US Environmental Protection Agency
Region III - Middle Atlantic States
1650 Arch Street
Philadelphia, Pennsylvania 19103-2029

QUALITY MANAGEMENT PLAN

Revision 2

Region III QUALITY MANAGEMENT PLAN APPROVALS

/s/ Monica D. Jones _____ 5/30/03 _____

Monica D. Jones — Date

Region III Quality Assurance Manager

/s/ Donald S. Welsh _____ 6/4/03 _____

Donald S. Welsh — Date

Regional Administrator

_____ _____

Nancy Wentworth — Date

Director, Quality Staff, Office of Environmental Information

_____ _____

Kim Nelson — Date

Assistant Administrator, Office of Environmental Information

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL - 7 2003

OFFICE OF
ENVIRONMENTAL INFORMATION

MEMORANDUM

SUBJECT: Approval of the Region 3 Quality Management Plan

FROM: Reggie Cheatham
Acting Director, Quality Staff (2811R)

TO: Donald S. Welsh
Regional Administrator, Region 3

I am pleased to approve the Quality Management Plan (QMP) for Region 3. Approval is valid for a period not to exceed five years from the date of this memorandum. Please remember that organizational and/or mission changes may make it necessary for you to revise and resubmit the QMP before the five-year approval period expires, per Section 3.2.4 of the EPA Manual 5360 A1, *EPA Quality Manual for Environmental Programs* (May 2000).

The Region3 QMP was reviewed in accordance with the specifications contained in Chapter 3 of EPA Manual 5360 A1. Our review determined that Region 3 has made a number of improvements to its QMP that will strengthen the quality system.

I look forward to the successful implementation of your QMP. Should you have further questions, please call me at (202) 564-6830.

Attachment

cc: Monica Jones, Regional QA Manager

Region III QUALITY MANAGEMENT PLAN APPROVALS

Monica D. Jones — 5/30/03
Monica D. Jones — Date
Region III Quality Assurance Manager

Donald S. Welsh — 6/4/03
Donald S. Welsh — Date
Regional Administrator

for Nancy Wentworth — 7/7/03
Nancy Wentworth — Date
Director, Quality Staff, Office of Environmental Information

Kim Nelson — Date
Assistant Administrator, Office of Environmental Information

TABLE OF CONTENTS

Page

1.0 **MANAGEMENT AND ORGANIZATION** 1
1.1. REGIONAL QUALITY ASSURANCE POLICY 1
1.1.1 Background 1
1.1.2 Region III QA Policy 1
1.1.3 Resources for the QA System 2
1.2 SCOPE OF THE QUALITY MANAGEMENT PLAN 3
1.2.1 Examples of Programs Covered by Region III Quality System 3
1.2.1.1 Air Protection Division 3
1.2.1.2 Chesapeake Bay Program Office 3
1.2.1.3 Environmental Assessment and Innovation Division 3
1.2.1.4 Hazardous Site Cleanup Division 4
1.2.1.5 Office of Enforcement, Compliance and Environmental Justice . . 4
1.2.1.6 Waste and Chemicals Management Division 4
1.2.1.7 Water Protection Division 5
1.2.2 Delegated Programs 5
1.3 REGION III ORGANIZATIONAL STRUCTURE 6
1.4 ROLES AND RESPONSIBILITIES 7
1.4.1 Regional Administrator and Senior Managers 7
1.4.2 Regional Quality Council (RQC) 8
1.4.3 Senior Management Representative to the Regional Quality Council 8
1.4.4 Regional Quality Assurance Manager (RQAM) 8
1.4.5 Regional Quality Assurance Officer (RQAO) 9
1.4.6 Quality Assurance Coordinator (QAC) 9
1.4.7 Quality Assurance Team 10
1.4.8 Program Managers 10
1.4.9 Project Officers and Work Assignment Managers 10
1.4.10 ASQAB Lab Quality Assurance Officer (QAO) 11
1.4.11 ASQAB Lab Technical Director (TD) 12
1.4.12 Analytical Team 12
1.4.13 Client Services Team 12
1.4.14 Freshwater Biology Unit 13
1.4.15 Office of Enforcement, Compliance and Environmental Justice (OECEJ) Field Personnel 13
1.5 COMMUNICATIONS 13
1.6 DISPUTE RESOLUTION 14

