or purchase. The quality requirements of the items or services to be purchased for a given program are defined in its Division/ Office QMP. The quality requirements of the items or services to be purchased for a given project are defined in the project QAPP, SOP or other planning document. When program needs/requirements change and the changes affect the technical specifications of the required goods and services, these changes need to be documented in the applicable QMP, QAPP, SOP or other planning document prior to initiating additional purchases or change orders.

E.2.a.1. Simplified Acquisitions

> ***Region III Policy***
>
> *Procurement of environmentally related measurements or data generation which qualifies as small purchases under the Federal Acquisition Regulations (FAR) is subject to QA requirements.*

Procurements qualifying as simplified acquisitions must meet established administrative and QA requirements of the Federal Acquisition Regulations (FAR), Federal Information Resources Management Regulations (FIRMR), Delegation 1-84 (1200 TN310), Office of Information Resource Management (OIRM) Delegation 1-10A (September 27, 1991), ARM's EPA Acquisition Regulations, and Chapters Four and Six of OIRM's *Information Resources Management Policy Manual*, July 1987 and *Region III Order 5361.5, Site Location Identification Policy and Responsibilities*. Bankcard, blanket purchase order, and federal supply schedule procurements involving environmental data operations will adhere to the above Region III requirements.

E.2.a.2. Procurement of Analytical Services

Procurement of analytical services obtained through the Region's Sample Brokerage, including the Superfund CLP, Headquarters' non-Routine Analytical Services (non-RAS) contracts, and regionally awarded contracts are subject to QA requirements.

In order to request analytical services, the requester, usually a Project Manager/Project Officer, must produce an approved QAPP or SAP. The QAPP or SAP includes information such as project objectives, number of samples to be collected and analyzed, parameters of interest, reporting limits, and other QA requirements. The QAPP and/or SAP are used to develop the analytical requirements for the procurement, which are incorporated into the Analytical Request Form. The Analytical Request Form and instructions can be found at http://www.epa.gov/region3/esc/labservices.htm.

When the analytical requirements are approved, Sample Brokerage personnel, in consultation with the requester, apply the Field and Analytical Services Team Advisory Committee (FASTAC) process to determine the most appropriate mechanism to acquire the data. The data may be acquired via one of the following mechanisms in the order presented:

1. EPA Regional Lab
2. CLP lab
3. Regional contract
4. Field contractor subcontract

If data are to be acquired via # 3, Regional contracts, Sample Brokerage personnel create a bid solicitation form that incorporates the approved analytical requirements. The bid solicitation is distributed to participating commercial laboratories for price quotations. Participating laboratories must provide the most current version of their Quality Manual for review. The lab's Quality System, as documented in the Quality Manual, is assessed to ensure that it conforms to the requirements found in the most recent version of ISO 17025, NELAC Chapter 5 or ANSI/ASQC Q2-1991. If the laboratory's documented quality system is acceptable, the laboratory's solicited bid is considered.

All environmental data acquired through the Sample Brokerage are reviewed to determine whether it meets the analytical requirements specified in the QAPP/SAP and analytical request. Remedies, including request for additional information, data qualification, and/or payment penalties may be applied to data that does not conform to requirements. See Section D.4.e. for additional information regarding acceptance criteria for participating laboratories.

E.2.a.3. Competency Policy for Acquisitions

In 2011, the Agency issued the *Policy to Assure Competency of Laboratories, Field Sampling and Other Organizations Generating Environmental Measurement Data under Agency-Funded Acquisitions*. The intent of the policy is to ensure that all recipients of government funding taking environmental measurements evaluate and attest the competency of the laboratories they use or plan to use.

Recipients of EPA contracts that include taking environmental measurements: 1) are required to submit a Quality Management Plan (QMP) for EPA Region III QA review and approval; and 2) must submit documentation of laboratory competency. Documentation of laboratory competency shall comply with Q12, Q13 or Q14 of the Competency Policy's accompanying *Frequently Asked Questions for Acquisitions* document and may be submitted with the QMP or, if not practicable, with the project-specific QAPP prior to beginning any work involving the generation or use of environmental data under the agreement. This policy became effective for implementation on March 28, 2011.

E.2.b. Financial Assistance

E.2.b.1. Grants and Cooperative Agreements

Region III Policy

All applicants for grants or cooperative agreements involving environmental data operations shall submit a QMP prepared in accordance with the specifications provided in the most current version of the EPA Requirements for Quality Management Plans, EPA QA/R-2, March 2001.

EPA quality assurance requirements for grants and cooperative agreements are contained in 40 CFR 30 for universities and other non-profits and 40 CFR Parts 31 and 35 for state, tribal, and local governments.

The QMP documents and describes the quality system implemented by the applicant. The EPA Project Manager/ Project Officer will ensure the agreement clearly describes the item or service needed and that associated technical and quality requirements are defined. The Project Manager/Project Officer will also indicate on the Funding Recommendation whether the project involves environmental data operations. If it does, EPA will insert a term and condition in the grant or assistance agreement per the *Region III Quality Assurance Requirements for Grants and Cooperative Agreements*, November 7, 2000 (Appendix A). The term and condition requires the recipient to submit the QMP within a specified time and notifies the recipient that they may not begin the work involving environmental data operations until the QMP has been approved by the EPA RQAM.

A condition will also be included in the assistance agreement requiring the recipient to submit a QAPP to EPA for review and approval by the EPA Project Officer prior to the initiation of projects involving environmental data operations. The QAPP shall be prepared in accordance with the specifications provided in the most current version of the *EPA Requirements for Quality Assurance Project Plans*, EPA QA/R-5; which describes the quality assurance and quality control activities to be implemented for the work involving environmental data operations.

The Grants Specialist will assure that the terms and conditions are included in the assistance agreements where QA requirements apply. The EPA Project Manager/Project Officer will assure that the grantee complies with the conditions. On a monthly basis, the RQAM reviews notifications of newly awarded grants, cooperative agreements and IAs to determine whether QA requirements were appropriately addressed. The results of this review

is tabulated and distributed to the Division/Office QA Coordinators for follow-up.

For certain financial assistance agreements, a combined QMP/QAPP may be supplemented for the individual QMP and QAPP document(s). The appropriateness and content of the combined QMP/QAPP shall be determined by the Project Manager/ Project Officer in consultation with the RQAM, or designee. At a minimum, the combined QMP/QAPP shall adhere to the QAPP requirements specified in Section B.3.b. of this QMP.

E.2.b.2. Inter-Agency Agreements

> ***Region III Policy***
>
> *All inter-agency agreements with environmental data operations in which Region III funds, or participates, shall require an approved QMP, or equivalent document.*

When Region III is providing funds to another Federal organization, the organization receiving the funds is responsible for preparing the QMP or equivalent document. If the external organization's documented quality system meets the requirements found in the *EPA Requirements for Quality Management Plans,* EPA QA/R-2, March 2001 or the *Intergovernmental Data Quality Task Force: Uniform Federal Policy for Implementing Environmental Quality Systems,* EPA-505-F-03-001, March 2005, their QMP, or equivalent document shall be acceptable. If comparable QA procedures do not exist, the QA procedures agreeable to both parties must be negotiated for the Inter-Agency Agreements (IA). Before any environmental data operations can be performed, the external organization must have an approved QMP and QAPP (or equivalent documents) or successfully negotiated and acceptable to both parties. These QA requirements are in accordance with the specifications provided in *EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5, March 2001* or the *Intergovernmental Data Quality Task Force: Uniform Federal Policy for Quality Assurance Project Plans,* EPA-505-B-04-900A, March 2005, as appropriate.

In order to document compliance with the above policy, the EPA Project Manager / Project Officer shall indicate in the IA Program Decision Memorandum (Office Authorization for the Award) whether QA requirements apply. If yes, the EPA Grants Specialist will include a condition in the IA. The special condition notifies the other Federal agency that they must submit a QMP and QAPP to the EPA Project Manager/Project Officer and that EPA will review and concur on the QA documents (e.g. QAPPs, SAPs and Workplan).

After the IA is executed by both parties, it is the responsibility of the EPA Project Manager / Project Officer to assure that the recipient of the IA is in compliance with the QA condition(s).

E.2.b.3. Competency Policy for Assistance Agreements

In 2013, the Agency issued the *Policy to Ensure Competency of Organizations Generating Environmental Measurement Data under Agency Funded Assistance Agreements*. The intent of the policy is to ensure that all recipients of government funding taking

environmental measurements evaluate and attest the competency of the laboratories they use or plan to use.

Recipients of EPA assistance agreements that include taking environmental measurements: 1) are required to submit a Quality Management Plan (QMP) for EPA Region III QA review and approval; and 2) must submit documentation of laboratory competency. Documentation of laboratory competency shall comply with Q11, Q12 or Q13 of the Competency Policy's accompanying *Frequently Asked Questions for Agreements – Update 9/12/13* document and may be submitted with the QMP or, if not practicable, with the project-specific QAPP prior to beginning any work involving the generation or use of environmental data under the agreement. This policy became effective for implementation on October 1, 2013.

E.2.c. Evaluation of Deliverables

Project Managers / Project Officers establish the framework for monitoring the quality of items or services by incorporating inspection and acceptance criteria into contract statements of work or work plans for grants/interagency agreements. They are responsible for oversight and for ensuring that products delivered are complete, accurate and meet contract, grant, co-operative and interagency agreement requirements. Oversight of contractor QA-related products is accomplished mainly by the efforts of the RQAM, QA Staff and/or other designated technical specialists (e.g., QACs, risk assessors, hydrologists, etc.) as requested by the Project Manager / Project Officer.

E.3. DOCUMENTATION AND RECORDS MANAGEMENT

> *Records include all books, papers, maps, photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value in them. (44 U.S.C. Chapter 33, Sec. 3301).*

Maintaining important QA documents and records is a continuous process in the Region. This process serves as a vehicle for identifying quality-related documents and records requiring management control. Moreover, this process serves to assure that QA documents and records are accessible and protected in storage from damage and deterioration. Finally, the process ensures compliance with all statutory, contractual, and assistance agreement requirements for records from environmental programs, while providing adequate preservation of key records necessary to support the mission of the Region.

Region III adheres to the most recent version of the following legislation, regulations, guidance and policies as they pertain to program requirements:

> ***Region III Policy***
>
> *It is Region III's policy to adopt and implement all Agency-approved records management policies and guidance developed and/or directed by the Office of Administration and Resources Management, and the Office of Environmental Information.*

- 44 U.S.C. Chapter 31, *Records Management by Federal Agencies*;
- 44 U.S.C. Chapter 33, *Disposal of Records*;
- 18 U.S.C. Chapter 101, *Records and Reports*;
- Paperwork Reduction Act of 1995;
- OMB Circular A-130, *Management of Federal Information Resources*;
- 36 CFR Chapter XII, Subchapter B
- *Records Management Policy* (CIO Policy 2155.0), U.S. Environmental Protection Agency;
- Managing Cartographic and Architectural Records (Instructional Guide Series), National Archives and Records Administration (NARA);
- Managing Electronic Records (Instructional Guide Series), NARA;
- Federal Records Management Laws and Regulations, http://www.archives.gov/records-mgmt/laws/;
- *Disposition of Federal Records: A Records Management Handbook*, NARA Personal Papers of Executive Branch Officials: A Management Guide (Management Guide Series);

- Records Disposition Schedules, U.S. Environmental Protection Agency;
- *A User Guide for Getting Started in ECMS E-mail* Records, U.S. EPA; and
- USEPA Region III OASQA *Records Management Handbook Standard Operating Procedures*

The Enterprise Content Management System (ECMS) is the official EPA email management system. Region III began implementation of ECMS in 2007. Enterprise content management integrates technologies, tools, and methods in order to capture, manage, store, preserve, and deliver content across an enterprise. Future versions of ECMS are expected to allow the management of unstructured information including images, office documents, graphics, drawings, and print streams, as well as the new electronic objects such as Web pages and content, e-mail, video and rich media assets throughout the content's lifecycle.

