QUALITY MANAGEMENT PLAN

FOR THE

WATER PROTECTION DIVISION

Jon Capacasa, Director

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WPD QUALITY MANAGEMENT PLAN
Concurrences and Approvals

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Quality Management Plan (QMP) for the Water Protection Division

1. MANAGEMENT AND ORGANIZATION

Introduction

This document describes the total quality system of the Water Protection Division (WPD), including the Division policies and responsibilities. This document is intended to help WPD managers, Project Officers (POs), other WPD staff and external partners implement the quality requirements for all environmental data collection activities and all activities which involve the evaluation and use of environmental data.

WPD is strongly committed to good science and to the implementation of a sound quality management system. This commitment is consistent with the goals of the Policy and Program Requirements for the Mandatory Agency-Wide Quality System, EPA Order 5360.1 A2, and the EPA Quality Manual for Environmental Programs (5360.1 A1). In addition, the WPD QMP has been prepared in conformance with the approved Region III QMP.

WPD has already developed and integrated Quality Assurance (QA) practices into the collection, use, and evaluation of its environmental data. These practices are specifically designed to generate and process data of known and acceptable quality in a cost-effective manner.

Coordination with Region III Quality Assurance Programs

Region III employs a decentralized approach to QA management, whereby each Division or Office is responsible for deciding how it will implement the general policies and procedures of the Regional QMP and the related Divisional QMP. The Regional Administrator has delegated responsibility for overseeing the Region's Quality System to the Environmental Assessment and Innovation Division (EAID). The Regional Quality Assurance Manager (RQAM) is located in the Immediate Office of the EAID Division Director. The RQAM is independent of direct environmental data generation, model development, or environmental technology development. On issues relative to the Region's quality system, the RQAM reports to the Senior Management Representative to the Regional Quality Council (RQC). The Regional QA Officer (RQAO) is located in the EAID's Immediate Office. Within EAID's Office of Analytical Services and Quality Assurance (OASQA), there is a Quality Assurance Team (QAT) which provides technical support to various Regional programs.

Each Division and Program Office which collects and/or evaluates environmental data assigns a Quality Assurance Coordinator (QAC) to the RQC. The RQC is responsible for the implementation of the Region's Quality System. The membership of the RQC includes the RQAM, a Senior Management Representative, the RQAO and the QACs. The structure and function of the RQC allows each level of the organization to participate in maintaining and improving the Region's Quality System. If there are QA issues that cannot be resolved by the RQC, the Senior Management Representative to the RQC, the RQAM and the RQC will raise

these issues to the Regional Administrator and Senior Managers.

WPD Quality Management Policy

This policy covers the collection, evaluation, and use of environmental data by or for EPA in the Clean Water Act (CWA) and Safe Drinking Water Act (SDWA) programs administered by the Water Protection Division. It is the policy of the WPD that its quality program will assure that all environmental data generated, processed, and used by the WPD will be scientifically valid; of acceptable completeness, representativeness, and comparability; of known and documented quality; and designed to meet the specific needs of our programs.

Specifically, it is WPD's policy that:

- A strategic approach will be taken to ensure implementation of the quality program and dedication of resources to the most important areas of data use or vulnerability. This will be based on the magnitude of the Agency investment, the regulatory cost to external parties, and the level of vulnerability based on the highest public concern or interest in a decision. Where resources are limited, these will become the priorities for implementation and action follow-up. It is the responsibility of the Division Director to make these priority-setting decisions.

- WPD Senior Managers will work with the WPD QAC to communicate the WPD commitment to quality procedures and implementation and to convey the components of this WPD QMP to all WPD staff. Briefings on the QMP will be made by the WPD QAC and steps will be taken with representatives from each Division Office to ensure that affected Office programs and their associated quality needs are understood.

- WPD will periodically inventory and identify places in our programs where environmental data is being obtained and used to make decisions. When resources are limited, WPD will denote the priority areas in which data is collected for the most critical or essential uses and the most vulnerable areas.

- QA practices and procedures will be implemented in the most cost effective manner possible without compromising quality. Data Quality Objectives (DQO) will be defined in advance of a new data collection activity and will be clear as to the intended use. The systematic planning process will be used when the Division is evaluating and using environmental data from alternative sources (e.g., databases, literature, historical data, etc.).

