United States Environmental Protection Agency
Region 3
1650 Arch Street
Philadelphia, PA 19103-2039

QUALITY MANAGEMENT PLAN

FOR THE

ENVIRONMENTAL ASSESSMENT

AND

INNOVATION DIVISION

Effective Date: March 22, 2012

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Environmental Assessment and Innovation Division
Quality Management Plan

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ACRONYMS

BRAC	Base Realignment and Closure
COE	U.S. Army Corps of Engineers
COR	Contracting Officer's Representative
CST	Client Services Team
DQA	Data Quality Assessment
DQOs	Data Quality Objectives
EAID	Environmental Assessment and Innovation Division
EMS	Environmental Management System
FBT	Freshwater Biology Team
GAO	General Accounting Office
GIS	Geographic Information System
IAs	Interagency Agreements
IQG	Information Quality Guidelines
LB	Laboratory Branch
LQAO	Laboratory Quality Assurance Officer
MSA	Management Systems Audit
MSR	Management System Reviews
OASQA	Office of Analytical Services and Quality Assurance
OEIA	Office of Environmental Information and Analysis
OEP	Office of Environmental Programs
OEI	Office of Environmental Innovation
OMA	Office of Monitoring and Assessment
OES	Office of Environmental Services
OGWDW	Office Ground Water and Drinking Water
OIG	Office of Inspector General
ORC	Office of Regional Counsel
ORD	Office of Research and Development
PPA	Performance Partnership Agreement
PT	Proficiency Testing
PO	Project Officer
QA	Quality Assurance
QAARWP	Quality Assurance Annual Report and Work Plan
QAC	Quality Assurance Coordinator
QAO	Quality Assurance Officer
QAPP	Quality Assurance Project Plan
QAT	Quality Assurance Team
QC	Quality Control
QM	Laboratory Quality Manual
QMP	Quality Management Plan
QS	Quality System
LIMS	Laboratory Information Management System
RPRC	Regional Peer Review Coordinator
RQAM	Regional Quality Assurance Manager
RQAO	Regional Quality Assurance Officer
RQC	Regional Quality Council

RSL	Regional Science Liaison
SDWA	Safe Drinking Water Act
SF	Superfund
SOP	Standard Operating Procedure
STPC	Science and Technology Policy Council
TD	Technical Director
TSA	Technical Systems Audit
TSB	Technical Services Branch

Environmental Assessment and Innovation Division
Quality Management Plan

The Environmental Assessment and Innovation Division (EAID) of the United States Environmental Protection Agency (EPA) Region 3 has prepared this Quality Management Plan (QMP) in accordance with USEPA Order CIO 2105.0 (formerly 5360.1 A2), *Policy and Program Requirements to Implement the Mandatory Quality Assurance Program*; USEPA Order CIO2105-P-01-0 (formerly 5360 A1), *EPA Quality Manual for Environmental Programs*; USEPA QA/R-2, *EPA Requirements for Quality Management Plans*; and USEPA's *Guidelines for Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by the Environmental Protection Agency* (a.k.a. EPA Information Quality Guidelines). As part of Region 3's Quality System, this QMP identifies the mission, roles and responsibilities of personnel with regard to quality assurance (QA) and quality management (QM), communication structure and measures of effectiveness in the EAID.

1.0 Management and Organization

1.1 Introduction

EAID developed this QMP to address EPA QA requirements and guidelines and to document the Division's quality management system. The primary goal of this QMP is to ensure that all environmentally-related data collection and processing activities performed by or for EAID will result in data that are documented and of known quality, and can be used with a high degree of certainty by the intended user to support specific decisions or actions. To achieve this goal, EAID will be guided by the procedures outlined in this QMP as it plans for, collects, analyzes, and interprets environmental data.

1.2 EAID Quality Assurance Policy Statement

EAID's QA Policy is that all environmental data generated, processed, and used by EAID will be scientifically valid; of acceptable completeness, representativeness, and comparability; and of known and documented quality. All reported data will include or incorporate by reference documented precision and accuracy data. To implement this policy, EAID will ensure that all data production efforts use adequate QA procedures. The division will continually strive to evaluate and improve its QA efforts so that data meets the needs and expectations of users.

For EAID, it is the policy that:

- Each activity within the Division that generates or uses environmental data (as defined in Section A.1.a of the Region 3 QMP) for decision making will be part of EAID's Quality Assurance program, complying with EPA 's QA policy, the Region 3 QMP and EAID QMP.

- Each program or activity that generates environmental data will develop and implement a QA Project Plan (QAPP) and/or Standard Operating Procedures (SOPs) which specify the detailed procedures required to assure production of quality data.

- Individuals responsible for monitoring and measurement activities supported by EPA through grants, contracts or interagency agreements will ensure that environmental data generated will meet the quality standards as set forth by the Regional QMP, EAID QMP, Federal regulations, and requirements and guidance issued by EPA's Office of Environmental Information Quality Staff.

- Information produced by EAID, or on behalf of EAID by an external provider, will be reviewed prior to its dissemination (pre-dissemination review) for its objectivity, utility and integrity as defined by EPA's Information Quality Guidelines (IQGs).

- EAID will continue to monitor and improve its quality system by implementing an ongoing system of evaluation of its QA efforts to ensure that its Quality System is meeting the needs and expectations of data users, and QA requirements and guidelines set forth by EPA Headquarters.

- EAID 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, EAID follows the procedures and guidance found in EPA's *Peer Review Handbook, 3rd Edition,* EPA/100/B-06/002, 2006, available at http://www.epa.gov/osa/spc/2peerrev.htm.

1.3 Organization Chart

EAID reports to the Regional Administrator as shown on the Region 3 organization chart in the Region 3 QMP. Within EAID, there are five Offices: Office of Environmental Information and Analysis (OEIA), Office of Analytical Services and Quality Assurance (OASQA), Office of Environmental Programs (OEP), Office of Environmental Innovation (OEI) and Office of Monitoring and Assessment (OMA). A unique aspect of EAID is that the division is trans-regional, incorporating two laboratories, one in Fort Meade, Maryland and one in Wheeling, West Virginia. The organization chart identifies the specific staff positions involved in the QA function and the Quality System. EAID's organization chart is presented in Figure 1.