The Project Manager / Project Officer is responsible for managing all project level quality-related documents and records (paper and electronic), including transmittal, distribution, retention, access, preservation (including protection from damage, loss, deterioration, theft or unauthorized removal), traceability, retrieval, removal of obsolete documents, and disposition, in accordance with the procedures specified in their Division/Office QMP. The Project Manager / Project Officer is also responsible for ensuring that records and documents accurately reflect completed work.

The RQAM, QACs and QA Staff are responsible for managing all regional and divisional quality-related policies and procedures, including transmittal, distribution, retention, access, preservation (including protection from damage, loss, deterioration, theft or unauthorized removal), traceability, retrieval, removal of obsolete documents, and disposition, in accordance with the policies and guidance listed above.

Each Division and Office is responsible for managing the custody and confidentiality of evidentiary quality-related documents and records in accordance with applicable regulations. Regional Records Center staff and resources are available to assist in carrying out these responsibilities.

Further information about ECMS and records management in general can be found on EPA Region III's intranet site, http://intranet.epa.gov/r3intran/oirm/recman.htm, and the EPA National Records Management Program website: http://intranet.epa.gov/records/index.htm. Region III staff may also contact their division/office records manager or the Region III Records Liaison Officer with requests for technical assistance and/or training.

E.3.a. Ensuring Documents and Records Accurately Reflect Completed Work

Each office is responsible for establishing and implementing procedures for ensuring consistency and technical accuracy of its work products. It is the Senior Leadership's responsibility to ensure that each Division/Office uses established procedures to ensure that disseminated information products are of adequate quality for their intended use and comply with EPA's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*, EPA/260R-02-008, October 2002 and EPA Region III's *Information Quality Guidelines Pre-Dissemination*

Review, PDR Version 1.1, July 2007.

E.3.b. Process for Establishing and Implementing Chain of Custody and Confidentiality Procedures

Each Division/Office is responsible for establishing and implementing chain of custody and confidentiality procedures, including confidential business information (CBI) as described in its respective QMP. It is the Program Manager's responsibility to ensure that required procedures and security are implemented and comply with current EPA policies.

E.4. COMPUTER HARDWARE AND SOFTWARE

The Environmental Protection Agency's ability to fulfill its mission is dependent upon a strong information technology infrastructure. Mission objectives rely on an infrastructure that is capable of supporting environmental information and dynamic communication among EPA offices. One of the most critical components of the EPA infrastructure is information technology. The hardware, software, and communications components that are encompassed by information technology form the foundation for environmental information and EPA-wide communication. The management of information technology, therefore, is critical to the success of the EPA.

The Office of Environmental Information (OEI) is responsible for managing the EPA's information technology infrastructure and components. In that role, OEI has established information technology standards to manage and ensure that information technology components integrate properly into the infrastructure.

E.4.a. Roles and Responsibilities

The Computer Services Branch (CSB) is responsible for local area and wide area network support; managing and operating the regional computer center; providing data communications services; personal computer planning and operational support; information technology security; and management of regional word processing support. CSB also participates in overall information management for the Region in cooperation with the Environmental Assessment and Innovation Division (EAID) and the Information Services Branch (ISB). CSB focuses on desktop applications when participating in information management activities.

ISB is responsible for the life cycle management of information systems (i.e., feasibility study, analysis, design, programming, implementation, testing, operations, maintenance and systems review). It provides management and operational support to the operating divisions for all information systems utilized by the region; and for managing and operating the Region III Library. ISB also participates in overall information management for the Region in cooperation with EAID and CSB for matters concerning information systems.

E.4.b. Region III Information Management Systems

All information management system development, improvements, and updates will comply with *Information Resources Management Policy Manual* CIO 2100 and will include a systematic and comprehensive dialogue among the data providers, data and system users, and system developers

prior to the design and installation of the system.

It is Regional policy to work closely with information system customers, as well as OEI and National Program Offices, as appropriate, on all phases of system development, improvements, and updates, including contractor-developed systems and those developed by other entities. During all life cycle phases of information management systems, the Region will comply with requirements within the *Information Resources Management Policy Manual*, the *System Life Cycle Management Policy*, and the *System Life Cycle Management Procedure* located on the OEI Internet site: http://www.epa.gov/irmpoli8/policies/index.html. The goal of this process is to have a uniform approach and review of applications under consideration by Region III. The process will determine if an application has management support, IRM support, is doable in the time frame needed, and is within the resource constraints identified. Compliance with the applicable information resource management standards will ensure that all hardware and software configurations are tested prior to use, to guarantee they perform as expected and meet user requirements.

For information technology contracts that involve applications development, the performance work statement will include, but not be limited to, requirements for system specification reviews; system development plans; data validation and transfer; acceptance testing, and report generation.

E.4.c. Data Standards

All Federal agencies are required to adhere to Federally-mandated data standards and regulations. It is the policy of Region III to comply with all applicable regulations, guidance, executive orders, and internal policy documents concerning data standards. These include, but are not limited to:

- The National Institute of Standards and Technology develops standards and guidelines to achieve the most effective use of Federal information.
- The *Federal Information Processing Standards* (available at http://www.itl.nist.gov/fipspubs/) are the Federal data standards for all data exchange among agencies.
- The EPA Data Standards Program is established and documented in the *Data Standards*, CIO Policy 2133.0.

Within EPA, adherence to data standards policy is accomplished through the direction of OEI. EPA's data-related policies apply to all EPA organizations and personnel, including contractors, Senior Environmental Employee (SEE) Program participants, and other personnel assigned to EPA who design, implement, and maintain information management systems for Region III and EPA.

Some Regional Divisions/Offices have their own database administrators who coordinate activities relating to their associated databases. Since these databases are national databases, requirements are defined by the national program offices at headquarters. Regional data are collected, processed, and managed by the Division/Office Project Managers in accordance with Section B.3.e. of this QMP and their respective Division/Office-specific QMPs. CSB manages the hardware, software and networking platforms. CSB also coordinates with the program

offices on hardware and software issues, purchases and upgrades, and pilot programs.

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Figures

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Figure 1
EPA Region III Organization Chart