- Where WPD has delegated programs and where WPD is providing funds to other organizations to conduct environmental data gathering, WPD is responsible for oversight of activities being performed by organizations which receive EPA funding. The Region must evaluate the organization's quality system to determine if it meets EPA quality requirements. The organization must submit a QMP to EPA for review and approval by the RQAM. It is the responsibility of the Division's QAC and POs, in conjunction with the RQAM, to ensure that the organization's quality system meets EPA requirements.

- Each grantee or contractor agency will develop and implement a Quality Assurance Project Plan (QAPP) and/or Standard Operating Procedures (SOPs) which specify how it will comply with this document. The QAPP or SOP will be prepared by the external organization and approved by the PO and Division QAC, as authorized quality representatives, prior to the start of any data collection effort. WPD will also place responsibility for implementing, evaluating, and self-auditing activities on the recipient organization.

- Consequences and implications for not properly fulfilling the strategically important quality procedures will be known to all and implemented and applied consistently. Such consequences could include EPA issuing stop-work orders, stopping payments, terminating the project, and prohibiting the organization from receiving other EPA funds. Grantees, contractors, and others providing data to WPD for public use shall be equally accountable for the provision of quality data. We will conduct spot monitoring of quality management efforts through all phases of the project (i.e., planning, implementation, and assessment) to ensure the plans are being implemented in the field.

- All reported data will include or incorporate by reference documented precision and accuracy data. This shall be implemented by ensuring that for all WPD data production efforts, adequate quality procedures will be employed through the entire monitoring process from the study design through data usage. The objectives for generating any new environmental data will be determined prior to data collection being initiated. Control methods will be applied to ensure a high level of quality commensurate with the intended use of the data.

- A minimum data set will be defined at the program level to ensure that certain data components, necessary for all decision-making in that program, are collected and reported.

- Databases will be inventoried periodically to consider ways to improve data management or quality and ensure that the data is accessible to and usable by other groups. This review will include identifying data that could be consolidated or eliminated; documenting sources of data; clarifying the data's purpose; and identifying users. Criteria for this review will be developed.

- WPD will assess implementation of this QMP annually and periodically report on the success of its quality program.

WPD is committed to ensuring that sufficient resources are dedicated to supporting the QMP. A total of approximately 3.0 FTE, composed of varying percentages of time of many staff, is dedicated to QA in the WPD.

WPD Organization for Quality Management Implementation

In May 2006, the WPD QA functions and the WPD QAC were assigned to the Office of Standards, Assessment and TMDLs.

For the quality function, the WPD QAC has organizational independence from groups generating, compiling, and evaluating environmental data and reports to the Division Director and Deputy Director. The QAC maintains a network of appropriate programmatic staff in the Division, convening meetings and scheduling training as necessary. The QAC transmits policies, guidances, and other information to all staff with quality responsibilities. WPD has identified a need for training specifically on several topics relating to quality, including QA orientation, QAPP review, and DQO concepts. WPD will participate in the training included in the Regional QA Training Plan. The Division also commits to providing periodic reminders about quality to state environmental secretaries and other external managers.

WPD will use the Region's organizational structure to resolve disputes related to quality. Any dispute, whether internal or external to EPA, will be identified promptly to the WPD QAC, who will seek to resolve the issue directly and/or in consultation with the RQAM. When unsuccessful, the WPD QAC will raise the issue to the Division's management, who will, as necessary, work to resolve the problem with the Senior Management Representative to the RQC. The resolving officials will document the resolution and provide it to the disputing parties.

2. QUALITY SYSTEM COMPONENTS

QAPPs and SOPs

QAPPs and SOPs are required of all data providers. They will be developed using EPA documents EPA Requirements for Quality Assurance Project Plans (EPA QA/R-5) and Guidance for the Preparation of Standard Operating Procedures (G-6). Technical and managerial staff will perform assessments of the data and the procedures used to obtain and evaluate the data. The POs are responsible for ensuring that the systematic planning process is followed and the results are documented in QAPPs.

Partner Agencies QMPs

A key point of coordination between the WPD and the work of the RQAM and OASQA staff is in the development and approval of QMPs by state, interstate and other partner organizations that work with WPD. Distribution of QMP status by agency is routinely checked by WPD staff to determine if follow-up action is needed. Appropriate action, e.g., identification of priority action by a WPD grant recipient to update a QMP, is brought to the attention of WPD by the WPD QAC. Working in conjunction with the RQAM, necessary follow-up tasks are planned to ensure QMP approval is obtained.