2.0 **QUALITY SYSTEM COMPONENTS** 15
2.1 PRINCIPAL COMPONENTS OF THE SYSTEM 15
2.2 QUALITY MANAGEMENT PLANS (QMP) 15
2.2.1 Region III Quality Management Plans 15
2.2.2 Division/Program Quality Management Plans 16
2.2.3 Quality Management Plans for Extramural Projects 16

Page
2.3 LABORATORY QUALITY MANUAL 17
2.3.1 Analytical Services and Quality Assurance Branch 17
2.3.2 Freshwater Biology Laboratory 17
2.4 QA ANNUAL REPORT AND WORK PLAN 17
2.5 QUALITY SYSTEM STATUS REPORT 18
2.6 QUALITY SYSTEM AUDITS 18
2.7 TRAINING PLANS 18
2.8 DATA QUALITY OBJECTIVES PROCESS 19
2.9 QUALITY ASSURANCE PROJECT PLANS (QAPPs) 19
2.10 STANDARD OPERATING PROCEDURES (SOPs) 20
2.11 TECHNICAL SYSTEMS AUDITS (TSA) 20
2.12 PROFICIENCY TESTING SAMPLES 20
2.13 DATA QUALITY ASSESSMENTS 21

3.0 QUALIFICATION AND TRAINING 22
3.1 Region III'S QA TRAINING PROGRAM 22
3.1.1 Courses 22
3.1.2 Logistics 23
3.1.3 Documentation of Training 23
3.2 TRAINING REQUIREMENTS 23
3.2.1 Regional Administrator and Senior Managers 24
3.2.2 Program Managers 24
3.2.3 Project Officers and Work Assignment Managers 24
3.2.4 Regional Quality Assurance Manager (RQAM) 24
3.2.5 Regional Quality Assurance Officer (RQAO) 25
3.2.6 Quality Assurance Coordinators 25
3.2.7 Quality Assurance Team 25
3.2.8 Analytical Team and Freshwater Biology Staff 25
3.2.9 Client Services Team 26
3.3 RECERTIFICATION 26

4.0 PROCUREMENT OF ITEMS & SERVICES 27
4.1 ACQUISITIONS BY US GOVERNMENT CONTRACTING OFFICERS 27
4.2 SMALL PURCHASES 28
4.3 GRANTS AND COOPERATIVE AGREEMENTS 29
4.4 INTERAGENCY AGREEMENTS (IAGS) 30

5.0 DOCUMENTATION AND RECORDS MANAGEMENT 31

6.0 COMPUTER HARDWARE AND SOFTWARE 33
6.1 COMPUTER HARDWARE/SOFTWARE REQUIREMENTS 33
6.2 SYSTEM DEVELOPMENT 33
6.3 DATA STANDARDS 34
6.4 INFORMATION SECURITY 35
6.5 GEOGRAPHIC INFORMATION SYSTEMS (GIS) 36

Page
6.5.1 Project Management . . . 36
6.5.2 Primary Data . . . 36
6.5.3 Secondary Use Products . . . 37
6.5.4 Summary . . . 38

7.0 PLANNING . . . 39
7.1 REGION-WIDE PLANNING . . . 39
7.1.1 Internal Strategic Planning . . . 39
7.1.2 External Data Coordination . . . 39
7.1.3 Annual QA Plan . . . 39
7.2 PROGRAM-SPECIFIC PLANNING . . . 39
7.3 PROJECT LEVEL PLANNING . . . 40
7.3.1 Quality Assurance Project Plan Preparation, Review, and Approval . . . 40
7.3.2 Generic Quality Assurance Project Plans . . . 41
7.3.3 Secondary Data . . . 42

8.0 IMPLEMENTATION OF WORK PROCESSES . . . 44
8.1 PROGRAM IMPLEMENTATION . . . 44
8.2 PROJECT . . . 45
8.2.1 Quality Assurance Project Plans . . . 45
8.2.2 Standard Operating Procedures . . . 46
8.2.3 EPA Region III Users' Guide for Acquiring Analytical Services . . . 46
8.2.4 Region III OASQA Sample Submission Guidelines . . . 46
8.2.5 Inspections . . . 46