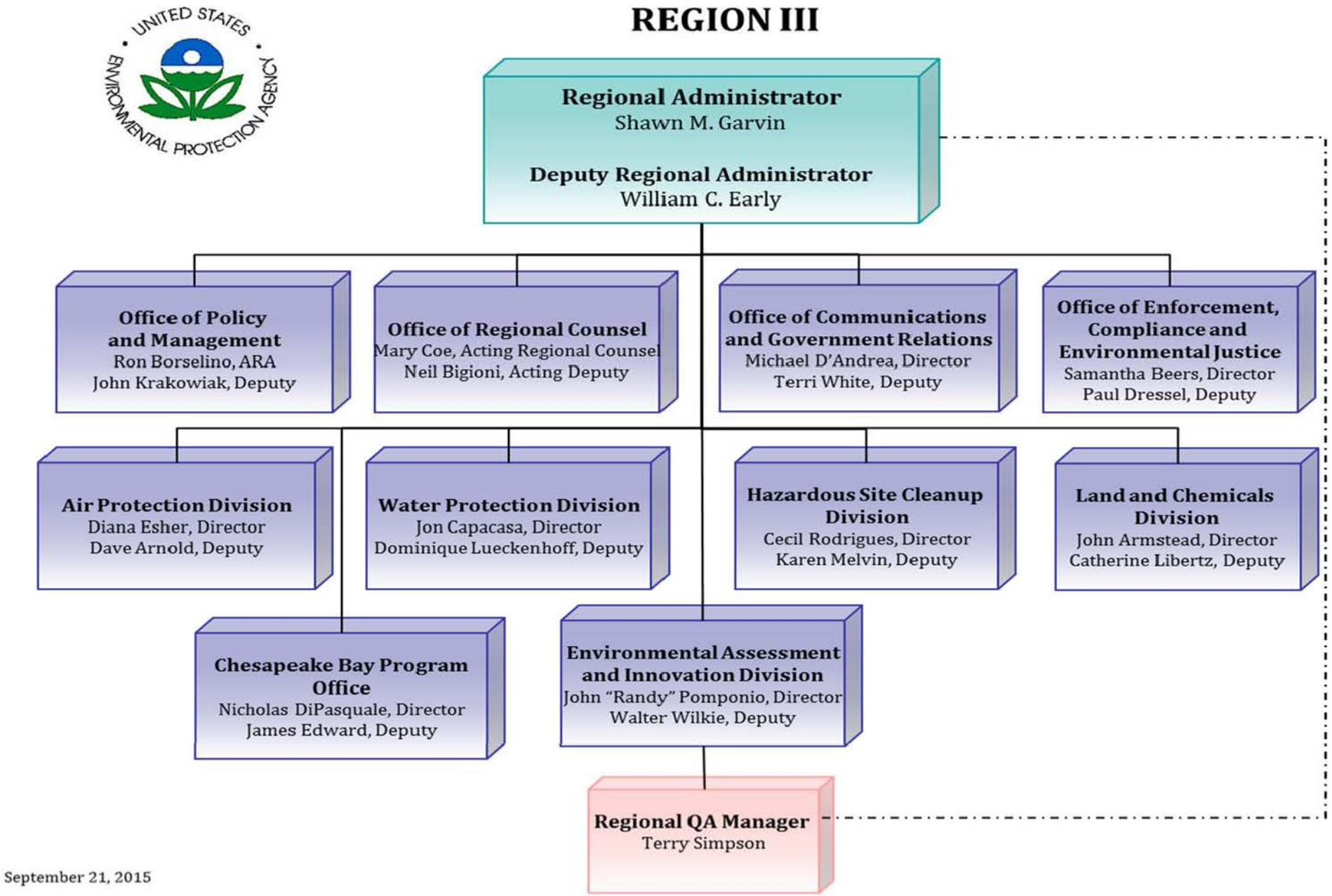


Figure 2
EPA Region III Organization Chart: QA Functional Responsibilities

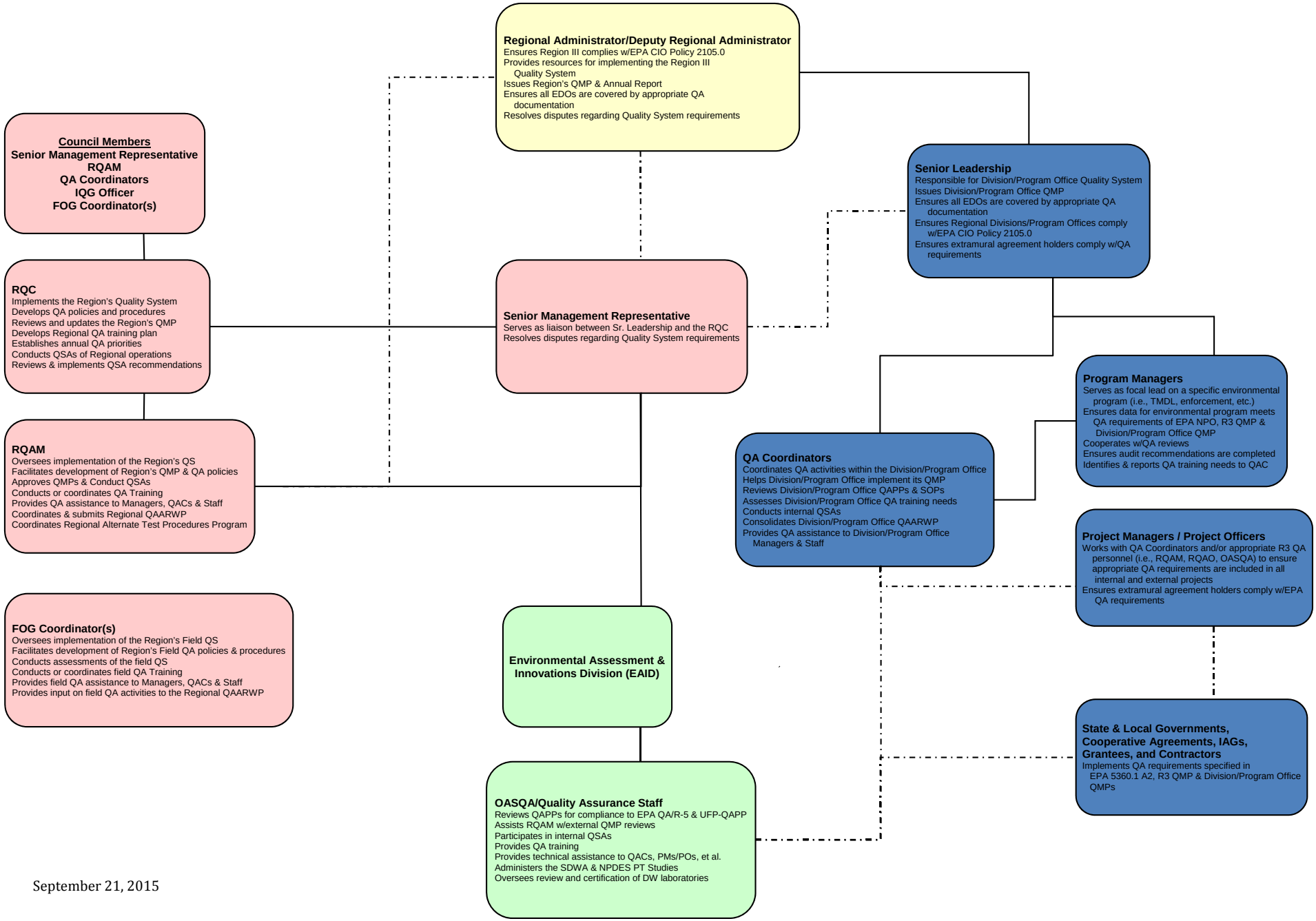


Figure 3
EPA IQG Request for Correction Process

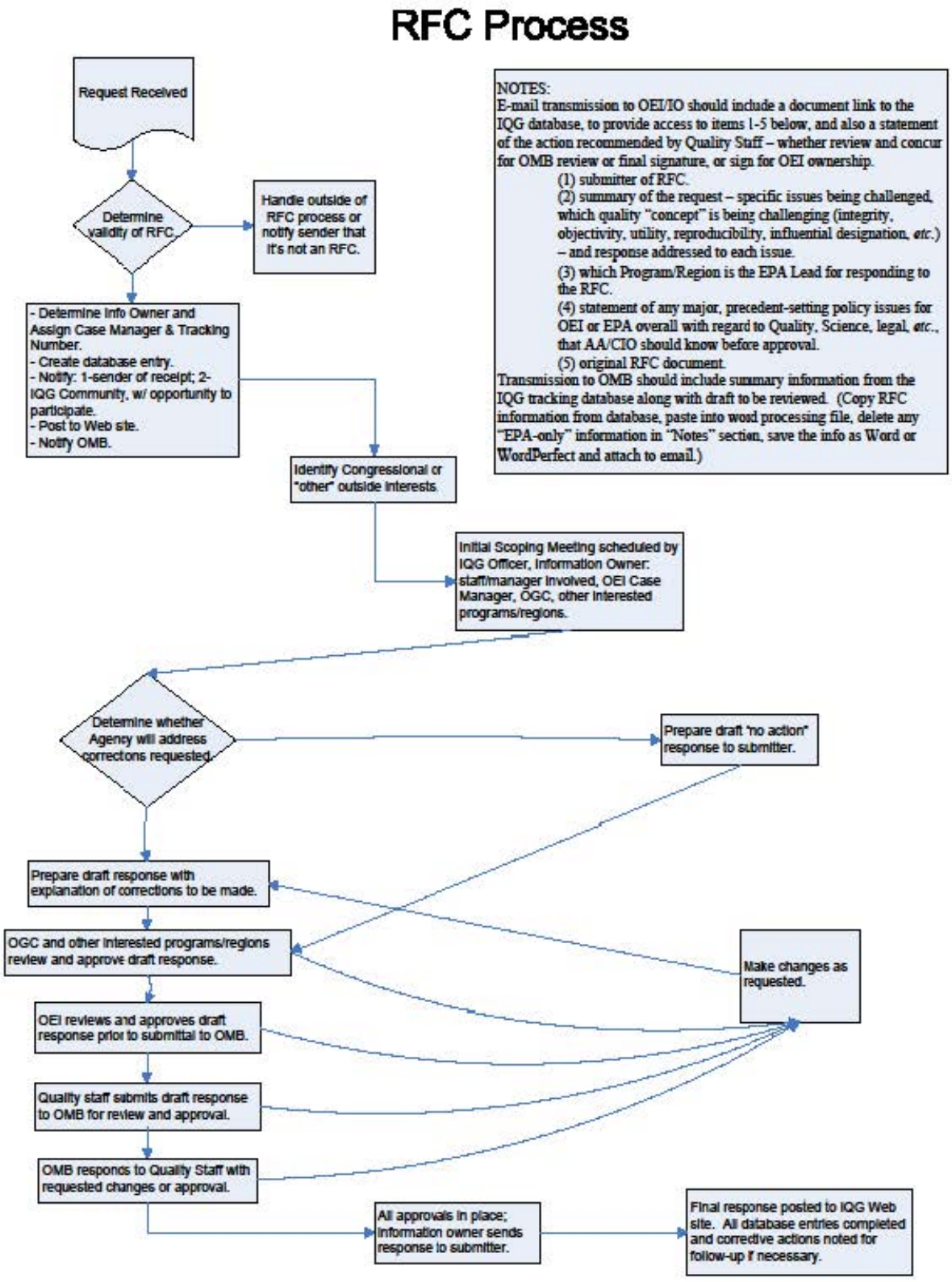
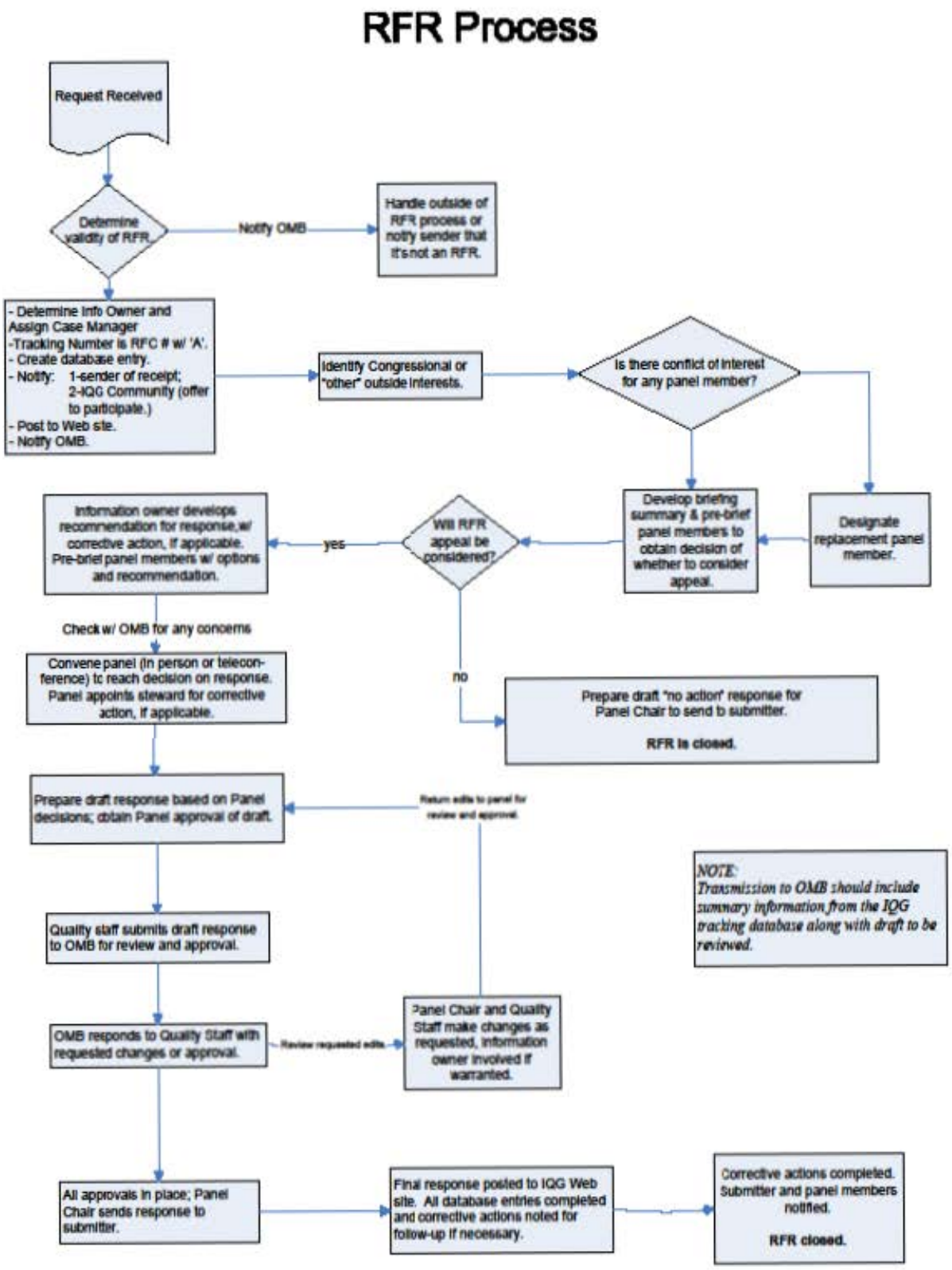


Figure 4
EPA IQG Request for Reconsideration Process



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Appendix A

Region III Quality Assurance Requirements for Grants and Cooperative Agreements

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
1650 Arch Street
Philadelphia, Pennsylvania 19103-2029

REGION III QUALITY ASSURANCE REQUIREMENTS FOR GRANTS AND COOPERATIVE AGREEMENTS
November 7, 2000

Quality Management Plan (QMP) Requirement

This QA requirement applies to all grants, cooperative agreements, contracts and interagency agreements that involve the use of environmental data. Environmental data is defined as direct measurements of environmental conditions or releases, such as sample collection and analysis. Environmental data also includes data collected from secondary sources of information, such as computer databases, computer models, literature files and historical databases. This data may be used for a variety of purposes, such as characterization of ecological effects, the health of human populations or the performance of environmental technology.