1.4 Mission Statement

The EAID, under the supervision of the Director and Deputy Director, has responsibility for developing, consolidating, assessing, and disseminating environmental information and statistics; developing and implementing strategies for ecosystem and human health protection efforts; assisting businesses in developing and implementing innovative non-regulatory approaches and promoting pollution prevention. The division also provides laboratory analytical services; quality assurance in support of program activities; and offers specific technical advice and assistance concerning data collection methodologies and quality control. The division also has responsibility for developing environmental indicators; administering and implementing regulatory responsibilities; and promoting effective outreach and environmental education in Region 3. In addition, EAID is the

home of the Regional QA Manager, the Regional Science Liaison and the Region's Peer Review Coordinator.

1.5 Key Roles and Responsibilities

Anyone in EAID directly or indirectly involved with environmental data collection, analysis or data usage, has the responsibility for ensuring data quality. This includes Senior Managers, Supervisors, Project Officers, Program Managers, and staff level personnel.

1.5.1 Regional Roles and Responsibilities

EAID has responsibility for managing the quality system for the Region as well as its own quality system. The EPA Region 3 Quality Management Plan, October 2008 outlines the responsibilities and duties of those individuals responsible for the Region 3 Quality System. The EAID QMP outlines the roles and responsibilities of the key individuals responsible for managing and implementing the EAID quality system and is defined below.

1.5.2 Divisional Quality System

Along with the responsibilities for the Region 3 Quality System, the division manages and implements its own quality system. The following describes key individuals involved in the EAID Quality System.

KEY ROLES FOR THE EAID QUALITY SYSTEM

EAID Division Director / Deputy Division Director
Regional QA Manager
EAID QA Coordinator / Regional QA Officer
POs / WAMs / CORs
Laboratory Director / Technical Director
Laboratory QA Officer
Technical Services Branch / QA Team
IQGO / GIS Coordinator
Regional Peer Review Coordinator
Regional Science Liaison

1.5.3 EAID Division Director / Deputy Division Director

The Director and Deputy Director have management responsibilities for the development, implementation and continued operation of the EAID Quality System. The overall divisional responsibilities of the Director and Deputy

Director include ensuring effective implementation of EAID's QMP and QAPPs, adequate resource support, appropriate documentation of environmental data collection activities, performance of audits to determine compliance, correction of deficiencies highlighted by audits, and provision of necessary training. The Director/Deputy Director delegates specific QA responsibilities and authorities to the EAID Quality Assurance Coordinator (QAC) and Project Officers (POs).

1.5.4 Regional Quality Assurance Manager

The RQAM has the primary responsibility for the oversight of the Regional Quality System. As such, the RQAM is responsible for providing expert assistance to Regional staff on QA/QC policies, requirements and procedures applicable to the EPA QA Program.

1.5.5 Quality Assurance Coordinator / Regional Quality Assurance Officer

For purposes of this QMP, the terms Quality Assurance Coordinator (QAC) / Regional Quality Assurance Officer (RQAO) are used interchangeably. The QAC ensures that EAID programs implement QA requirements. The QAC provides continued oversight of the EAID Quality System and reports to the Director on QA issues. Organizationally, the QAC is located in the Immediate Office of the Division Director. The QAC performs the following duties:

- Acts as the EAID contact for QA and QC issues;
- Disseminates QA information to EAID staff;
- Conducts QA briefings for the Division and Deputy Division Directors;
- Participates in RQC meetings;
- Facilitates preparation and/or revision of the EAID QMP;
- Helps implement the EAID QMP;
- Identifies and responds to QA and QC needs, resolve problems, and answer requests for guidance and assistance;
- Helps Project Managers and/or Project Officers resolve data quality issues with contractors and financial assistance recipients;
- Reviews and/or approves program/project QAPPs and SOPs (according to the policies and procedures described in the EAID QMP);
- Assesses EAID's QA-related training needs and arranges the delivery of training;
- Consolidates EAID'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 EAID and state QA programs to assure that they adhere to their approved QMPs.

1.5.6 Project Officers/Work Assignment Managers/Contracting Officer Representatives

For the purpose of this document, references to Project Officer(s) will include the roles and responsibilities of Project Managers (PMs), Work Assignment

Managers (WAMs), Program Managers (PMs) and Contracting Officer Representatives (CORs). The Project Officer ensures that grantees and/or contractors adhere to QA requirements as outlined in their grants, contracts or interagency agreements as defined in the Region 3 Quality Management Plan. Project Officers reside in each of the five Offices, and as such, are not specifically identified on the organizational chart.

Since POs may not be closely familiar with QA procedures, they are encouraged to work with the EAID QA Coordinator to ensure that QA requirements are addressed. The specific responsibilities of 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 IAG 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 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 of the Region 3 QMP);
- All grant and IAG 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 of the Region 3 QMP);
- For contracts, the *Region III Quality Assurance Review Form for Contract Actions* (Appendix B of the Region 3 QMP) is completed, and approved in writing by the RQAM (or designee) and Project Officer;
- For grants and assistance agreements, the funding recommendation form in 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.

1.5.7 Laboratory Director, Technical Director and Laboratory Quality Assurance Officers

Two laboratories exist in EAID which produce environmental data - Fort Meade, Maryland and Wheeling, West Virginia. The Fort Meade Laboratory is located in the Office of Analytical Services and Quality Assurance (OASQA) under the

leadership of the Associate Director and Laboratory Branch Chief/Technical Director. The Fort Meade Laboratory is accredited according to the 2003 National Environmental Laboratory Conference Standards. The Wheeling Laboratory is located in the Office of Monitoring and Assessment under the leadership of its Associate Director and Team Leader. As supervisors of these laboratories, they are responsible for ensuring appropriate documentation of the laboratory's quality system, utilization of performance audits for data generating activities, correction of deficiencies highlighted by such audits, maintenance of accreditation status (where applicable), and provision of necessary training to laboratory staff. Specific QA responsibilities and authorities are delegated to each Laboratory QA Officer (LQAO). These specific responsibilities and duties are documented in each laboratory's Quality Manual.