Direct Program Responsibilities

Several CWA and SDWA programs are directly administered by WPD, including the Public Water Supply Supervision program for the District of Columbia and the Underground Injection Control Program for the District of Columbia, Pennsylvania and Virginia. Data management and related database management issues involved in these programs will be performed in a manner consistent with this QMP and the QA practices in these programs will be

periodically assessed.

Database and Data Tools Management

The CWA National Pollutant Discharge Elimination System (NPDES) and SDWA Drinking Water programs maintain national data bases called Permit Compliance System (PCS) and Safe Drinking Water Information System (SDWIS), respectively. These systems comply with Agency-wide standards for ensuring the quality of data entered into the data bases. Information for this data base is supplied by both the EPA Regional Offices and the authorized States. Both systems are in the process of changing from legacy to the new modernized Integrated Compliance Information System (ICIS). States now have a choice of being a direct user or using their state developed systems to transfer data into ICIS-PCS through the use of the interim data exchange format (IDEF).

The National water quality database STORET (STOrage and RETrieval system) is used by participating states and other organizations to provide the results of various water quality sampling initiatives. WPD provides assistance to these organizations in conjunction with Headquarters Office of Water staff.

Water quality assessment data and information on impaired waters and Total Maximum Daily Load (TMDL) studies are maintained in the Assessment Database and National TMDL Tracking System. An effort is currently being led by Office of Water staff to merge these two programs into a consolidated database. This is expected to be completed by the end of 2016.

In addition to the national databases, several WPD programs maintain databases to track program status. An example is the Well Information Management System for the Underground Injection Control program.

All database functions and data tools management will be periodically assessed for conformance with this QMP and QA practices.

Information Dissemination Guidelines

EPA issued its Information Quality Guidelines (IQG) in October 2002 in response to guidelines issued by OMB pursuant to the 2001 Information Quality Act. Pre-dissemination Review Guidelines were issued by the Agency in September 2006.

EPA's Information Quality Guidelines (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. "Information" generally includes any communication or representation of knowledge or position/policy such as facts or data, in any medium, or form. This includes "preliminary" information that EPA has endorsed or adopted, and also conclusions or facts drawn from or based upon other, existing information. This QMP incorporates by reference all definitions, principles, policies, and procedures found in EPA's IQGs.

This QMP incorporates by reference all definitions, principles, policies, and procedures found in Region 3's QMP on information dissemination. Implementation procedures for Region 3 implementation of the Information Dissemination are contained in section B.4 of the Region 3 Quality Management Plan.

Pre-Dissemination of Information 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. WPD will use the *EPA Region III Information Quality Guidelines Pre-Dissemination Review* document which is included as Appendix E in the Region 3 QMP. The Region 3 QMP also contains the Region's checklist for pre-dissemination of information.

3. PERSONNEL QUALIFICATIONS AND TRAINING

WPD commits to ensuring that all managers and staff who are involved in the use, generation, or processing of data receive training in the context of tasks and functions related to data quality for WPD programs. In addition, they are required to draw upon their educational background, professional experience, and on-the-job training.

WPD will work to ensure that only trained and qualified staff will be used to perform their work. Such training will include PO Certification, which is required of all grant managers in the Region, and inspector training for staff working in the field. In addition, under EPA's contracting policy, quality training for Work Assignment Managers (WAMs) is required. In addition, appropriate WPD staff will participate in the EPA Quality System training when it is made available. A prioritized list of WPD staff involved in quality functions will be used to identify the participants in the training.

WPD will maintain attendance lists for training sessions so that the managers can ensure full coverage by appropriately trained staff. The Office of Policy and Management (OPM) maintains lists of POs' and WAMs' attendance at certification courses. Training needs will be identified by the WPD QAC, in cooperation with the RQAM, and training will be targeted to the particular needs of the staff. Currently available training programs will be used or specific training will be developed as needed.

4. PROCUREMENT OF ITEMS AND SERVICES

Environmental data for WPD programs is obtained in a variety of ways. WPD uses EPA staff, grantees (including states), contractors, staff of other agencies (via Inter-Agency Agreements – IAGs), and private sector resources including volunteer monitoring to sample and analyze environmental conditions. All suppliers of environmental data must submit a QMP. In addition, a QAPP (generic or project-specific) is required for each activity that includes environmental data collection. QAPPs from grants and IAGs are approved by the PO and the

WPD QAC. QAPPs from contractors are approved by the Contracting Officer Representative (COR) and the WPD QAC. At the discretion of the PO, COR and the WPD QAC and/or the RQAM, a combined QMP/QAPP may be submitted. Procurement of services in WPD is under the authority of the WPD Division Director and his designees.