In accordance with 40 CFR 30.54 and 31.45, the recipient must develop and implement quality assurance policies and practices that are sufficient to produce data of adequate quality to meet program objectives. These policies and practices must be documented in a Quality Management Plan (QMP). The QMP should be prepared in accordance with EPA QA/R-2: EPA Requirements for Quality Management Plans. EPA QA/R-2 replaces EPA guidance document QAMS-004/80. The recipient's QMP should be reviewed and updated annually as needed.

Should there be multiple programs involved in a grant, cooperative agreement or interagency agreement, at the recipient's discretion, they may submit one of the following:

a. A single QMP covering all of the programs in the grant or agreement or

b. A separate QMP for each program receiving the grant or agreement funds.

For certain grants and agreements, the EPA Project Officer may allow the recipient to submit a combined Quality Management Plan/Quality Assurance Project Plan (QMP/QAPP). The minimum EPA requirements for a Quality Management Plan and a Quality Assurance Project Plan must be included in the combined QMP/QAPP.

The QMP or combined QMP/QAPP must be submitted to the EPA Project Officer at least 45 days prior to the initiation of data collection or data compilation. Prior to environmental data collection or data compilation, the QMP or combined QMP/QAPP must be approved by the EPA Regional Quality Assurance Manager.

Quality Assurance Project Plan (QAPP) Requirement

This QA requirement applies to all grants, cooperative agreements, contracts and interagency agreements that involve the use of environmental data. Environmental data is defined as direct measurements of environmental conditions or releases, such as sample collection and analysis. Environmental data also includes data collected from secondary sources of information, such as computer databases, computer models, literature files and historical databases. This data may be used for a variety of purposes, such as characterization of ecological effects, the health of human populations or the performance of environmental technology.

In accordance with 40 CFR 30.54 and 31.45, the recipient must develop and implement quality assurance and quality control procedures, specifications and documentation that are sufficient to produce data of adequate quality to meet project objectives. The Quality Assurance Project Plan (QAPP) is the document that provides comprehensive details about the quality assurance/quality control requirements and technical activities that must be implemented to ensure that project objectives are met. The QAPP should be prepared in accordance with EPA QA/R-5: EPA Requirements for Quality Assurance Project Plans. EPA QA/R-5 replaces EPA QAMS 005/80.

The QAPP must be submitted to the EPA Project Officer at least 30 days prior to the initiation of data collection or data compilation.

Prior to environmental data collection or data compilation, the QAPP must be approved by the EPA Project Officer. When the recipient is delegating the responsibility for an environmental data collection or data compilation activity to another organization, the EPA Regional Quality Assurance Manager may allow the recipient to review and approve that organization's QAPP.

QA Requirement for Lead Grants (Combined QMP/QAPP)

For lead grants, the recipient must develop a combined QMP/QAPP that meets the requirements found in the Region III Lead Program Quality Assurance Project Plan Guidance. A copy of this guidance document can be obtained from the Region III Hotline. The hotline number is 1 (800) 438-2474. The combined QMP/QAPP must be submitted to the EPA Project Officer at least 30 days prior to the initiation of data collection or data compilation. Prior to environmental data collection or data compilation, the combined Lead QMP/QAPP must be approved by the EPA Project Officer and the Land and Chemicals Division (formerly the Waste and Chemicals Management Division) QA Coordinator.

QA Requirement for Brownfields Cooperative Agreements (Combined QMP/QAPP)

For cooperative agreements awarded for Brownfields' projects, the recipient must develop QA documents that meet the requirements found in 40 CFR Part 30, Subpart O and the US EPA Quality Assurance Guidance for Conducting Brownfields Site Assessments. A copy of the US EPA Quality Assurance Guidance for Conducting Brownfields Site Assessments can be downloaded from the Internet at http://www.epa.gov/swerosps/bf/pdf/bfqag4.pdf.

In accordance with 40 CFR Part 30, Subpart O, the recipient must develop and implement quality assurance policies and practices that are sufficient to produce data of adequate quality to meet program objectives. Phase I environmental site assessments are non-intrusive, desktop studies which must be conducted in accordance with the most recent version of the American Society for Testing and Materials (ASTM) Practice E1527 (Standard Practice for Environmental Site Assessments: Phase I Environmental Site Assessment Process). E1527 identifies the practices that constitute all appropriate inquiry into the previous ownership and uses of the property consistent with good commercial or customary practice. Upon completion of the Phase I assessment, the recipient must submit a copy of the Phase I Report to the EPA Brownfields Project Officer or designated EPA Brownfields Project Representative.

If the EPA Brownfields Project Officer or designated EPA Brownfields Project Representative authorizes the initiation of a Phase II assessment, the recipient must prepare a combined QMP/QAPP. This combined QMP/QAPP must be prepared in accordance with the U.S. EPA Region III Generic Quality Assurance Project Plan (QAPP) Template. A copy of the US EPA Region III Generic Quality Assurance Project Plan Template can be obtained from the EPA Brownfields Project Officer, designated EPA Brownfields Project Representative or the Regional Quality Assurance Manager. At least 30 days before the initiation of the Phase II assessment, the recipient must submit the generic QAPP to the EPA Brownfields Project Officer or designated EPA Brownfields Project Representative. The EPA Brownfields Project Officer or designated EPA Brownfields Project Representative must approve the recipient's generic QAPP before the Phase II assessment begins.

In addition, at least 30 days before the initiation of any site sampling and analysis investigation, the recipient must submit a site-specific Sampling and Analysis Plan. This site-specific Sampling and Analysis Plan must meet the requirements found in the U.S. EPA Region III Site-Specific Sampling and Analysis Plan Template. A copy of the US EPA Region III Site-Specific Sampling and Analysis Plan Template can be obtained from the EPA Brownfields Project Officer, designated EPA Brownfields Project Representative or the Regional Quality Assurance Manager. Before sampling and analysis begins, the site-specific Sampling and Analysis Plan must be approved by the EPA Brownfields Project Officer or designated EPA Brownfields Project Representative.

Appendix B

Region III QA Review Form for Contract Actions

APPENDIX 46.1D U.S. EPA QUALITY ASSURANCE REVIEW FORM FOR CONTRACT ACTIONS
****** Modified for Region III ******

I. General Information

a. Vehicle Type:
[ ] Solicitation/Sole Source _____

[ ] Delivery Order/Work Assignment /Task Order
(SOW #: and Contract #:)

b. Descriptive Title: _____

c. Sponsoring Organization *(e.g., Branch, Division, Office, etc.)***:** _____
_____

d. Project Duration: _____

e. Is this a new [ ] or continuation of an existing [ ] project?

II. Scope of Work

[For example activities, see www.epa.gov/quality/examples.html.]

a. Does the work involve:	**Yes**	**No**
• the collection, generation, use and/or reporting of environmental data? (Environmental data are defined as any measurements or information that Describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.)	**[ ]**	**[ ]**
• design, construction, and/or operation of environmental technologies?	**[ ]**	**[ ]**
• development and/or use of models?	**[ ]**	**[ ]**
• other activities that need quality assurance or quality control	**[ ]**	**[ ]**
• requirements as identified in your organization↘s Quality Management Plan? If yes, list:_____.		

If all answers are No, skip Section III and complete Section IV.

b. Estimate of percentage of costs or level-of-effort allocated to the activities identified above: _____ %

III. Quality-Related Requirements

[Where applicable, reference a specific section of the Statement of Work.]

a. For Solicitations Only *[complete (b) - (f) below, as well]*

1. Insert the percentage of technical evaluation points assigned to offeror's quality system documentation, or P/F if the evaluation is pass/fail: _____

2. List any quality standards (from your organization's Quality Management Plan) that you will use in lieu of, or in addition to, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs* (ANSI/ASQC E4).

   Title: EPA Requirements for Quality Management Plans
   Numbering: EPA QA/R-2
   Date: March 2001
   Requirements (Tailoring): Submit QMP to RQAM for review & approval. Prior to the initiation of environmental data activities, the contractor's QMP and QAPP must be approved. The recipient's QMP shall be reviewed and updated annually, or more frequently as needed.

   Title: EPA Requirements for Quality Assurance Project Plans
   Numbering: EPA QA/R-5
   Date: March 2001
   Requirements (Tailoring): Submit QAPP to Project Officer for review & approval. Prior to the initiation of environmental data activities, the contractor's QMP and QAPP must be approved. QAPPs that are developed for multiple projects and/or span over one year shall be reviewed and updated at least annually.

   Title: Region III Quality Assurance Requirements for Grants and Cooperative Agreements
   Numbering:
   Date: November 7, 2000
   Requirements (Tailoring):

b. QA Documentation Options: *[For solicitations, complete items 1-4; for all actions other than solicitations, complete items 3-4. All documentation specified under "Other" must be defined in your organization's Quality Management Plan and be consistent with requirements defined in EPA Manual 5360 A1. For items checked under #2, there must be adequate information in the SOW for the offeror to develop this documentation.]*

Before Award Documentation[1]

[1] QMP refers to a Quality Management Plan. Programmatic QA Project Plan refers to a QA Project Plan that would cover multiple projects with similar activities. R-2 refers to EPA Requirements for Quality Management Plans

1. ___Documentation of an organization's Quality System: Either **[ ]** QMP developed in accordance with R-2 or **[ ]** Other: _____.

   ___ Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by contract: Either developed in accordance with **[ ]** R-2 and R-5 or **[ ]** Other: _____

2. ___ Programmatic QA Project Plan: Either developed in accordance with R5 or **[ ]** Other:_____

   ___ Application of QA and QC activities to the single project covered by contract: Either **[ ]**QA Project Plan developed in accordance with R-5 or **[ ]** Other: _____

   ___ Not applicable.

After Award Documentation [1]

3. ___ Documentation of an organization's Quality System: Either **[ ]** QMP developed in accordance with R-2 or **[ ]** Other: _____

   ___ Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by the contract: Either developed in accordance with **[ ]** R-2 and R-5 or **[ ]** Other: _____

   ___ Not applicable.

4. ___ Documentation of the application of QA and QC activities to applicable project(s): Either developed in accordance with **[ ]** R-5; **[ ]** A supplement to the following Programmatic QA Project Plan ; or **[ ]**Other: _____

   ___ Programmatic QA Project Plan with supplements for each specific project: Developed in accordance with: _____

   ___ Existing documentation of the application of QA and QC activities will be used: Either **[ ]** Documentation developed pre-award; **[ ]** Documentation will be identified in individual Statements of Work or **[ ]** Documentation identified in Section ____ of the Statement of Work.

c. Reports: Are quality reports or reports containing quality assurance information (for example, status of quality system implementation, review of a quality system, quality

(QA/R-2) (EPA/240/B-01/002, 03/20/01) and R-5 refers to EPA Requirements for Quality Assurance Project Plans (QA/R-5) (EPA/240/B-01/003, 03/20/01) – copies of these documents are available at www.epa.gov/quality.

control data, etc.) required? **[X] Yes [ ] No**

If yes, identify the required reports and the time frame for submission:
Indication of annual review and update of QMP and/or QAPP(s) shall be reported in the contractor's annual report of performance.

d. Assessments: Select all quality assessments that will be performed either pre-award or post-award:

	Pre-Award	**Post-Award**
• On-site evaluation of offeror's/contractor's facility	**[ ]**	**[ ]**
• Assessments of the offeror's/contractor's Quality System (e.g., quality system audits, management system reviews, etc.)	**[ ]**	**[X]**
• Project-specific assessments (e.g., technical systems audits, surveillance, performance evaluations, data quality assessments. peer reviews, readiness reviews)	**[ ]**	**[X]**

For each assessment, specify type, date to perform, and who will perform it (if known):

- On-Site Evaluation - To be performed by the CO/PO with the assistance of other qualified EPA personnel as requested, annually, or more frequently if deemed necessary.