1.5.8 Technical Services Branch

The Technical Services Branch (TSB), located in OASQA and led by a Branch Chief, includes the Client Services Team and the Quality Assurance Team. TSB manages the acquisition and oversight of laboratory analytical services for regional program offices. The Branch conducts on-site inspections; monitors performance; recommends corrective actions; and provides guidance, direction and technical assistance to Superfund Contract Laboratory Program laboratories in Region 3. TSB shares responsibility for implementing the Region's Quality System by providing technical support and assistance during project planning; reviewing quality assurance related documents such as Quality Assurance Project Plans, Work Plans, Field Sampling Plans, Laboratory Plans, and Standard Operating Procedures; and overseeing the completion of data validation by the Environmental Services Assistance Team (ESAT). The TSB provides oversight of the ESAT on-site contractors and oversees the records management contractor who retains OASQA records for the accreditation process.

1.5.9 Information Quality Guidelines Officer

The Information Quality Guidelines Officer (IQGO) resides in the Office of Environmental Information and Analysis (OEIA). The IQGO serves as a coordinator within the Region for Information Quality Guidelines activities. The IQGO coordinates IQG activities with the RQAM, the Region's Product Review Officer and the Office of Environmental Information's Quality Staff in Headquarters. Specific responsibilities are as follows:

- Provide technical assistance to Regional staff on IQG policies, requirements, and procedures.
- Serve as EAID and Regional point of contact on IQG procedures.
- Implement IQG pre-dissemination review procedures in EAID and Region 3.
- Facilitate communication on IQG policies and procedures within the Region and with HQ Quality Staff.
- Coordinate responses from Region 3 information owners to requests for correction and requests for reconsideration with HQ Quality Staff.

1.5.10 GIS Coordinator

The GIS Coordinator is located in the Office of Environmental Information and Analysis (OEIA). The GIS Coordinator assists in the procurement of GIS services and software for environmental analysis in the Region. The coordinator's primary responsibilities include:

- Provide hardware and software technical support.
- Provide graphics and map generation support to the Region 3 user community.
- Provide technical assistance for development of cross-media and/or data integration projects to EAID, Regional programs and other federal, state and local users.
- Coordinates with the Region 3 Computer Services Branch on GIS operations and software.

1.5.11 GIS Point of Contact

The GIS Point of Contact is located in the Office of Environmental Programs (OEP) and serves as the point of contact for EAID staff seeking technical assistance on GIS projects.

1.5.12 Regional Peer Review Coordinator

The Peer Review Coordinator is the main point of contact for EAID and EPA Region 3 who can direct and advise interested parties on Regional policy and procedures for peer review of work products.

Specific responsibilities of the Peer Review Coordinator are:

- General oversight responsibility for the Region and EAID peer review processes;
- Report peer review activities to the Division Director for EAID activities and the Regional Administrator for the compilation of Regional activities;
- Help mediate difficult issues between Divisions/Program Offices;
- Function as liaison with the Office of Research and Development (ORD) and the Science and Technology Policy Council (STPC);
- Submit information on Region 3's peer review plans and activities as needed to implement the Peer Review Policy;
- Establish procedures to ensure that the work product peer review documentation (i.e., peer review record) is filed and maintained in an appropriate manner;
- Provide advice, guidance, and support to Region 3 managers and staff for the performance of the peer reviews; and
- Distribute Agency-wide peer review guidance and materials to Regional personnel.

1.5.13 Regional Science Liaison

It is the responsibility of the ORD Regional Science Liaison (RSL) to seek opportunities to bring ORD research products to Region 3 and its clients (States, local governments). The RSL also integrates Region 3 research needs, supporting high priority policy and regulatory actions into the ORD research planning process. The RSL co-chairs the Regional Science Council and represents the Region on the National Science Council.

1.6 Technical Activities and Programs Supported by the EAID Quality System

The Region 3 QMP requires all programs, activities, grants, contracts, and interagency agreements that generate environmental data for decisions or in support of actions to comply with quality management practices. Furthermore, the Region 3 QMP defines environmental data as information or measurements resulting from any data collection activity, laboratory analyses or models involving the assessment of chemical, physical, or biological factors relating to the environment. Data collection activities include those activities in which data are generated by and for EAID and/or with EAID funds. EPA Order CIO 2105.0 also applies to the use of environmental data collected for other purposes or from other sources (so called, secondary or existing data), including literature, industry surveys, compilations from computerized databases and information systems, and results from computerized or mathematical models of environmental processes and conditions. EAID has determined that the following activities meet these requirements and, therefore, are covered by the EAID QMP.