Generally, extramural agreements for WPD are in the form of grants/cooperative agreements or IAGs. Quality review processes follow the same basic set of actions regardless of whether the procurement occurs via grant or IAG. For IAGs, the WPD QAC takes a lead role in ensuring that the other Agency involved has requisite QMP and other quality procedures in place.

EPA has established policies on general lab competency which can be found at http://www.epa.gov/fem/lab_comp.htm. This QMP incorporates by reference the policies put into place under the 2011 document *Policy to Assure Competency of Laboratories, Field Sampling, and Other Organizations Generating Environmental Measurement Data under Agency-Funded Acquisitions* and the 2012 document *Policy to Assure the Competency of Organizations Generating Environmental Measurement Data Under Agency-Funded Assistance Agreements.* When the Region 3 QMP is updated to reflect these new EPA policies, the WPD will adopt by reference all Region 3 policies on laboratory competency as well.

WPD will comply with procedures in the Regional QMP relating to documenting that quality requirements have been met. All extramural agreements are reviewed by POs in WPD and Grants or Contracts Specialists in OPM. This review includes ensuring that the services are needed and accurately and fully described; that the quality system is adequate and documented; and that all Federal requirements for data quality are satisfied. In addition, during the grant close-out process, the Region will determine that all grant requirements, including those relating to quality, have been met.

5. DOCUMENTS AND RECORDS

Grantee and Contract Records

Documents such as Work Plans, QAPPs, and other project-related reports are submitted to the PO or COR as appropriate. The PO or COR has the responsibility and authority to request review from the appropriate Division staff, such as water quality specialists, geologists, surface water modelers, and quality contacts. All POs shall maintain current grant files, including the relevant QAPPs, under their management until the project is completed and the funding mechanism closed out. If any updates to approved QAPPs are found necessary, the WPD review process will be repeated and the PO or COR will make appropriate documentation in the project file. The grant files are sent to the central file room or archived according to Agency guidelines. The PO or COR should use the approved QAPP to determine if procedures being implemented during the life of the project are consistent with those included in the approved QAPP. The WPD QAC will maintain WPD's Quality System Audit reports and Corrective Action reports in the central file room.

Documents for data submissions are grouped into two (2) categories. The first category

consists of ongoing projects (e.g. grant, IAG, etc.), where data is submitted on a periodic basis throughout the length of the project. The second category consists of fixed projects, i.e., those projects where data is submitted only once at the end of the project.

Copies of national guidance or requirements documents that are specific to the programs administered by WPD will be maintained by the WPD QAC and by the POs within WPD that are responsible for the administration of that program. The WPD QAC will ensure that staff have the current QMP and SOPs and will provide updates or additional information through electronic transmittal.

WPD Records Management

WPD has established a Records Manager position and a centralized recordkeeping process. WPD central file room functions are under the direction of Clarissa Poole who has received appropriate records training. Documents are maintained in the WPD file room in accordance with established policies for records retention. A draft manual for records management in WPD has been prepared and this manual specifies how records are to be submitted and files, retrieved and archived/disposed. The integrity of the file room is maintained through a file sign-out process. Implementation of the procedures established by WPD for file/records management ensures that required records for evidentiary proceedings are properly maintained and available.

The WPD Records Manager will also provide oversight to the WPD implementation of the Enterprise Content Management System for email records.

6. COMPUTER HARDWARE AND SOFTWARE

Computer hardware and software which is procured or used exclusively in WPD's environmental operations and which directly impacts the quality of the results of its environmental programs must comply with Agency standards. WPD works closely with the Computer Services Branch (CSB), relying on that organization to ensure that computer-related purchases meet Agency standards and comply with all hardware and software standards delineated in the Office of Environmental Information's Guidance on Hardware and Software Standards. These standards address Compatibility, Hardware, Operating Systems, Communication, Database Management, User Interface/Printer Interface, Application Development and Applications. This includes those policies and requirements related to the Americans with Disabilities Act. Bankcard procurement will also follow the Region's specified procedures.