- Quality System Assessment - To be performed by the CO/PO with the assistance of other qualified EPA personnel as requested, annually, or more frequently if deemed necessary.

- Project-Specific Assessments - To be performed by the CORs (the Work Assignment Managers) on a routine basis for all sites/projects that each COR manages. Annually, the CORs will also prepare Performance Evaluations for each Site/Project that received Contractor support. These evaluations will be provided to the PO to be included in the Contractor's Annual Performance Evaluation.

e. Procedures to Update Documentation: Identify any procedures/requirements for updating EPA-approved quality-related documentation:
The recipient's QMP shall be reviewed and updated annually, or more frequently as needed. QAPPs that are developed for multiple projects and/or span over one year shall be reviewed and updated at least annually. Minor organizational and/or policy changes shall be reported to EPA per requirements in III.c. above.

f. Other Requirements: Identify any other pertinent quality-related requirements (as identified in your organization's Quality Management Plan):
Prior to the initiation of environmental data activities, the contractor's QMP must be

approved by the RQAM, the QAPP must be approved by the Project Officer.

IV. Approvals

The signatures below verify that the Statement of Work has been reviewed to ascertain if quality assurance or quality control activities are needed and that the appropriate quality requirements have been established.

Contracting Officer's Representative	Date	Quality Assurance Manager	Date

Appendix C

US EPA Region III Quality Management Plan Review Checklist

US EPA REGION III
QUALITY MANAGEMENT PLAN
REVIEW CHECKLIST

Organization:		Contact:		Phone Number:	
EPA Organization:		EPA Contact:		Phone Number:	
EPA Program:		EPA Contract/Grant/IAG Number:			

Reviewer:		Reviewer Organization:			Phone Number:	
Date Reviewed:		Check One:	New Plan:	Revised Plan:	Response to Comments:	

Recommendation:	Acceptable:	Acceptable w/comments:	Unacceptable w/comments:

Key: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

US EPA REGION III
QUALITY MANAGEMENT PLAN
REVIEW CHECKLIST

MANAGEMENT AND ORGANIZATION	A	U	NI	NA	SECTION	COMMENTS
1. Is there an approval page for signatures of senior managers, senior line management (as appropriate) and the QA manager?						
2. Has management established and implemented a quality policy to ensure that the environmental program produces the type and quality of results needed and expected?						
2a. Does the policy discuss the importance of QA/QC activities and why?						
2b. Does the policy include general objectives and goals of the quality system?						
2c. Does management provide adequate resources and assign sufficient authority and independence to staff to enable them to plan, implement, assess and improve the organization's quality system?						
3. Is there an organizational chart that identifies all relevant organizations, functional responsibilities, levels of accountability and authority, and lines of communication?						
4. Does the organizational chart document the independence of the QA Manager from the groups generating environmental data?						
5. Is there a discussion of the responsibilities and authorities of the QA Manager? Does the QA Manager report to senior management on quality issues?						
6. Is there a discussion of the technical activities or programs that are supported by the quality system?						
6a. Does the plan discuss where oversight of delegated, contracted, or other extramural programs is needed?						
6b. Does the plan identify where internal coordination of QA and QC activities among organizations is needed?						
7. Does management ensure that the applicable elements of the quality system are understood and implemented in the environmental program(s) under their authority?						

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US EPA REGION III
QUALITY MANAGEMENT PLAN
REVIEW CHECKLIST

8. Does the document describe the process for resolving disputes?						
9. Does the document state that when physical changes in the organization and/or changes in policy occur, the QMP will be updated to reflect this information?						
QUALITY SYSTEM AND DESCRIPTION	A	U	NI	NA	SECTION	COMMENTS
1. Does the document include a description of the quality system?						
1a. Does the document describe the principal quality system components (e.g., quality system documentation, annual reviews and planning, management assessments, training, systematic planning, project specific quality documentation, project & data assessments) and how they are implemented?						
1b. Is there a list of tools for implementing each component (e.g., QMPs, Quality Systems Audits, Training Plans, QA Project Plans, Data Assessment)?						
1c. Does the description of components includes the responsibilities of management and staff?						
PERSONNEL QUALIFICATIONS AND TRAINING	A	U	NI	NA	SECTION	COMMENTS
1. Does the document contain a policy statement regarding QA training for management and staff?						
2. Is there a process for identifying, ensuring, and documenting that personnel have and maintain the appropriate knowledge; skill; and statutory, regulatory, professional or other certifications, accreditations, licenses?						
3. Does the document describe the process for identifying the need for quality-related retraining based on changing requirements?						

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US EPA REGION III
QUALITY MANAGEMENT PLAN
REVIEW CHECKLIST

4. Does the document include roles, responsibilities, and authorities in its description of the above processes?						

PROCUREMENT OF ITEMS AND SERVICES	A	U	NI	NA	SECTION	COMMENTS
1. Does the document describe or reference the process for reviewing and approving all extramural agreements (grants, cooperative agreements and contracts)?						
1a. Does the review process ensure documents are complete and accurate?						
1b. Does the review process ensure agreements clearly describe the item or service needed?						
1c. Does the review process ensure agreements describe the associated technical and quality requirements?						
1d. Does the review process ensure agreements describe the quality system elements for which the supplier is responsible?						
1e. Does the review process ensure that the supplier's conformance to the customer's requirements will be verified?						
2. Does the document describe the process to ensure procured items and services are acceptable?						
3. Does the document describe the process for review and approval of suppliers' quality-related documentation (e.g., QA Project Plans and QMPs)?						
4. Does the document describe the process to ensure EPA extramural agreement policies are satisfied?						
5. Are the roles, responsibilities, and authorities of managers and staff included in the description of the above processes?						

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US EPA REGION III
QUALITY MANAGEMENT PLAN
REVIEW CHECKLIST

DOCUMENTS AND RECORDS	A	U	NI	NA	SECTION	COMMENTS
1. Does the document describe the process for identifying quality-related documents (i.e., SOPs, QAPPs, MSRs, etc.) and other project-related records (both paper and electronic) requiring control?						
2. Does the document describe the process for preparing, reviewing, approving, issuing, using, authenticating, and revising documents and records?						
3. Does the document describe the process for ensuring that records and documents accurately reflect completed work?						
4. Does the document describe the process for maintaining documents and records; including transmittal, distribution, retention, access, preservation, traceability, retrieval, removal of obsolete documentation, and disposition?						
4a. Have retention times for records been established based on contractual and statutory requirements? If not, has management specified appropriate retention times?						
4b. While in storage, are records protected from damage, loss and deterioration?						
5. Does the document describe the process for ensuring documents and records comply with all applicable statutory, regulatory, and Agency policies?						
6. When evidentiary records are involved, are appropriate chain of custody and confidentiality procedures established and implemented?						
7. Are the roles, responsibilities, and authorities of managers and staff included in the description of the above processes?						

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US EPA REGION III
QUALITY MANAGEMENT PLAN
REVIEW CHECKLIST

COMPUTER HARDWARE AND SOFTWARE	A	U	NI	NA	SECTION	COMMENTS
1. Does the document describe the process for developing, installing, testing, using, maintaining, controlling, and documenting computer hardware/software used in environmental programs to ensure that it meets user requirements?						
2. Does the document describe the process for assessing and documenting the impact of changes to user requirements and/or the hardware and software on performance?						
3. Does the document describe the process for evaluating purchased hardware and software to ensure it meets user or contractual requirements?						
4. Does the document describe the process for ensuring that data and information produced from or collected by computers meet applicable information resource requirements and standards?						
5. Are the roles, responsibilities, and authorities of managers and staff included in the description of the above processes?						
PLANNING	A	U	NI	NA	SECTION	COMMENTS
1. Does the document describe the process for planning environmental data operations using a systematic planning process, such as EPA's Data Quality Objectives Process?						
1a. Does the planning process include identification and involvement of all project personnel, scientific experts, customers and suppliers?						
1b. Does the planning process include a description of the project goal, objectives, and questions/issues to be addressed?						

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US EPA REGION III
QUALITY MANAGEMENT PLAN
REVIEW CHECKLIST

1c. Does the planning process include identification of project schedule, resources, milestones, and any applicable requirements?						
1d. Does the planning process include identification of the type and quantity of data needed and how the data will be used to support the project's objectives?						
1e. Does the planning process include specification of performance criteria for measuring quality?						
1f. Does the planning process include specification of needed QA and QC activities to assess the quality performance criteria?						
1g. Does the planning process include a description of how, when, and where the data will be obtained (including existing data) and identification of any constraints on data collection?						
1h. Does the planning process include a description of how the acquired data will be analyzed, evaluated, and assessed against its intended use and the quality performance criteria?						
2. Does the document state that the results of the systematic planning process will be documented in a Quality Assurance Project Plan, or equivalent?						
3. Does the document describe the process for developing, reviewing, approving, implementing, and revising QA Project Plans?						
4. Does the document state that an environmental data operation cannot begin until there is an approved Quality Assurance Project Plan, or equivalent?						

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US EPA REGION III
QUALITY MANAGEMENT PLAN
REVIEW CHECKLIST

5. Does the document describe the process for evaluating and qualifying previously collected data and other information that will be used to make project decisions?						
6. Are the roles, responsibilities, and authorities of managers and staff included in the description of the above processes?						
IMPLEMENTATION OF WORK PROCESSES	A	U	NI	NA	SECTION	COMMENTS
1. Does the document state that work shall be performed according to approved planning and technical documents?						
2. Does the document describe the process for ensuring that work is performed according to approved planning and technical documents?						
3. Does the document list the source and title of Standard Operating Procedures (SOPs) that are being used for routine, standardized and critical operations?						
3a. Does the document describe the process for preparation, review, approval, revision, and withdrawal of SOPs?						
3b. Does the document describe the policy for use of these procedures?						
4. Does the document describe the process for controlling and documenting the release, change, and use of these SOPs?						
4a. Does the process include a description of required approvals?						
4b. Does the process include removal of obsolete documentation from work areas?						
4c. Does the process include verification that the changes are made as prescribed?						
5. Are the roles, responsibilities, and authorities of managers and staff included in the description of the above processes?						

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US EPA REGION III
QUALITY MANAGEMENT PLAN
REVIEW CHECKLIST

ASSESSMENT AND RESPONSE	A	U	NI	NA	SECTION	COMMENTS
1. Does the document describe the process for assessing the adequacy of the quality system? Does the review occur at least annually?						
2. Does the document describe the process for planning, implementing and documenting assessments and reporting results to management?						
2a. Does the process include selecting an assessment tool (e.g., quality system audits, management system reviews, peer reviews, technical reviews, performance evaluations, data quality assessments, readiness reviews, technical systems audits, and surveillance), the expected frequency of their application to environmental programs, and the roles and responsibilities of assessors?						
2b. Does the process include determining the level of competence, experience and training needed for assessment personnel?						
2c. Does the process include ensuring that personnel have no real or perceived conflict of interest, and have no direct involvement or responsibility for the work being assessed?						
2d. Does the process include ensuring that personnel conducting assessments have sufficient authority, access to programs and managers; access to documents and records; and organizational freedom to identify problems and noteworthy practices, propose recommendations for resolving problems, and/or independently confirm implementation & effectiveness of solutions ?						
3. Does the document describe the process for management's review of, and response to, findings?						