Activities that generate, collect or use environmental data where EAID has direct authority:

- Laboratory analyses performed at Fort Meade and Wheeling
- Compliance inspections and investigations
- Management of grants, contracts and interagency agreements that involve data collection and measurement activities
- Development of methods or protocols
- Analytical method validation
- Procurement of services which result in environmental data
- Laboratory inspections, performance evaluations and accreditation programs
- Community-based special studies
- Freshwater bio-assessments
- Coastal and Oceans Monitoring Programs
- Children’s Health
- Natural Infrastructure Programs
- Environmental Decision Support
- Environmental Indicators
- Sustainability

Activities that generate, collect or use environmental data where EAID provides support to other Divisions/Programs:

- Review of QMPs, QAPPs, Sampling and Analysis Plans, Lab Quality Assurance Plans
- Development of policies and/or guidance that involve data collection activities
- Data quality assurance, data validation, data assessment
- Special request sampling studies (examples include support for TMDLs, biological monitoring and habitat surveys for acid mine drainage or mining operations)
- Procurement of services which result in environmental data
- Management of grants, contracts and interagency agreements that involve data collection and measurement activities
- GIS mapping and application development
- QA training
- Quality System Assessments
- Information Quality Guidelines
- GIS metadata
- Natural resource extraction impact analysis
- Scientific diver operations
- Environmental Management Systems

The EAID QMP also applies to environmental data operations when implementing the following programs:

- Clean Air Act
  - NEPA
- Safe Drinking Water Act
  - Drinking Water Laboratory Certification Program
- Clean Water Act
  - National Pollutant Discharge Elimination System (NPDES) Program
  - Watershed Protection Program
  - Water Quality Standards Program
  - Wetlands Program Grants
  - Non-Point Source Pollutant Program
  - NEPA
  - Section 404 Wetland Jurisdictional Determinations
  - Section 309/404 Wetland Enforcement Activities
- CERCLA
  - Site Investigations Program
  - Remedial Program
  - Enforcement Program
  - Brownfields Program
  - Federal Facilities and BRAC Programs
- Marine Protection, Research, and Sanctuaries Act (MPRSA)
  - Ocean Dumping Program

Emergency Response and Removal Program
- RCRA
  Corrective Action Program
  Enforcement Program
- TSCA
- NESHAPS
- Environmental Monitoring and Assessment Program
- Mid-Atlantic Highlands Action Program (HAP)

1.7 Communication

As stated in the Region 3 QMP, the EAID QMP must not only be complete, circulated and updated to be effectively implemented, but understood by those responsible for its implementation. The EAID QMP will also be posted on the EAID intranet site. The QAC/RQAO, IQGO, and RQAM, will inform the EAID Director and other managers within EAID of QA issues on a regular basis. The QAC will participate on the Regional Quality Council and work closely with the RQAM. Since some of the activities listed in Section 1.6 of this QMP are in support of programs that are managed in other Divisions within Region 3, communication with other Divisions, their management and QACs is critical. Therefore, when necessary to resolve disputes related to quality assurance, EAID will follow the dispute resolution process as described in the Region 3 QMP, Section A.

2.0 EAID's Quality System

2.1 Principal Components of the Quality System

Due to the variety of activities EAID performs, its Quality System is decentralized. Each Office within the Division specifies QA operating procedures using SOPs or Quality Manuals. Although the QAC is the main focal point for Divisional QA issues, each office may have assigned individuals to address their QA procedures. This section of the QMP describes the tools that are used by EAID to ensure uniform implementation of QA requirements for all of its environmental data collection activities.

2.2 Principle Tools and Practices

To ensure the integrity of the data to which EAID provides its customers and which EAID uses to make program decisions, EAID uses a variety of tools and practices. They are described below.

2.2.1 Divisional QMP

This Divisional QMP describes the policies, procedures and systems governing the EAID Quality System. The QMP serves as the Division's framework for applying QA requirements to environmental measurements and data collection

activities. Additionally, each Office has its own processes to implement quality requirements in its programs where necessary.
Future revisions and updates to this QMP will be prepared by the QAC working with EAID management and staff. All modifications to the QMP must be approved by the Division Director and RQAM. This QMP will be reviewed annually and updated as necessary.

2.2.2 Data Quality Objectives

Data Quality Objectives (DQO) are statements of the quality of environmental data required to support decisions or actions. DQOs establish the level of risk or uncertainty that the decision maker is willing to accept in the environmental data and still maintain a defensible decision. To develop DQOs, the project lead will use the DQO process to engage the decision maker in determining which environmental data are needed, what data quality is required, and the appropriate balance between time, resources, and data quality. The DQOs will be documented in the QAPP for the environmental activity. The use of DQOs by EAID staff is appropriate for those activities where EAID has the responsibility for the entire project and/or decision-making.

2.2.3 Quality Assurance Project Plans

EAID will develop and implement QAPPs for all of its data collection and secondary data activities as described in the Region 3 QMP and Section 8.3 of this document. These QAPPs will be reviewed by the QAC, QAT and/or other qualified personnel and must be approved by the Project Officer or his/her designee. An environmental data operation cannot begin until there is an approved QAPP. Figure 2 provides EAID's process for QAPP review and approval.

2.2.4 Standard Operating Procedures

EAID will use Standard Operating Procedures (SOPs) to ensure comparability across programs and individual environmental data collection projects. SOPs are written documents that give a precise description of routine procedures. Technical staff develops SOPs and are approved by the appropriate Associate Director or his/her designee. SOPs may be referenced by QAPPs or other planning documents. All sample collection efforts performed by EAID staff are required to be documented as SOPs. SOPs are required for all analyses performed by the two laboratories. SOPs are to be maintained by each office and are to be updated, at a minimum, every three years. Associate Directors are responsible for ensuring adequate resources for the preparation, review and updating of SOPs. The Director of the laboratory or his/her designee (Laboratory QA Officer or Technical Director, Team Leader), is responsible for maintaining, tracking and filing of Laboratory SOPs. The GIS Team has developed a set of Standard Operating Procedures that describe routine procedures in the display and analysis of geospatial data. Tasks included in the SOPs include archiving, project

management, metadata creation, spatial data library management and others. These SOPs may be referenced in projects requiring a QAPP.

2.2.5 Technical Systems Audits

Technical Systems Audits (TSAs) involve a review of facilities, equipment, sampling and analysis procedures, documentation, data validation and management, and reporting aspects of the total data collection activity. As cited in the Region 3 QMP, the EAID program manager can request a TSA to identify and document problems, to identify and cite noteworthy practices, and to request recommendations for improvements. For those activities where EAID has direct authority, Associate Directors will ensure that these areas routinely receive TSAs by appropriate staff.