WPD will work with CSB to ensure that any Agency-approved hardware and software procured conforms with Agency information management architecture standards and complies with EPA Directive 2100. Prior to any purchases, the PC Site Coordinator and/or LAN Manager will evaluate requested software and hardware to determine its conformance to Agency standards, compatibility with existing products and services, performance capabilities and impact

on the existing infrastructure. PC Site Coordinator will approve purchases only if it meets all of the above requirements.

Programs using national databases rely on data verification and auditing protocols established by the National Program Manager. WPD programs handling national data work with the data team staff located in the OSAT office to perform periodic data verifications and audits. Evaluations of all data systems are routine, and changes in hardware and software are made as user needs and management requirements change.

7. PLANNING

WPD uses a systematic planning approach which clearly identifies the goals and objectives of projects; the schedules for completion and the responsible parties; the type of data needed, including the specification of performance criteria for measuring quality; how data will be collected, analyzed, evaluated, and reviewed against performance criteria; required resources; applicable regulatory and contractual requirements; required QA activities (e.g., audits, P/T samples); and a description of how the data will support the project objectives

The use of the systematic planning process will ensure that adequate data quality is obtained at the project level. The primary vehicle for ensuring adequate data quality at the project level is the QAPP. The QAPP will document the outcome of each step of the systematic planning process. WPD will use a system similar to the DQO process and will ensure that the outputs of the process are documented in the QAPP. The POs are responsible for ensuring that the process is being followed.

In general, QAPPs will be prepared by the grantee/organization receiving EPA financial assistance for a project that includes environmental data collection or management. Reviews of draft QAPPs are a combined responsibility of the PO, COR and the WPD QAC. Technical assistance in the reviews is provided by the OASQA QAT. QAPP approval will be made by the PO, COR and the WPD QAC and documentation provided in project file.

QAPPs must be approved prior to any data gathering work or use, except under circumstances requiring immediate action to protect human health and the environmental or operations conducted under police powers, per EPA Order 5360.1 A2.

Currently, OASQA is reviewing documents for the several grant and other programs under the Clean Water Act and Safe Drinking Water Act. POs for other programs in WPD, in consultation with program technical staff, are responsible for ensuring that staff in OASQA reviews quality documents for those programs. WPD also uses OASQA staff to evaluate data obtained from sources outside EPA that did not use an EPA-approved QAPP for data collection. The WPD QAC will evaluate options to improved WPD oversight of the status of QAPPs submitted for review as well as the development of a QAPP administrative checklist to assist these reviews.

Secondary Data

According to EPA Order 5360.1 A2, secondary 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. If a project intends to use secondary data, the project 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;
- Identify the individual(s) responsible for evaluating and qualifying the secondary data.

The Project Manager/Project Officer is responsible for ensuring that the issue of secondary data is addressed in a project-specific QAPP. For those projects which involve the compiling 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 RQAM or the EAID/OASQA Quality Assurance Team as needed. The Project Manager/Project Officer is responsible for ensuring a QAPP is prepared for these types of environmental data projects.

8. IMPLEMENTATION OF WORK PROCESSES

A systematic planning process and a QAPP are required for all projects that involve the use of environmental data in WPD programs. All organizations that provide environmental data to WPD must use the systematic process and must develop a QAPP. Based on the nature of the project, the organization may submit a combined QMP/QAPP.

Any changes to WPD's QMP will be documented and revisions will receive the same level of review and approval as the original plan. Division managers will provide technical oversight of environmentally related data operations. Independent oversight of the implementation of the QMP will be performed by the RQAM and the Division QAC.

All programs within WPD that directly collect environmental data or that require data to be collected by others will prepare a QAPP and/or appropriate SOP for their program. QAPPs will include criteria for evaluating data generated by others. For WPD programs requiring SOPs, each program will assign a senior technical staff to develop the SOP. SOPs will be prepared in

accordance with EPA QA/G-6, will be documented in writing, and will be made accessible to all persons involved in the implementation of the program. WPD has many senior POs who are responsible for the management of their assigned projects, including the implementation of necessary quality procedures. POs are also responsible for ensuring that QAPPs are submitted by grantees who are engaged in data collection activities for approval by EPA.

The work plan and quality products outlined in the QAPP will be implemented as approved. Any changes to the QAPP will be documented and the QAPP amended. Any amendments to the QAPP will be reviewed and approved by the PO and the WPD QAC.

As resources allow, WPD will conduct selected reviews of approved QAPPs to determine if the activity covered by the QAPP is or has been performed in accordance with provisions of the QAPP. The WPD QAC will work with the PO of the selected project in these evaluations. Similarly, WPD SOPs will also receive selected evaluations. These SOP reviews will be performed by the WPD QAC.