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US EPA REGION III
QUALITY MANAGEMENT PLAN
REVIEW CHECKLIST

4. Does the document describe the process for identifying how and when corrective actions are to be taken in response to the findings of the assessment?						
4a. Does the process include ensuring corrective actions are made promptly?						
4b. Does the process include confirming the implementation and effectiveness of any corrective action?						
4c. Does the process include documenting actions?						
5. Does the document describe the process for addressing disputes encountered as a result of assessments?						
6. Are the roles, responsibilities, and authorities of managers and staff included in the description of the above processes?						
QUALITY IMPROVEMENT	A	U	NI	NA	SECTION	COMMENTS
1. Does the document describe the process for ensuring that conditions adverse to quality are prevented, promptly identified and corrected; and that actions are taken to prevent reoccurrence?						
1a. Are these actions documented and tracked to closure?						
2. Does the document describe the process for encouraging staff to establish communication between customers and suppliers, identify process improvement opportunities, and identify and propose solutions for problems?						
3. Are the roles, responsibilities, and authorities of managers and staff included in the description of the above processes?						

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Appendix D

Region III QAPP Review Checklist

REGION III QAPP Review Checklist

Document Number:

Site Name:

Document Title:

Account Number:

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Reference Code **(Section #)**	**Elements & Required Information**	**IA**	**IU**	**NI**	**NA**	**Location of Element in Submitted Document (Section #, Table #, figure #, etc)**	**COMMENTS**
PROJECT MANAGEMENT							
1 (A1)	Title & Approval Page						
	Includes title of plan						
	Includes name of the organizations						
	Includes names, titles, signatures of appropriate officials and their approval dates						
1 (A2)	Table of Contents (Lists sections, figures, tables, references, and appendices)						
	Effective Document Control Format						
1 (A3)	Distribution List (Lists all the individuals and their organizations who will receive copies of the approved QAPP and any subsequent revisions.)						
1 (A4)	Project Organization						
	Identifies key individuals or organizations participating in the project with their responsibilities (e.g., data users, decision-makers, project QA manager, subcontractors, etc.)						

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PROJECT MANAGEMENT							
	Identifies/Describes individual(s) responsible for overall QA/AC (Project QA manager is independent of the data generating unit)						
	Identifies individual(s) responsible for sampling operations and sampling QC						
	Identifies individual(s) responsible for data processing and data processing QC						
	Identifies organization(s) involved with data analysis						
	Identifies individual(s) responsible for data validation (needs to be independent of data generator/laboratory)						
	Project Organization Chart(s) [Shows lines of authority and reporting responsibilities, includes contractors and subcontractors]. Includes EPA's role and other stakeholders/decision makers.						
1 (A5)	Site Background						
	Includes a list of the known and suspected contaminants in each medium and estimates of their concentration, variability, distribution, and location.						
	Includes the site's physical and chemical characteristics that influence migration and associated human, environmental and physical targets.						
	Includes a conceptual site model and exposure pathways						

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PROJECT MANAGEMENT							
	Includes a summary of the outcome and status of any previous response(s) at the site, such as early actions or previous data collection activities						
	Includes Site Maps (historical & present)						
1 (A5)	Problem Definition						
2 (Chap.1)	Includes statement(s) of the decision(s) that will be made based on the outcome of the field investigation						
3 (Chap. 1)	Includes list of actions that will be taken toward remediation or removal of the potential contamination problem based on the outcome of the field investigation						
4 (Chap. 1)							
	Includes the types of informational inputs needed for decision (e.g., sampling, modeling, or a combination of these approaches). If applicable, include collection of previous data collection (identifying sources).						
	Identifies Applicable technical quality standards or criteria (e.g., ARARS, State standards, other federal agency standards, action levels).						
	Includes specific action levels and the criteria for choosing between alternative actions						

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PROJECT MANAGEMENT							
	Includes a decision rule - an "if...then...." statement that defines the conditions that would cause the decision maker to choose among alternative courses of action. The decision rule should include the decision, the actions, the parameter of interest and the action level.						
1 (A6) 4 (Chap. 3)	Project Description & Schedule						
	Provides a description of the work to be performed; provides sufficient information as to the project's goals and types of activities to be conducted						
	Includes special personnel and equipment requirements that may indicate the complexity of the project (particularly for any new or innovative sampling or analytical technique being employed)						
	Includes Project Schedule Timeline (graphical or tabular format). Includes start and completion dates for all project activities (including quality assurance assessments).						
	Includes procedure for notification of project participants concerning schedule delays (identify job function, org. name, personnel responsible for providing and receiving such notification, and personnel responsible for approving schedule changes)						

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PROJECT MANAGEMENT							
	Includes discussion of resource and time constraints, such as seasonal sampling restrictions and considerations (if applicable)						
1 (A7)	Quality Objectives & Criteria						
	Lists measurement methods for each item of necessary information (list chemical and/or biological analytical methods). Specific tables may be included here or under A7 and/or B4 of this checklist. Tables need to include Project Action limits, project quantitation limits and laboratory detection limits.						
	Includes the range of anticipated concentrations of the parameters of interest						
	Defines and evaluates the potential consequences of decision errors (i.e., false positive error or false negative error) near the action level.						
	Includes how sufficient data will be collected to ensure that the proposed action limits are not exceeded after remediation and/or removal of contaminants of concern.						

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PROJECT MANAGEMENT							
	Describes when screening and definitive data[2] will be used to make site decisions. Also, defines limitations on the use of screening data. For screening data being used for site decisions, at least 10% must be confirmed by fixed laboratory. Provides justification when not confirming.						
	Addresses Precision (quantitative measurement performance criteria, QA/QC activities, and/or QC checks/samples being used to determine acceptable precision for each matrix, analytical parameter and concentration level). Includes equations to be used to calculate precision.						
	Addresses Accuracy (quantitative measurement performance criteria, QA/QC activities, and/or QC checks/samples being used to determine acceptable accuracy/bias for each matrix, analytical parameter and concentration level). Includes equations to be used to calculate accuracy.						
	Addresses Representativeness (quantitative measurement performance criteria, QA/QC activities being used to determine representativeness for each matrix, analytical parameter and concentration level).						

[2] For definition of screening and definitive data see reference 2.

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PROJECT MANAGEMENT							
	Addresses Comparability (quantitative measurement performance criteria, QA/QC activities, and/or QC checks/samples being used to determine comparability for each matrix, analytical parameter and concentration level). Sampling and analytical procedures are consistent within and between data sets.						
	Provides criteria for comparing oversight split sampling, if applicable.						
	Provides Comparability criteria for field screening/confirmatory results, if applicable.						
	Addresses Completeness. If applicable, includes a list of critical samples. Includes equations to be used to calculate completeness.						
	Includes a table with the project's QA objectives for precision, accuracy and completeness. The QA objectives should include requirements for "Total system" variability and bias not just laboratory error or criteria (Total system = sampling design error + measurement error).						
1 (A8)	Special Training Requirements/Certification Listed (Unique methods, Validators, Water Plans)						
	Lists or states how training is provided, documented, and assured						
1 (A9)	Documentation and Records						

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PROJECT MANAGEMENT							
	Itemizes the information and records (field operation records, laboratory records, data handling records) that must be included in the data report package and specifies the desired reporting format for hard copy and electronic forms						
	Identifies any other records and documents applicable to the project, such as audit reports, interim progress reports, and final reports, that will be produced. Includes electronic data from instrumentation (tapes).						
	Specifies or references all applicable requirements for the final disposition of records and documents, including location and length of retention period.						
	States Revisions/updates to QAPP are every 3-5 years						
MEASUREMENT/DATA ACQUISITION ELEMENTS							
1 (B1)	Sample Design						
	Identifies Type (composite, grab, etc.) and number of samples required. Table format recommended. Provides justification for type and number of samples; MDL rationale/impact. Identifies Background samples (if applicable)						

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PROJECT MANAGEMENT							
	Sampling Process Design (Experimental Design) [Describes the experimental design or data collection design for the project]						
	Sample Locations and frequency (e.g. map)						
	Sample & Analysis Methods (General description)						
	Sample matrices						
	Classifies each measurement parameters as either critical or needed for information only						
	Provides Appropriate validation study information; for nonstandard situations						
1 (B2)	Sampling Methods Requirements						
	Identifies sample collection procedures and methods (if referencing sampling, SOPs may be attached to QAPP)						
	Describes filtering procedures, if applicable.						
	Describes sequencing of samples, if applicable						

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PROJECT MANAGEMENT							
	Describes homogenizing of samples, if applicable						
	Identifies support facilities						
	Identifies individuals for corrective action. Describe decision/who's responsible and documentation required						
	Includes Sampling SOP Modifications						
	Provides Cleaning & Decontamination Procedures of Equipment/Sample Containers [Decontamination Procedures includes acid, water, and solvent rinse (methanol is preferred solvent)]; SOPs						
	Provides Sampling Containers, Volumes, Holding Times, & Preservation Table						
	Provides Field Sampling Equipment Calibration w/ table						
	Identifies Field Equipment Maintenance, Testing & Inspection Requirements						
	Provides Inspection & Acceptance Requirements for Supplies/Sample Containers						

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PROJECT MANAGEMENT							
1 (B3)	Sample Handling, Tracking & Custody Requirements *Note: Laboratory QAP should included information about laboratory sample handling and custody.*						
	Provides Sample Handling, Tracking & Custody SOPs with Sample Handling Flow Diagram (used for multiple sampling events with multiple laboratories)						
	Provides Sample Collection Documentation (includes form to track custody)						
	Provides Sample Container Label / Sample Tag (include examples)						
	Identifies Field Notes (lists information to be entered in field logbook)						
	Documents source of field reagents or supplies, includes sample containers						
	Includes procedures/forms for recording the location & specific consideration associated with samples						
	Documents specific preservation method (including temperature upon receipt)						
1 (B4)	Analytical Methods Requirements						

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PROJECT MANAGEMENT							
	Provides SOPs and validation information for nonstandard methods						
	Provides 10% offsite laboratory confirmation for screening methods						
	Identifies laboratory (ies)						
	Includes laboratory(ies) information (QA Manual, SOPs, PE results, certifications) *[Use LQAP checklist if LQAP submitted separately]*						
	Identifies individuals responsible for corrective action						
	Specifies needed laboratory turnaround time (if important to the project schedule)						
	Provides Field Analytical Methods & SOPs (includes modifications if applicable)						
	Provides Field Analytical Instrument Calibration						
	Provides Field Analytical Instrument/ Equipment Maintenance Testing & Inspection Requirements						

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PROJECT MANAGEMENT							
	Identifies Field Analytical Inspection & Acceptance Requirements for Supplies						
	Provides Fixed Lab Analytical Method Requirements (include sub-sampling, preparation, cleanup, or extraction methods/procedures)						
	Provides Fixed Lab Analytical Methods & SOPs (includes modifications if applicable; includes reporting limits, etc.) *[Use LQAP checklist if LQAP was submitted separately]*						
	Provides Fixed Lab Instrument Calibration procedures *[Use LQAP checklist if LQAP was submitted*						
	Identifies Fixed lab Instrument/Equipment Maintenance, Testing & Inspection Requirements *[Use LQAP checklist if LQAP was submitted separately]*						
	Identifies Fixed Lab Inspection & Acceptance Requirements for Supplies (audits) *[Use LQAP checklist if LQAP was submitted separately]*						
1 (B5)	Quality Control Requirements (Identifies required measurement QC checks for both the field and the laboratory)						
	Includes Trip blank (1/cooler containing volatiles)						