2.2.6 Laboratory Quality Assurance Plans or Manuals

Laboratory Quality Assurance Plans, including Laboratory Quality Manuals, are used to document the Laboratories' Quality Systems. OASQA and the Freshwater Biology Team (Wheeling) Laboratories document their quality systems in respective Quality Manuals and associated SOPs. All EAID environmental data collection efforts will ensure that acceptable QA requirements are included and implemented. Quality assurance activities will be designed in the most cost effective manner possible without compromising data quality objectives.

2.2.7 Data Quality Assessments

A Data Quality Assessment (DQA) is the scientific evaluation of data to determine if data obtained from environmental data operations are of the right type, quality, and quantity to support their intended use. The most recent version of EPA QA/G-9R, *Data Quality Assessment: A Reviewer's Guide* and EPA QA/G-9S, *Data Quality Assessment: Statistical Tools for Practitioners*, found at http://www.epa.gov/quality/qs-docs/g9r-final.pdf and http://www.epa.gov/quality/qs-docs/g9s-final.pdf respectively, may be used during the DQA. At a minimum, all environmental data will be reviewed to ensure that the analytical measurement criteria specified in the approved Quality Assurance Project Plan (QAPP) has been achieved. Data shall be qualified in accordance with the data validation criteria specified in the approved QAPP.

After this initial review, the data will be evaluated to determine if the project's data quality objectives and sampling design criteria have been achieved. Data validation reports, field and laboratory audit reports, proficiency testing sample results and other quality control information may be used to make this determination. In addition, various statistical tests (e.g., t-tests, quantile tests, etc.) may also be conducted to help draw conclusions about the data.

3.0 Personnel Qualification and Training

3.1 Policy for QA Related Training

This section describes the policy and processes used by EAID to ensure that staff and managers working in the various environmental programs highlighted in Section 1.6 are trained and qualified to perform their required QA responsibilities.

It is EAID's policy to have EAID staff trained in the context of tasks and functions related to data quality for EAID programs. Additionally, they will use their educational background, experience, professional symposia, and on-the-job training to help them assure the quality of data. EAID employs the training policy for persons involved in environmental data generation, collection and/or use as described in the Region 3 QMP, Section E.1. Laboratory personnel in EAID are also required to comply with training requirements outlined in their respective quality manuals.

It is the responsibility of the Associate Directors, with assistance from the QAC, RQAM and the QAT, to ensure that the appropriate staff has the necessary QA training. Such training needs will be identified during the preparation of Individual Development Plans (IDPs) and/or internal Management System Reviews. Identified training needs will be reported in the Quality Assurance Annual Report and Work Plan (QAARWP) and training files will be maintained by the Associate Director.

4.0 Procurement of Items and Services

EAID obtains environmental data collection services through the use of contracts, grants, Interagency Agreements, and small purchases. For each of these extramural agreements and procurements, EAID will follow the requirements outlined in Section E.2 of the Region 3 QMP and Office-specific SOPs.

5.0 Documentation and Records

5.1 Identifying Quality-related Documents and Records

EAID maintains a variety of documents and records related to documenting the quality of environmental data. In Section 2 of this QMP, tools were identified that EAID uses to manage and assess its quality system, all of which generate documents or records. The following is a list of those types of documents:

- Quality Management Plans
- Quality Assurance Project Plans
- Sampling and Analysis Plans/Field Sampling Plans
- Audit/Inspection Reports
- Analytical Results Packages
- QC Data Packages

- Data Validation Reports
- Standard Operating Procedures/Procedural Manuals
- Laboratory Quality Manuals
- Quality Assurance Directives

Other documents or records that document the process(es) used during an environmental data collection activity are to be considered quality-related documents and are to be handled as stated in the remainder of this section.

5.2 Handling and Retention Processes

5.2.1 External Quality-Related Documents

EAID is involved in national programs that have associated quality assurance documents. The personnel responsible for participating in these programs are required to maintain current copies of the latest applicable QA documents and ensuring that EAID has the latest version.

For those activities in which EAID is providing programmatic support (e.g., Superfund QAPP review, Safe Drinking Water Act), EAID personnel will follow the applicable Divisional QMP for handling and retention procedures. In most instances, EAID is maintaining a copy of these documents while the Division-lead is retaining the original documents.

5.2.2 Internally Generated Quality-Related Documents

Documents that are generated by EAID (e.g., laboratory data, QA directives, SOPs) are to be maintained by the EAID Office generating the document(s). Each office is responsible for retaining these documents for the time specified in the Regional Records Management Plan, or Branch specific plan. The Federal Records Center is used for long-term retention of documents, where applicable. Each EAID Office is responsible for the inventory of its own quality-related documents.

Quality guidance documents developed by EAID are peer reviewed by QA staff personnel (RQAM, Laboratory QAOs, Quality Assurance Team or their designee) and by the appropriate program office. Quality Assurance Project Plans and SOPs prepared by EAID are reviewed by qualified staff. SOPs are approved by the appropriate Associate Director or his/her designee; QAPPs are approved by the Project Officer. Systems for indicating revisions and ensuring distribution of updated material are in place for each EAID Office that generates quality-related documents.

5.3 Documents Covered by the EPA Information Quality Guidelines

Documents which contain “information” as defined by EPA’s Information Quality Guidelines and which are “disseminated” to the public under the IQGs

must undergo a pre-dissemination review. Each information owner must maintain documentation verifying that a pre-dissemination review has been completed. The Region's policy and a checklist for this review are contained in the Region 3 QMP, Appendix C.

5.4 Compliance Process

EAID will follow statutory, contractual, and/or assistance agreement requirements for records from environmental programs. The procedures outlined in Section E.3 of the Region 3 QMP will be followed.

6.0 Computer Hardware and Software

EAID and its extramural agreement holders will comply with EPA standards and regulations pertaining to hardware, software, system development, and data as stated in Section E.4 of the Region 3 QMP.