9.0 ASSESSMENT AND RESPONSE . . . 48
9.1 QUALITY SYSTEM AUDITS (QSA) . . . 48
9.1.1 Internal Quality System Assessments . . . 48
9.1.2 External Quality System Assessments . . . 49
9.2 TECHNICAL SYSTEMS AUDITS (TSA) . . . 50
9.3 LABORATORY ASSESSMENTS . . . 51
9.3.1 National Pollution Discharge Elimination System (NPDES) . . . 50
9.3.2 Safe Drinking Water Act (SDWA) . . . 51
9.3.3 Superfund Program: Laboratories used by Principally Responsible Parties (PRP) . . . 51
9.3.4 Contract Laboratory Program (CLP)–Routine Analytical Services (RAS) . . . 52
9.3.5 Delivery of Analytical Services (DAS) . . . 52
9.3.6 National Environmental Laboratory Accreditation Conference(NELAC) 53
9.4 DATA QUALITY ASSESSMENTS . . . 53

10.0 QUALITY IMPROVEMENT . . . 54
10.1 APPROACH TO IMPROVEMENT . . . 54
10.2 IMPROVEMENT LEADERS . . . 54
10.2.1 Program Level . . . 54
10.2.2 Project Level . . . 55

Page
APPENDIX A: List of Standard Operating Procedures A-1
APPENDIX B: References B-1
APPENDIX C: Glossary of Terms C-1

LIST OF FIGURES

Organizational Chart: Environmental Protection Agency, Region III ..... Figure 1
Region III Organization Chart: QA Functions ..... Figure 2

LIST OF ABBREVIATIONS

AA	Accrediting Authorities
ADP	Automated Data Processing
APD	Air Protection Division
ASQAB	Analytical Services and Quality Assurance Branch
CAA	Clean Air Act
CBPO	Chesapeake Bay Program Office
CLP	Contract Laboratory Program
COR	Contracting Officer's Representative
DAI	Data Audit Inspection
DAS	Delivery of Analytical Services
DMRQA	Discharge Monitoring Reports Quality Assurance
DQA	Data Quality Assessment
EAID	Environmental Assessment and Innovation Division
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right to Know Act
FAR	Federal Acquisition Regulations
FIRMA	Federal Information Resources Management Regulations
GIS	Geographic Information Systems
HSCD	Hazardous Site Cleanup Division
IAG	Interagency Agreement
ICMS	Integrated Contract Management System
IRM	Information Resources Management
ISB	Information Services Branch
ISO	Information Security Officer
LCM	Laboratory Certification Manual
NARA	National Archives and Records Administration
NELAC	National Environmental Laboratory Accreditation Conference
NELAP	National Environmental Laboratory Accreditation Program
NPDES	National Pollution Discharge Elimination System
OECEJ	Office of Enforcement, Compliance and Environmental Justice
OEI	Office of Environmental Information
OIRM	Office of Information Resource Management
OPM	Office of Policy and Management
ORC	Office of Regional Counsel
PADEP	Pennsylvania Department of Environmental Protection
PRP	Potentially Responsible Parties
P/T	Proficiency Testing
QA	Quality Assurance
QAARWP	Quality Assurance Annual Report and Work Plan
QAC	Quality Assurance Coordinator
QAO	Quality Assurance Officer
QAPP	Quality Assurance Project Plan
QC	Quality Control
QMP	Quality Management Plan
QSA	Quality System Assessment

LIST OF ACRONYMS

RCRA	Resource Conservation and Recovery Act
RQAM	Regional Quality Assurance Manager
RQAO	Regional Quality Assurance Officer
RQC	Regional Quality Council
SARA	Superfund Amendments and Reauthorization Act
SAP	Sampling and Analysis Plan
SDWA	Safe Drinking Water Act
SOP	Standard Operating Procedure
TD	Technical Director
TMDL	Total Maximum Daily Load
TSA	Technical Systems Audit
TSCA	Toxic Substances Control Act
WAM	Work Assignment Manager
WCMD	Waste and Chemicals Management Division
WPD	Water Protection Division

CHAPTER 1: MANAGEMENT AND ORGANIZATION

1.1. REGIONAL QUALITY ASSURANCE POLICY

1.1.1 Background

Region III has maintained the fundamental components of a quality system since the establishment of the Regional Office in the early 1970's. Following the issuance of EPA Order 5360.1 CHG 1 in 1998, the Region began to systematically implement its quality management system. The Region III Quality Management Plan (QMP) describes the policies, procedures and management systems within the organization that govern the quality control activities. Quality assurance (QA) requirements are integrated into each of the Region's media programs.