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	PROJECT MANAGEMENT						
	Includes Field blank (1 blank/matrix/day or 1 blank/20 samples/matrix, whichever is more frequent)						
	Includes Rinsate/Equipment Blank (1 blank/matrix/day or 1 blank/20 samples/matrix, whichever is more frequent)						
	Includes Temperature Blank (1/cooler)						
	Includes Field Duplicate (1 duplicate/20 samples)						
	Includes Matrix Spike/Matrix Spike Dup (1/20 samples/matrix)						
	Identifies acceptance criteria and corrective action for QC procedures						
	Identifies Field Analytical QC (calibration check samples), includes frequency and limits						
	Provides Fixed Laboratory QC procedures, frequency and limits *[Use LQAP checklist if LQAP was submitted separately]*						
1 (B6)	Instrument/Equipment Testing, Inspection, and Maintenance Requirements						
	Identifies acceptance testing of sampling and measurement systems						

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PROJECT MANAGEMENT							
	Describes equipment preventative and corrective maintenance						
	Notes availability and location of spare parts						
1 (B7)	Instrument Calibration and Frequency						
	Identifies equipment needing calibration and frequency for such calibration						
	Identifies frequency of calibration verification or continuing calibration						
	Notes required calibration standards and/or equipment						
	Cites calibration records and manner traceable to equipment						
1 (B8)	Inspection/Acceptance Requirements for Supplies and Consumables						
	States acceptance criteria for supplies and consumables						

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PROJECT MANAGEMENT							
	Notes responsible individuals						
1 (B9)	Data Acquisition Requirements for Non-Direct Measurements (Historical/Databases/Modeling)						
	Identifies types of data needed for non-measurement sources (e.g., computer databases and literature files), along with acceptance criteria for their use						
	Describes any limitations of such data						
	Documents rationale for original collection of data and its relevance to this project						
1 (A9, B10)	Data Management *Can be included in separate Data Management Plan*						
	Describes Data Recording (Describes standard record-keeping and data storage and retrieval requirements)						

IA = Included and Adequate for Data Quality IU = Included and Inadequate for Data Quality NI = Not included NA = Not Applicable							
***Reference Code* (Section #)**	**Elements & Required Information**	**IA**	**IU**	**NI**	**NA**	**Location of Element in Submitted Document (Section #, Table #, figure #, etc)**	**COMMENTS**
PROJECT MANAGEMENT							
	Describes Data Validation (Details the process of data validation; should address how the method, instrument, or system preforms the function it is intended to -consistently, reliably, and accurately when generating the data) *Note: Part D addresses the overall project data validation*						
	Describes Data Transformation (Documents Procedures) Data transformation is the conversion of individual data point values into related values or possibly symbols using conversion formulas or a system for replacement) *Note: Transformation and aberration of data for statistical analysis should be outlined in element D3.*						
	Describes Data Transmittal (Describes each data transfer step and the procedures used to characterize data transmittal error rates and to minimize information loss in transmittal)						
	Describes Data Reduction - involves irreversible reduction in the size of the data set and an associated loss of detail. (For manual calculation, includes an example of how raw data is reduced; for automated data process, indicates how the raw data are to be reduced with a well-defined audit trail, and references specific software documentation)						

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***Reference Code* (Section #)**	**Elements & Required Information**	**IA**	**IU**	**NI**	**NA**	**Location of Element in Submitted Document (Section #, Table #, figure #, etc)**	**COMMENTS**
PROJECT MANAGEMENT							
	Describes Data Analysis (includes an outline of the proposed methodology with a more detailed discussion included in final report)						
	Describes Data Tracking (describes procedures for tracking the flow of data through the data processing system)						
	Describes Data Storage and Retrieval (describes procedures for data storage and retrieval including security and time of retention included; includes documentation of the complete control system; discusses performance requirements of the data processing system, including provisions for the batch processing schedule and the data storage facilities). Includes storage and retrieval of electronic data (needs to be available upon EPA request)						
ASSESSMENT/OVERSIGHT ELEMENTS							
1 (C1)	Assessments and Response Actions						
	Lists required number, frequency and type of assessments, with approximate dates and names of responsible personnel (assessments include but are not limited to peer reviews, management systems reviews, technical systems audits, performance evaluations, and audits of data quality)						

IA = Included and Adequate for Data Quality IU = Included and Inadequate for Data Quality NI = Not included NA = Not Applicable							
***Reference Code* (Section #)**	**Elements & Required Information**	**IA**	**IU**	**NI**	**NA**	**Location of Element in Submitted Document (Section #, Table #, figure #, etc)**	**COMMENTS**
PROJECT MANAGEMENT							
	Identifies individual(s) responsible for corrective actions						
	Provides Feedback from performance audits (field and laboratory)						
	Includes Schedule of audits						
1 (C2)	Reports to management						
	Identifies frequency and distribution of reports for project status						
	Identifies frequency and distribution of reports for results of performance evaluations and audits						
	Identifies frequency and distribution of reports for results of periodic data quality assessments						
	Identifies frequency and distribution of reports for changes in the QAPP						
	Identifies frequency and distribution of reports for any significant QA problems indicating EPA is notified immediately						
	Identifies frequency and distribution of reports for preparers and recipients of reports						
DATA VALIDATION AND USABILITY ELEMENTS							
1 (D1)	Data Review						

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***Reference Code* (Section #)**	**Elements & Required Information**	**IA**	**IU**	**NI**	**NA**	**Location of Element in Submitted Document (Section #, Table #, figure #, etc)**	**COMMENTS**
PROJECT MANAGEMENT							
	Describes the procedures being used to review field and laboratory data to ensure that it meets requirements specified in field and analytical SOPs.						
	Includes project-specific calculations or algorithms						
	Identifies issue resolution procedure and title(s) of individual(s) responsible for issue resolution						
1 (D2) 5 6 7	Data Verification and Validation Methods						
	Describes process for data validation and verification (provide SOPs or reference Region III Modifications to National Functional Guidelines for Data Review)						
	Identifies issue resolution procedure and title(s) of individual(s) responsible for issue resolution						
	Identifies method for conveying these results to data users						
1 (D3)	Data Quality Assessment						
	Describe the procedures used to evaluate the uncertainty of data acquired during sampling and analytical procedures.						
	Describes the procedures that will be used to reconcile project results with DQOs.						

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Reference Code **(Section #)**	**Elements & Required Information**	**IA**	**IU**	**NI**	**NA**	**Location of Element in Submitted Document (Section #, Table #, figure #, etc)**	**COMMENTS**
PROJECT MANAGEMENT							
	Describes how the limitation on use of the data will be reported.						

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References

1. EPA Requirements for Quality Assurance Project Plans, EPA QA/R5, March 2001. Can be downloaded from the Internet at http://www.epa.gov/QUALITY/qa_docs.html.

2. Data Quality Objectives Process for Superfund: Interim Final Guidance (EPA, 1993)

3. Guidance on Systematic Planning using the Data Quality Objectives Process. EPA /240/B06?001, February 2006. Can be downloaded from the Internet at http://www.epa.gov/QUALITY/qa_docs.html

4. Data Quality Objectives Process for Hazardous Waste Site Investigations, EPA QA/G-4HW, January 2000. Can be downloaded from the Internet at http://www.epa.gov/QUALITY/qa_docs.html

5. Region III Modifications to the National Functional Guidelines for Inorganic Data Review, April 1993. http://www.epa.gov/region3/esc/QA/docs_dataval.htm

6. Region III Modifications to the National Functional Guidelines for Organic Data Review, November 1994. http://www.epa.gov/region3/esc/QA/docs_dataval.htm

7. Region III Innovative Approaches to Data Validation, June 1995. http://www.epa.gov/region3/esc/QA/docs_dataval.htm

8. Region III Dioxin/Furan Data Validation Guidance, March, 1999. http://www.epa.gov/region3/esc/QA/docs_dataval.htm

Appendix E

EPA Region III Pre-dissemination Review Document

EPA Region III
Information Quality Guidelines Pre-Dissemination Review

Overview

EPA issued its Information Quality Guidelines (IQG) in October 2002 in response to guidelines issued by OMB pursuant to the 2001 Information Quality Act.

EPA's IQG contain EPA's policy and procedural guidance for ensuring and maximizing the quality of information it disseminates. The EPA IQG provide definitions for "information", "dissemination", "utility", "objectivity", "integrity" and others and should be referred to for detailed information. The EPA IQG document is available on the IQG public web site at http://www.epa.gov/quality/informationguidelines/index.html . Additional IQG documents and training materials for EPA staff are available on the IQG intranet site at http://intranet.epa.gov/quality/informationguidelines/

A Pre-Dissemination review as defined in section 7 of the IQG is intended to insure that information EPA disseminates is of the highest quality possible and meets standards for objectivity, utility and integrity. Any disseminated information not meeting these standards can be subject to a "request for correction" (RFC) and its appeal, a "request for reconsideration" (RFR) by any person. OEI has a formal process in place for the administration of RFCs and RFRs. Past and current RFCs and RFRs can be viewed on the EPA website.

EPA issued its Pre-Dissemination Review Guidelines in 2006 to assist offices and regions in implementing their own pre-dissemination review procedures. This document therefore serves as a basis for Region III's procedure for conducting pre-dissemination reviews. Region III offices may expand upon the review procedure presented here.

Please note that EPA's pre-dissemination review guidelines provide non-binding internal policy and procedural guidance intended solely for EPA management and staff[3]

Pre-Dissemination Review

One of the most important things to remember about conducting a pre-dissemination review is that it is not intended to consist solely of a final review in the development of a product. Rather, it should be conducted throughout a product's development life cycle. This document provides a checklist which can be used to document the results of pre-dissemination review during development.

Determine Eligibility

1. Determine if you need to conduct a pre-dissemination review using the IQG definitions of "information" and "dissemination" (Steps 2 and 3 below and IQG Section 5.3). The Region III IQG officer can be consulted should you have questions about whether the IQG apply (and thus a review is needed). Examples of non-applicability of the IQG are given in IQG Section 5.4

2. Determine whether the product to be reviewed is information. "Information," generally includes any communication or representation of knowledge such as facts or data, in any medium or form.

3. Determine whether the product will be disseminated by EPA. EPA disseminates information to the public when EPA initiates or sponsors the distribution of information to the public.

4. If neither step 2 or 3 applies then no PDR is necessary at this time. Otherwise continue to step 5. Note that under certain circumstances a product may become eligible for a review (e.g. EPA decides it would like to disseminate a report that had been only available within EPA).

Determine whether quality is maximized and IQG quality criteria are met

5. Determine whether the product to be disseminated has maximized quality and has met the IQG criteria for utility, objectivity and integrity. "Utility" refers to the usefulness of the information to the intended users. "Objectivity" focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased. "Integrity" refers to security, such as the protection of information

[3] EPA Final Pre-Dissemination Review Guidelines. September 2006.

from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification. (See IQG, Sections 5.1 and 6.1)

6. Determine whether the product is influential. "Influential," when used in the phrase "influential scientific, financial, or statistical information," means that the Agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact (i.e., potential change or effect) on important public policies or private sector decisions. If the product is influential then a higher degree of transparency for data and methods will be required. Consult IQG Section 6.3 on transparency requirements.