6.1 Geographic Information System Software

EAID and the Region use Geographic Information System (GIS) software provided through a national EPA agreement with the software vendor for the software and upgrades. EAID and other regional programs use of GIS software are coordinated through the GIS Coordinator in OEIA. Technical issues with GIS software are also handled by the GIS Point of Contact.

6.2 Laboratory Information Management System

OASQA uses a Laboratory Information Management System (LIMS) to manage the flow of samples and analytical data. Access rights to LIMS are assigned to users which allow them access to only that part of the database required to perform their assigned duties (e.g., analysts have rights to enter data for samples currently in the system, but not to create new samples). All new users to the system are given a comprehensive users guide and one-on-one training on how to access the system, enter data and create reports. Additionally, several members of the staff who have in-depth knowledge of LIMS have been designated "LIMS Mentors" to assist users with problems. All data which are entered into the LIMS database are verified by a second analyst. Copies of the original software and a record of modifications to the system and data tables are kept in a centralized file. All data entered into the LIMS system is backed-up daily, weekly and monthly. The monthly back-ups are stored offsite for protection per the LIMS Back-up and Recovery Plan, which is maintained by the LIMS/Oracle Database Administrator. Only the LIMS/Oracle Database Administrator can make the enhancements and modifications which have been deemed necessary to maintain the LIMS, bring LIMS into compliance with the Region 3 Quality Management Plan and validate the system as a whole.

7.0 Planning

7.1 Planning and Documenting Environmental Data Operations

For many of the programs that EAID implements, National Program Offices have developed or are developing Data Quality Objectives. EAID staff serves on workgroups to develop national guidance or uses finalized national guidance in its program planning. Program managers work with their customers to ensure that the expectations of data quality are clear.

For activities in which EAID provides support to other divisions within Region 3, an annual planning process is facilitated by EAID management and the respective divisional management. Annual planning efforts will be recorded in a Work Plan, documenting the role of EAID staff and level of effort.

When EAID generates, collects or uses environmental data, applicable EAID personnel will develop the required documentation or ensure that such documentation (e.g., QAPPs, Laboratory QA Plans, and SOPs) is developed by the grantee/contractor or assistance agreement holder(s). Technical expertise on sampling procedures, statistics, analytical services, and QA/QC are provided from an array of resources, which include Headquarters and Regional Program Offices, OEI Quality Staff, Quality Assurance Officers, Technical Director, RQAM, Quality Assurance Team, and specialists within EAID.

7.2 Quality Assurance Project Plan (QAPP) Process

The Quality Assurance Project Plan is the primary vehicle for ensuring adequate data quality at the project level; QAPPs are to be prepared and utilized as described in the Region 3 QMP and Section 2.2.3 of this QMP. EAID personnel responsible for preparing, reviewing and/or approving a QAPP will adhere to the requirements of EPA QA/R-5, *EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations*. The Quality Assurance Team, QAC or other qualified personnel will review QAPPs prepared by EAID staff prior to sample/data collection. Project Officers are responsible for approval and obtaining the appropriate review of QAPPs generated by their grants, contracts or assistance agreements. The process for review and/or approval of QAPPs generated by grantees, contractors, and assistance agreement holders is shown in the flow diagram of Figure 2.

EAID Associate Directors will oversee the effectiveness of the planning process. Management System Reviews may be used at management's discretion.

8.0 Implementing QA Procedures

8.1 Division-wide Policy

The EAID QMP applies to all EAID programs generating, collecting or utilizing environmental data as defined in Section 1.6. The EAID QAC is responsible for reviewing and updating the QMP on an annual basis to ensure it is current with enacted policies and procedures. Individual Laboratory Quality Manuals apply to each of the EAID laboratories. These documents are reviewed and updated as specified in the respective manuals. EAID management will provide technical oversight of environmentally-related data operations. Independent oversight of the implementation of the EAID quality system will be performed by a team consisting of some combination of QACs from other divisions, members of the QAT, the RQAM, and the EAID QAC.

8.2 Program Implementation

All programs that generate, use or require others to collect environmental data will document their QA procedures in a Quality Assurance Project Plan and develop appropriate SOPs for their program. If SOPs are lacking for a particular program, the management of that program has the responsibility to ensure development of the SOPs. Line management, with the assistance of the QAT and the EAID QAC, will develop a plan and schedule for completing SOPs.

8.3 Secondary or Existing Data

Programs may use data generated by others. EPA Order CIO 2105.0 (formerly EPA Order 5360.1A2) defines secondary/existing data as data that are collected for other purposes or from other sources such as literature, industry surveys, compilations from computerized databases and the results from computerized mathematical models of environmental processes and conditions. If secondary data is intended to be used on a project, the QAPP shall:

- Identify the types of secondary data needed for project implementation or decision making;
- Describe the intended use of the secondary data;
- Define the acceptance criteria for the use of secondary data;
- Specify any limitations on the use of the secondary data; and
- Identify the individual(s) responsible for evaluating and qualifying the secondary data.

For those projects which involve the compilation and use of secondary data exclusively (i.e., there will be 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 secondary data projects may be provided by the QAC, RQAM or the OASQA Quality Assurance

Team as needed. Use of secondary/existing data by EAID will conform to requirements cited here and in the Region 3 QMP, Section B.3.d.

8.4 Project-Level Implementation

All environmental data collection and analyses must be implemented in accordance with an approved QAPP. Any changes to the QAPP will be documented and the QAPP amended. Any amendments to the QAPP will need review and approval. The PO should include identifiable QA milestones and target dates in the project time line so that progress and completion of the QA/QC activities can be effectively tracked. The PO is responsible for initiating the project, reviewing the progress reports, and receiving applicable data and reports.

9.0 Assessment and Response

EAID uses a variety of internal management and technical reviews, proficiency testing, and audits to assess the effectiveness of its quality system. Depending on available resources, EAID will use independent reviews by contractors or personnel from other regions or divisions to evaluate the systems and procedures outlined in the EAID QMP. The procedures used for planning, implementing and reporting such assessments are similar to those outlined in Section D.2 of the Region 3 QMP. The respective Laboratory Quality Manuals also outline specific procedures to be followed for laboratory assessments and responses.