WPD will work to ensure that QA requirements are fulfilled in the TMDL work assignment contract process and other appropriate program responsibilities.

9. ASSESSMENT AND RESPONSE

WPD will fully utilize reviews of its quality management system conducted by the RQAM, EPA's Office of Environmental Information's quality staff, as well as assessments and audits conducted by GAO and the EPA OIG office, as important supplements to its own reviews. The Director and Deputy Director, WPD, are responsible for ensuring that corrective actions are implemented.

Among the options available to WPD to review its quality system implementation are the following:

Internal Quality System Assessments

A formal QSA of each Division or Program Office that is a part of the quality system shall be conducted every three years. Information found in the most recent version of EPA QA/G-3: Guidance on Assessing Quality Systems may be used in the development of the QSA. The use of standard checklists developed by the RQAM help ensure that the appropriate QA requirements are evaluated during the QSA.

The QSA Team shall determine the scope of the audit and the tentative QSA schedule. Typically, the RQAM, or designee serves as the QSA team leader. The audited Division or Program Office's QAC shall assist the QSA Team in handling the logistics of the QSA and scheduling interviews. The Senior Management Representative to the RQC shall be responsible for sending QSA notifications, Findings Reports and requests for Corrective Action Plans to the Division or Program Office Director.

During the QSA, managers and active participants in the organization's quality system are interviewed. In addition, QA files, previous audit reports and corrective action plans are also reviewed. The results of the QSA shall be documented in a Draft Findings Report. Findings may include objective evidence of non-conformance with the organization's quality system or noteworthy accomplishments.

Upon completion of the audit, the preliminary results of the internal QSA shall be shared with the Division or Program Office's Senior Management. Within 45 days, the audit team shall submit a written draft findings report to the Division or Program Office's Senior Management. The Division or Program Office shall review the draft findings report to ensure it accurately describes the QA procedures being implemented by their organization. Upon completion of its review, the Division or Program Office shall provide the audit 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. The audit team shall submit the final audit report to the Division or Program Office's Senior Management. Upon receipt of the final findings report, the Division or Program Office shall prepare a written corrective action plan. The Corrective Action Plan must identify the corrective action, responsible official(s), and the projected completion date for each finding requiring corrective action. This Corrective Action Plan shall be submitted to the QSA team within 30 days.

External Quality System Assessments

External assessments are conducted by the OEI Quality Staff, Office of Inspector General auditors, or Headquarters' program 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 consists of members of the OEI Quality Staff and at least one person from another Region. The scope of this audit 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, the Region's 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. Region III managers are responsible for ensuring compliance with the approved corrective actions. Bi-annually, the RQC will provide Senior Managers with information about the Region's progress on implementation of the Corrective Action Plan.

Technical Systems Audit (TSA)

The goal of the TSA is to determine whether environmental data collection activities and related results comply with the project's QAPP and other planning documents. TSAs may also be used as an investigative tool when problems are suspected. 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 TSA is documented in the QAPP. The Project Manager or Project Officer is responsible for ensuring the specified TSA is accomplished. The individuals conducting the technical system audit should be knowledgeable of the procedures being audited.

Laboratory Assessments

The EAID OASQA Technical Director in conjunction with members of the OASQA Analytical Team, Client Services Team and Quality Assurance Team conduct assessments of laboratories that support the NPDES and the SDWA programs.

OASQA staff conduct laboratory assessments of National Pollution Discharge Elimination System (NPDES) permittees' and commercial laboratories analyzing compliance samples, as requested by the NPDES program in the WPD. 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 DMRQA 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.

EAID OASQA performs laboratory inspections of Region III State Laboratories using procedures specified by the Agency's Laboratory Certification Manual (LCM), EPA 815-B-97-001(March 1997) and by SOP, R3-QA801.0: On-site Laboratory Assessments in the Drinking Water Laboratory Certification Program (September 2001). On-site assessments are conducted every three years and corrective actions are tracked and official certification update reports are issued. Recommendations for changes in certification status are based upon corrective actions. The EAID OASQA Technical Director is responsible for tracking corrective actions. OASQA also performs reviews of the Region III State 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.

Data Quality Assessments

The goal of the DQA is to determine if data obtained from environmental data operations are of the right type, quality, and quantity to support its intended use. The scope of the DQA should be commensurate with the project objectives and intended use of the data. The 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 should 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.