Approval of information prior to dissemination

7. Obtain approval for the information to be disseminated from the appropriate program director. Approval can include other types of reviews such as legal reviews, peer reviews, programmatic reviews, scientific and technical review clearance processes, stakeholder reviews, and product review in accordance with the Office of Public Affairs guidelines.

Records management

8. Pre-dissemination review records (such as the checklist) should be retained with other product documents. Records should be retained using the appropriate records schedules.

Region III Pre-Dissemination Review Checklist

Product Title	
Document Number or Month / Year of Release	

Product Owner		
Work Product Owner Name	Originating Division or Office and Branch	Signature and date

IQG-related questions on the work product			
	Yes	No	Comments / description of actions taken to fulfill requirements.
Is the product objective?			
Is the product useful?			
Is the product integrity assured?			
Is the product influential?			

Other Quality Reviews		
List additional reviews	Review type	Comments

Approving Official			
Name	Title	Program or Office	Signature and date

Appendix F

Region III QSA Checklist

EPA REGION III
QUALITY SYSTEM AUDIT CHECKLIST

Person Interviewed:		**Date:**	
Job Title:		**Yrs Experience (Current Position):**	
Interviewer(s):			

	COMMENTS
Duties and Responsibilities	
1. What decisions are supported by the data being generated by your Section? 2. What are your roles and responsibilities relative to the collection and/or use of that data? 3. Does your program use data generated by a third party (i.e., contractors, IAG, grant)? How is this data being used? (If yes, go to #4. If no, go to #5) 4. Are you involved in the award of contracts, extramural agreements and IAGs, which involve environmental data? If yes, describe your duties relative to the award of contracts, extramural agreements and IAGs, which involve environmental data. How long have you been doing this? 5. What technical support do you routinely use or give to assist in making project and/or program decisions?	
QMP	
1. What role did/do you play in the development, review and/or revision of the Office/Division QMP? 2. How do managers ensure that QA roles and responsibilities designated in this document are performed? 3. To your knowledge are Standard Operating Procedures being used for any activities in your jurisdiction? 4. If yes, how do you ensure that the most recent version of the SOP is being used? 5. If yes, who is responsible for maintaining these documents?	
Quality System Assessments	

EPA REGION III
QUALITY SYSTEM AUDIT CHECKLIST

1. Please describe the quality system assessments and/or audits that you or a member of your section has been subjected to in the last two years? 2. Who performed these assessments and/or audits? 3. Who is responsible for ensuring that the quality system being implemented by others (i.e., PRPs, states, contractors, other government Agencies (IAG's)) who provide data for your projects is adequate? If this is your responsibility, how do you do this? 4. Who is responsible for ensuring that corrective actions from quality system audit/assessment reports are implemented? How are these actions being documented?	
Extramural Agreements	
Contracts	
1. How do you ensure that requests for proposals, work assignments, task orders or acquisitions that involve environmental data collection and/ or use contain acceptable QA requirements? If you are not responsible for this task, who is? 2. What are the typical QA requirements that are included in RFPs, work assignments, task orders, etc? 3. For contracts, do you use a QA Review Form? If yes, when is it used? If no, how are QA requirements being communicated to the Contracting Officer? 4. When applicable, who is responsible for ensuring that QMPs are reviewed and approved before the collection and/or use of environmental data? How are the results of QMP reviews and approvals distributed to you? *(Reviewers - Does the file have evidence that there was an approved QMP for this grant? If no, ask where this information can be found.)* 5. When applicable, who is responsible for the review of QAPPs for projects that involve environmental data collection or use? If you are not responsible, how are the results of QAPP reviews being given to you? *(Reviewers - Does the file have evidence that there was a QAPP review before approval? If no, ask where this information can be found.)*	

EPA REGION III
QUALITY SYSTEM AUDIT CHECKLIST

6. Who is responsible for the approval of contractor QAPPs? How is this information transmitted to the contractor*? (Reviewers - Does the file have evidence that there was an approved QAAP before data collection and/or use? If no, ask where this information can be found.)* 7. Who is responsible for ensuring that contractors implement the QA/QC activities found in the approved QAPP? How is this being done? *(Reviewers - Does the file have evidence of audits, assessments, etc.? If no, ask where this information can be found.)* 8. How is the data being evaluated to ensure that the contractor met the requirements specified in the QAPP? Who is responsible for this task? *(Reviewers - Does the file have evidence of data validation reports, data assessments, etc.? If no, ask where this information can be found.)*	
Grants/IAG	
9. How do you ensure that grants and IAGs that involve the collection and/or use of environmental data contain acceptable QA requirements? If you are not responsible for this task, who is? 10. What are the typical QA requirements found in extramural agreements and IAGs? 11. Would you provide examples of how this requirement is being communicated to grantees, IAG participants and OPM? *(Reviewers - Does the grant contain information about QA requirements? If no, ask where this information can be found.)* 12. When applicable, who is responsible for ensuring that QMPs are reviewed and approved before the collection and/or use of environmental data? How are the results of QMP reviews and approvals distributed to you? *(Reviewers - Does the grant file have evidence that there was an approved QMP for this grant? If no, ask where this information can be found.)* 13. When applicable, who is responsible for the review of QAPPs for projects that involve environmental data collection or use? If you are not responsible, how are the results of QAPP reviews being distributed to you? *(Reviewers - Does the grant file have evidence that there was*	

EPA REGION III
QUALITY SYSTEM AUDIT CHECKLIST

a QAPP review? If no, ask where this information can be found.) 14. Who is responsible for the approval of QAPPs for grantees? How is this information transmitted to the grantee or government agency? *(Reviewers - Does the grant file have evidence there was an approved QAPP before data collection or use? If no, ask where this information can be found.)* 15. Who is responsible for ensuring that grantees or government agencies implement the QA/QC activities found in the approved QAPP? Who is responsible for this task? *(Reviewers - Does the grant file have evidence of audits, assessments, etc.? If no, ask where this information can be found.)* 16. How is the data evaluated to ensure it met the requirements specified in the QAPP? Who is responsible for this task? *(Reviewers - Does the grant file include data validation reports, data assessments, etc? If no, ask where this information can be found.)*	
Training	
1. What QA-related courses have you taken? Did you find the information presented in the course(s) helpful? 2. What QA-related courses would you like to take? Why? 3. How is training being documented? Who maintains the records?	
Systematic Planning *(Project Officers, Toxicologist, Hydrologists, Geologists)*	
1. Are you involved in project planning (i.e., level of QA/QC required, sampling and analytical protocols, establishing project goals, etc.)? If no, go to next section. If yes, go to question #2. 2. What process is being used to define intended data uses, level of quality required, sampling and analytical protocols, project goals and objectives, etc. before the initiation of a project which involves environmental data collection or use? 3. Who is responsible for ensuring that a systematic planning process is being performed? 4. Who is currently involved in the planning process? 5. How is the process documented?	

EPA REGION III
QUALITY SYSTEM AUDIT CHECKLIST

6. Is this process being used for all of your projects? If not, why not? 7. Would you provide a copy of documentation (i.e., notes, scoping meeting minutes, etc.) which shows systematic planning process for two sites that have had activity in the last 2 years?	
Quality Assurance Project Plans *(Project Officers, Hydrologist, Toxicologists, Geologists)*	
1. Are you involved in the review and/or approval of QAPPs? If yes, go to question #2. If no, go to next section. *(For toxicologists, hydrologists, geologists)* 2. Who is responsible for the review and approval of QAPPs before the initiation of environmental data activities? 3. Where are approved QAPPs being kept? *(Project Officer)* 4. Would you provide a copy of an approval letter or a signature page for a site-specific Sampling and Analysis Plan and/or QAPP for two sites that have had activity in the past 2 years? *(Project Officer)* 5. Who is responsible for ensuring that contractors, grantees and/or EPA personnel implement the QA/QC activities found in the approved QAPP? How is this being done? 6. Describe the technical assessments/audits (i.e., readiness reviews, surveillance, technical system audits, P/Ts, etc.) that are being conducted at your sites? *(Project Officer)* 7. When are these assessments being performed? What is your involvement in this process? 8. Would you be able to provide copies of TSA reports performed at two of your sites in the past 0-3 years? Also, briefly describe how the results of these assessments were used?	
Data Verification and Validation	
1. Do you use secondary data (i.e., databases, literature, models) to make environmental decisions? How do you evaluate this data before use to determine that it meets your project objectives? 2. Describe the procedures being used to ensure that the data is adequate for the intended use. Who is responsible for this task?	

EPA REGION III
QUALITY SYSTEM AUDIT CHECKLIST

3. Would you provide examples of data verification and/or validation reports for two sites that have had activity in the past 0-2 years? 4. Is this process being followed by all parties (i.e., States, contractors, PRPs, etc.) who submit data for your use? If not, why not? 5. How are the results of these data validation reports being used? 6. How are qualifiers being interpreted in final reports? 7. What procedures are being used to evaluate data to ensure it meets project and/or program objectives? 8. Who is responsible for conducting this task? 9. Would you provide two examples of data quality assessment reports for two sites that have had activity in the past 0-2 years? 10. How are the results of these DQA reports being used?	
Quality Improvement	
1. What recommendations would you make to improve your Division's quality system? 2. Do you believe you are getting sufficient management support to perform your job effectively? 3. Do you believe you have sufficient resources to perform your job effectively?	
Other Comments	

EPA REGION III
QUALITY SYSTEM AUDIT CHECKLIST

INTERVIEWER EVALUATION			
Requirement (EPA ORDER 5360.1 A2)	YES	NO	N/A
1. Develop a QMP and implement this plan following Agency approval.			
2. Perform assessments of the effectiveness of the quality system at least annually and implement corrective actions based on assessment results in a timely manner.			
3. Submit information for Region 3 QA Status Report.			
4. Implement Agency-wide Quality System requirements in all applicable EPA-funded extramural agreements.			
5. Provide appropriate QA/QC training for all levels of management and staff.			
6. Use a systematic planning approach to develop acceptance or performance criteria for all work covered by the Division/Program Quality System.			
7. Have approved QA Project Plans, or equivalent documents for all applicable projects and tasks involving environmental data.			
8. Assess existing data, when used to support Agency decisions or other secondary purposes, to verify that they are of sufficient quantity and adequate quality for their intended use.			

Requirement #	For each item that has NO response, briefly describe the documented and/or verbal evidence that this has not occurred. Describe impact on quality of data being generated by or for this Division/Program. Include recommendations to alleviate the problem.

Appendix G

References

REFERENCES

Quality System Documents (Web site: http://www.epa.gov/quality/)

Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (ANSI/ASQC E4-1994); American Society for Quality Control (ASQC), 1994.

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System Life Cycle Management Policy; CIO Policy 2121.0; U.S. Environmental Protection Agency, Office of Environmental Information, Washington, DC, 2006.

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Managing Cartographic and Architectural Records (Instructional Guide Series), National Archives and Records Administration (NARA). (Web site: http://www.archives.gov/research/formats/cartographic.html)
Managing Electronic Records (Instructional Guide Series), NARA. (Web site: http://toolkit.archives.gov/pls/htmldb/f?p=102:1:10272796255933812381)
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