As appropriate and available, the Division will use established accreditation programs for an assessment of its laboratory and field activities (e.g., NELAP Accreditation of the OASQA Laboratory). The Office of Ground Water and Drinking Water conducts an assessment of the OASQA Laboratory for oversight of the Safe Drinking Water Act (SDWA) Laboratory Certification Program. These assessments will identify any data quality problems; benchmark practices that could be used in other regional programs; propose recommendations for solving quality problems; and confirm implementation and effectiveness of any recommended corrective actions.

EAID will also use Proficiency Testing (PTs) to assess laboratory measurement systems. The PTs normally consists of a reference or blind sample that has known concentrations of chemical constituents or pollutants. The results obtained are compared to the known concentrations to determine the laboratory's ability to identify and quantify pollutants within established or calculated control limits. Each individual Office is responsible for ensuring that PTs are utilized on a regular or as needed basis. For specific programs, such as drinking water and National Pollutant Discharge Elimination System (NPDES), PTs are required on a regular basis.

EAID is in the process of developing and implementing a Peer Review policy and procedures for Region 3. Upon approval for implementation, EAID will follow these policies and procedures. Until such time, EAID implements the Agency's peer review

policy as it is specified in US EPA, Science Policy Council, *Peer Review Handbook*, EPA 100-B-00-001, December 2000 and in Section D.8 of the Region 3 QMP.

10.0 Quality Improvement

The EAID QMP serves as the framework for applying QA requirements to environmental measurement and data collection activities. The two EAID laboratories will review and update their Laboratory Quality Manuals and SOPs as specified in their respective manuals. Additionally, each EAID Office will develop its own processes, documented as QA plans, SOPs or manuals to implement quality requirements in its programs. Across the Division, the Program Managers, QAC, Project Officers, and individuals involved in field and analytical environmental data activities must be actively involved to assure the quality of data. They are in the best position to understand the process, identify problems, and correct deficiencies. When deficiencies in the quality system are identified, EAID management, working with these individuals, will promptly develop and implement a corrective action plan.

11.0 Information Quality Guidelines

EPA's Information Quality Guidelines apply to information produced by EPA to support or represent EPA's viewpoint, formulate or support a regulation, guidance or other Agency decisions or positions. Information from external suppliers is also covered if the Agency uses it in a manner that EPA endorses or agrees with; supports or represents an EPA viewpoint; or formulates or supports a regulation, guidance, policy or other Agency decision or position. Some types of information are not covered by the IQGs, such as information intended only for government employees. A complete listing of covered information types may be found in the EPA Information Quality Guidelines document.

The Information Quality Guidelines Officer resides in EAID in the Office of Environmental Information and Analyses (OEIA). EAID staff understands the IQG principles and policies and will work with Region 3 management and the IQGO to respond to any Request for Correction or Request for Reconsideration that may occur. Each information owner must maintain documentation verifying that a pre-dissemination review has been completed. The Region's policy and a checklist for this review are contained in Appendix C of the Region 3 QMP.

12.0 References

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U.S. Environmental Protection Agency, 2011. *Laboratory Quality Manual, Version 8*, Region 3, Office of Analytical Services and Quality Assurance.

The NELAC Institute, 2003. *National Environmental Laboratory Accreditation Conference (NELAC) Standards;* EPA/600/R-04/003.