10. QUALITY IMPROVEMENT

All WPD staff are responsible for quality improvement within their program areas. WPD Senior managers communicate critical activities of the WPD at office-wide staff meetings and solicit input for improvements. 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 WPD Quality System is to incorporate quality assurance as a critical component of all the work functions within our programs. All WPD staff are encouraged to raise issues that impact the quality of data and information being generated or used by the Division. These issues should be raised to their immediate supervisor, and, it necessary, to the WPD QAC. Issues that affect more than one WPD program will be elevated to the WPD Director. If the issues cannot be resolved internally, the WPD QAC will consult with the RQAM. If the issue is relevant to other Regional Division or Offices, it will also be brought before the RQC.

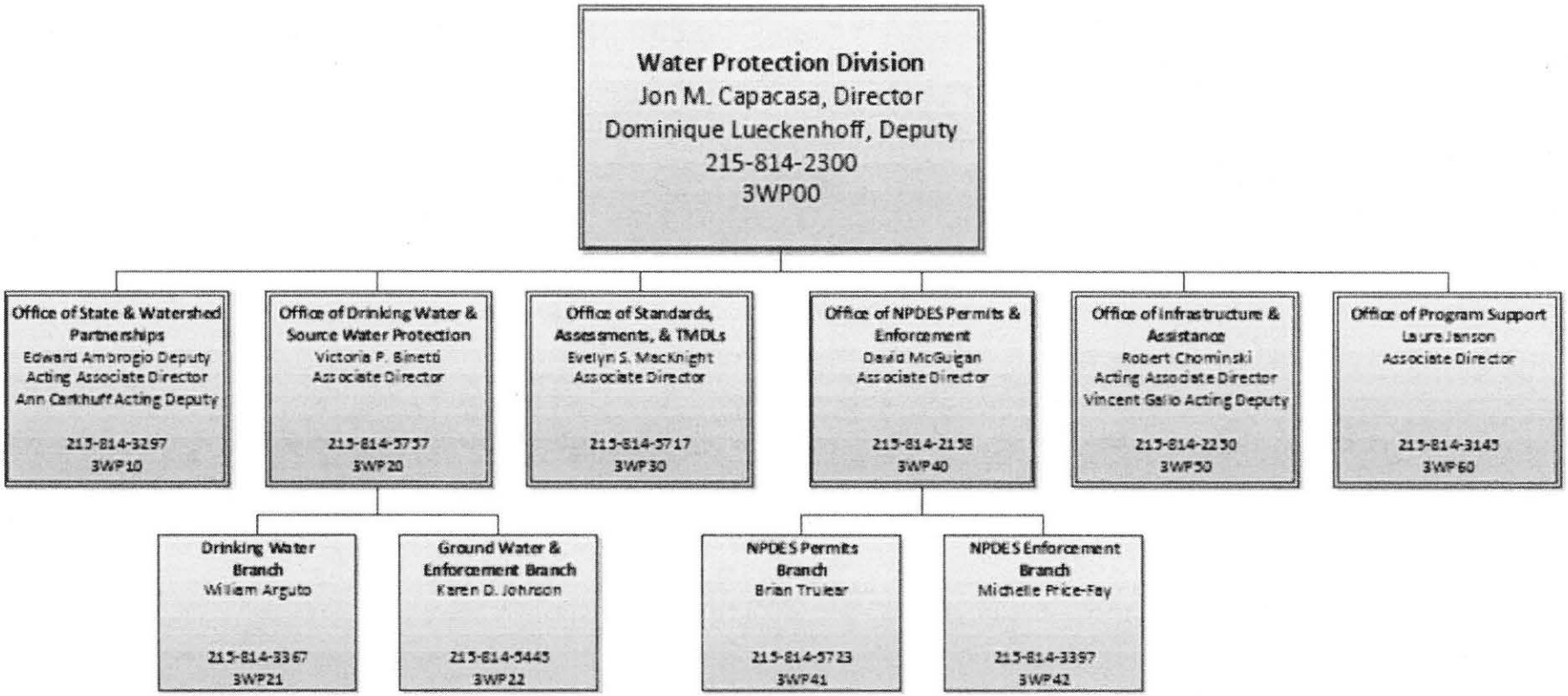
Appendices

A. WPD Organization Chart

B. Quality System References

C. Quality System Glossary

Appendix A – WPD Organization Chart



Appendix B - Selected Quality System Reference Documents

EPA Quality System Website: http://www.epa.gov/quality/

Region III Quality System: http://www.epa.gov/region03/esc/qa/index.htm

I. **Policy and Program Requirements for the Mandatory Agency-wide Quality System 5360.1 A2** May 5, 2000

II. **EPA Quality Manual for Environmental Programs 5360 A1** May 5, 2000

III. **EPA Requirements for Quality Management Plans EPA QA/R-2** March 2001

IV. **EPA Requirements for Quality Assurance Project Plans EPA QA/R-5** March 2001

V. **Guidance for Geospatial Data Quality Assurance Project Plans EPA QA/G-5G** March 2003

VI. **Guidance for Quality Assurance Project Plans for Modeling EPA QA/G-5M** December 2002

VII. **Guidance for Preparing Standard Operating Procedures (SOPs) EPA QA/G-6** April 2007

VIII. **Guidance on Environmental Data Verification and Data Validation EPA QA/G-8** November 2002

IX. **The Volunteer Monitor's Guide To Quality Assurance Project Plans** September 1996

X. **Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency** October 2002

XI. **EPA Region III Quality Management Plan Revision 2** July 2003

XII. **Guidance on Hardware and Software Standards. EPA Office of Environmental Information IRM Policy Manual Chapter 20** (last updated August 2001)

XIII. **EPA Directive 2100.1 Accessible Electronic and Information Technology** April 2006

XIV. **EPA Region III Water Protection Division Records Management Manual** February 2005 (Draft)

Appendix C - Quality System Glossary

Acquired data - data or information used for project implementation or decision making which may meet some of the following criteria: is compiled from other sources; was originally collected for some other purpose; or is obtained from non-measurement sources such as computer databases, programs, literature files, historical data bases, or any other sources.

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

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

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

Document - any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures or results pertaining to environmental operations. Examples include: QAPP, QMP, technical manuals, manuals, SOPs, etc.

Environmental data - 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/or compiled from other sources such as databases, the literature, or any other sources.

Environmental data operations - work performed to obtain, use, or report information pertaining to environmental processes and conditions.

Environmental programs - work or activities involving the environment, including but not limited to: characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and operation of environmental technologies; and laboratory operations on environmental samples.