Figure 1

EAID ORGANIZATIONAL CHART

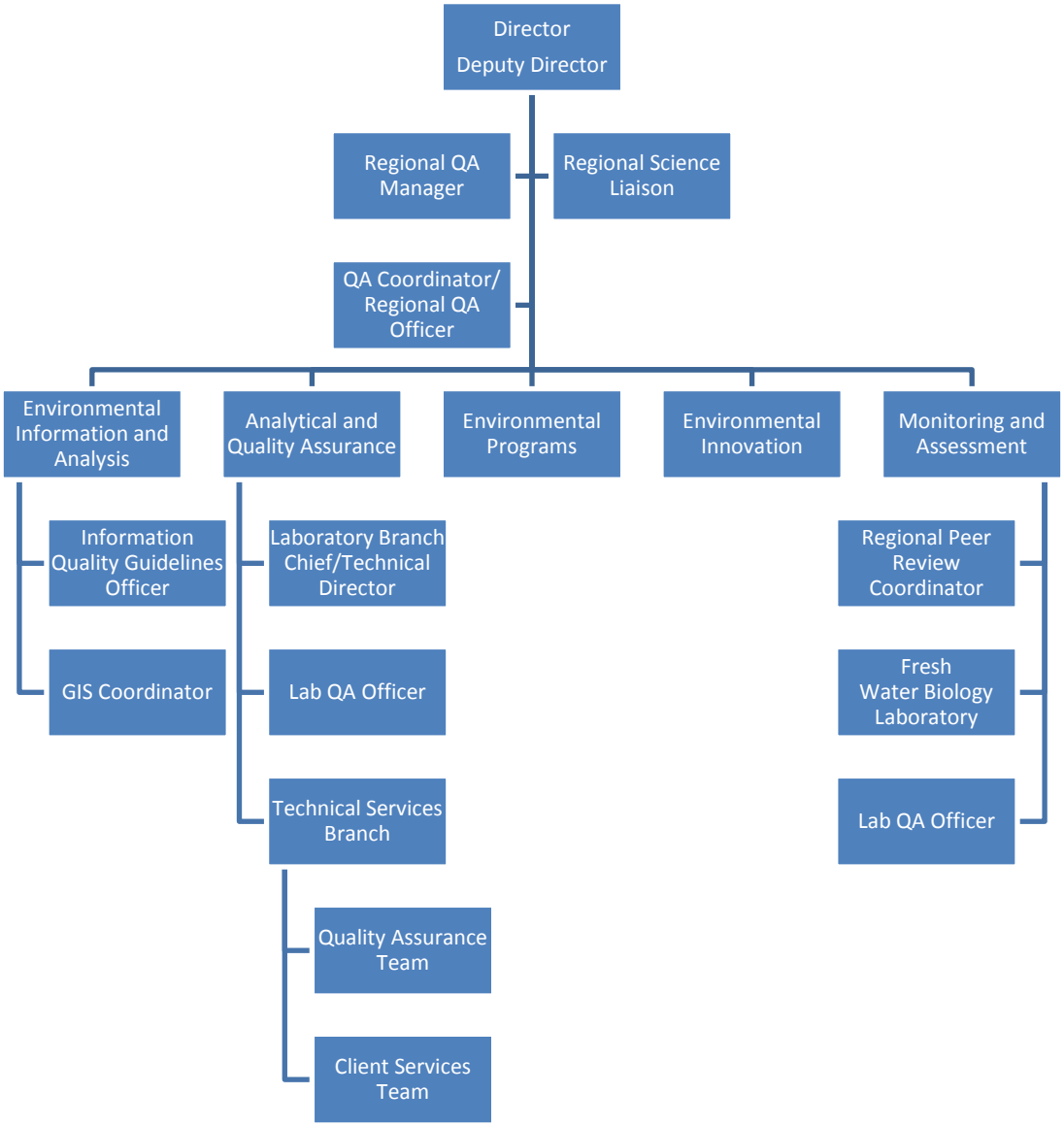
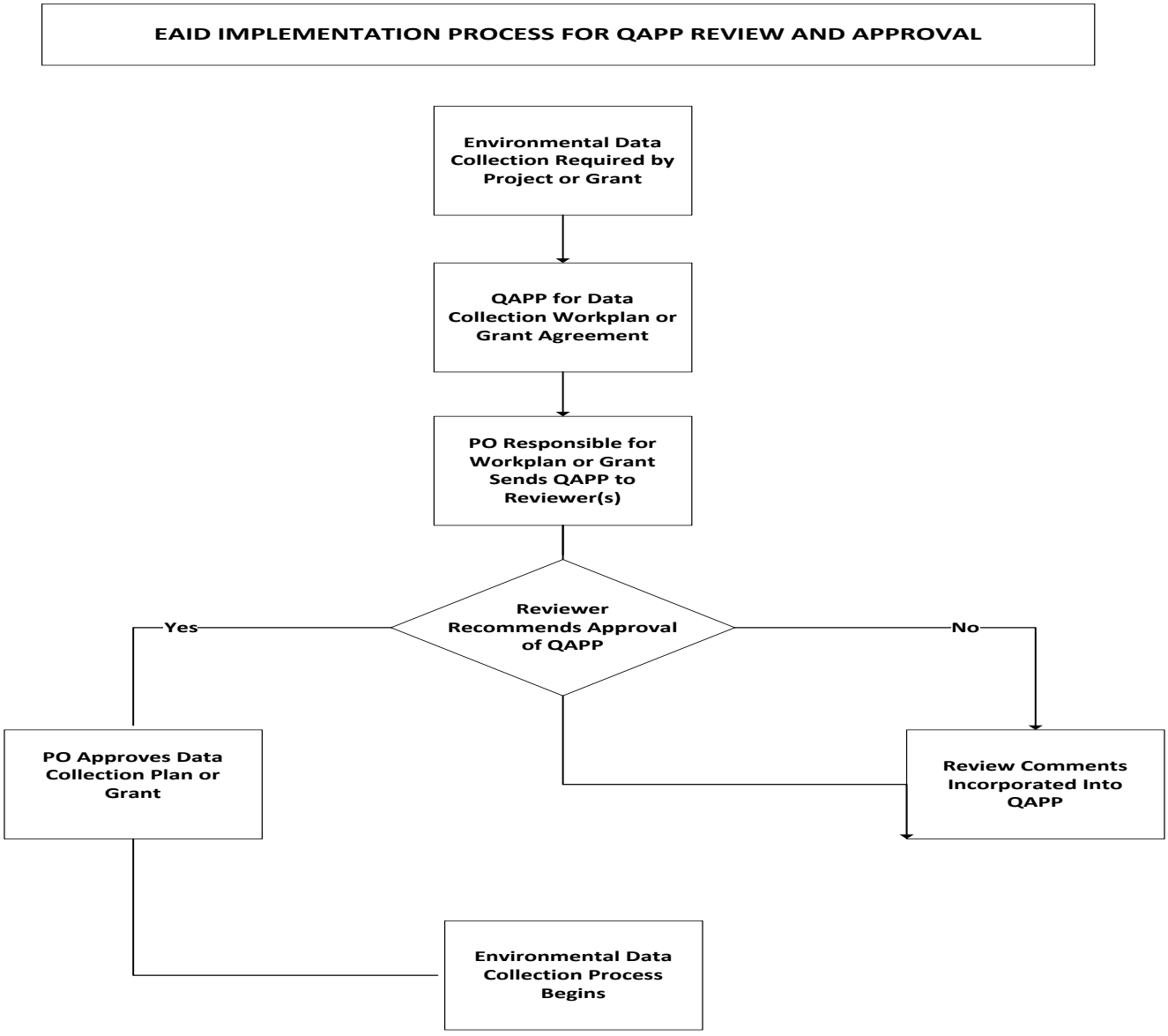


Figure 2


EAID IMPLEMENTATION PROCESS FOR QAPP REVIEW AND APPROVAL
Environmental Data Collection Required by Project or Grant
QAPP for Data Collection Workplan or Grant Agreement
PO Responsible for Workplan or Grant Sends QAPP to Reviewer(s)
Reviewer Recommends Approval of QAPP
Yes
No
PO Approves Data Collection Plan or Grant
Review Comments Incorporated Into QAPP
Environmental Data Collection Process Begins