Environmental technology - an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply to hardware-based systems; however, it will also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

Generic Quality Assurance Project Plan - a formal document for multiple projects or sites with the same objectives and environmental decision(s) describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

Graded approach - the process of basing the level of application of managerial controls applied to an item or work according to the intended use of the results and the degree of confidence needed in the quality of the results.

Independent evaluation - an evaluation performed by a qualified individual, group, or organization that is not a part of the organization directly performing and accountable for the work being assessed.

Management - those individuals directly responsible and accountable for planning, implementing, and assessing work.

Management system - a structured, non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

Organization - an agency, entity, company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration.

Peer review - a documented critical review of work by qualified individuals (or organizations) who are independent of those who performed the work, but are collectively equivalent in technical expertise. A peer review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. The peer review is an in-depth evaluation of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them.

Proficiency Testing Sample - a type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

Process - a set of interrelated resources and activities which transforms inputs into outputs. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

Quality - the totality of features and characteristics of a product or service that bear on its ability to meet the stated or implied needs and expectations of the user.

Quality Assurance (QA) - an integrated system of management activities involving planning, implementation, documentation, evaluation, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

Quality Assurance Project Plan (QAPP) - a formal document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

Quality Control (QC) - the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.

Quality improvement - a management program for improving the quality of operations. Such management programs generally entail a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation.

Quality management - that aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, documentation, and evaluation) pertaining to the Quality System.

Quality Management Plan (QMP) - a document that describes the Quality System in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all activities conducted.

Quality System - a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The Quality System provides the framework for planning, implementing, documenting, and assessing work performed by the organization.

Record - a completed document that provides objective evidence of an item or process. Records may include photographs, drawings, magnetic tape, and other data recording media.

Senior Manager - an individual that serves as a Division Director or Program Office Director.

Specification - a document stating requirements and which refers to or includes drawings or other relevant documents. Specifications should indicate the means and the criteria for determining conformance.

Standard Operating Procedure (SOP) - a written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks.

Surveillance (quality) - continual or frequent monitoring and verification of the status of an entity and the analysis of records to ensure that specified requirements are being fulfilled.

Technical review - a documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.

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