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

1.1.2 Region III QA Policy

It is Region III's QA policy that all environmental data operations result in the collection of environmental data of known and documented quality, suitable for its intended use. This policy applies to all data collected under environmental operations and environmental technology activities performed directly by the Region; Federal, State, Tribal and local partners under interagency agreements and financial assistance agreements; contractors funded by EPA; regulated entities and potentially responsible parties.

Specifically, **it is the policy of Region III that:**

o Each Regional program or activity that is responsible for the characterization of environmental or ecological systems and the health of human populations; or the direct measurement of environmental conditions or releases; or the use of environmental data collected from other sources will be part of an effective quality system. This quality system shall be documented *in* a Program, Division or Office QMP.

o The objectives for generating any new environmental data *shall* be determined prior to data collection and control methods can be applied to ensure a level of data quality commensurate with the intended use(s) for the data. These objectives will be documented in the project's Quality Assurance Project Plan (QAPP).

o Prior to the use of environmental data collected from other sources, such as literature, industry surveys, databases or computerized models, the data *shall* be evaluated to ensure a level of data quality that is commensurate with the intended use(s) of the data.

o Each program or activity that generates environmental data shall develop and implement a QAPP and/or Standard Operating Procedures (SOPs) which specifies the detailed procedures required to assure production of data of known quality and sufficient quantity to support environmental decisions. These QAPP's shall be prepared by the originating program, and reviewed and approved by an authorized QA representative prior to the start of any data collection effort.

o All Regional programs that receive externally generated environmental data through contracts, grants or interagency agreements shall ensure that acceptable QA requirements are included in the appropriate extramural agreement documents. These external parties must submit a QMP and a QAPP or a combined QMP/QAPP to EPA for review and approval.

o QA practices and quality control (QC) procedures will be implemented in the most cost effective manner possible without compromising data quality objectives.

o There shall be an annual assessment of the Region's Quality System to ensure that it is meeting the needs and expectations of our external and internal customers and QA requirements and guidelines set forth in the EPA Quality Manual (5360.1 A1) and EPA Order (5360.1 A2). The annual assessment of the Region's Quality System will be conducted by the Regional Quality Assurance Manager (RQAM), in conjunction with the Regional Quality Council (RQC).

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

1.1.3 Resources for the QA System

The level of QA resources needed for an environmental program or project is determined by the relevant Regional program. Each Division or Program Director shall ensure that there are adequate resources to successfully implement their environmental programs. Since there exists no assigned national program element for QA, most resources needed for QA are taken from a variety of program elements which utilize QA functions and services.

Annually, the RQC will assess the adequacy of QA resources and the level of expertise necessary to support the various programs in the Region. This assessment will evaluate the Region's environmental program activities to determine if the number and type of QA resources are adequate. The assessment will also evaluate the adequacy of intramural and extramural funding to determine if adequate funding is provided for QA-related activities. The RQC will provide Senior Managers with the results of their assessment of the Region's QA resources and

recommendations for ways to resolve any outstanding issues. Senior Managers are responsible for making final decisions about the allocation of QA resources.

1.2 SCOPE OF THE QUALITY MANAGEMENT PLAN

This QMP establishes the foundation for implementing an effective quality system within EPA Region III. The QMP applies to all Region III programs, activities, grants, contracts and interagency agreements that collect or evaluate environmental data which is used to make decisions or support actions related to our defined mission and responsibilities. **Environmental data** is defined as any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA Region III, environmental data also includes information produced from models, and compiled from other sources such as data bases or the literature. Therefore, programs, activities, grants, contracts and interagency agreements which generate and/or compile environmental data are required to comply with the requirements of this QMP.

EPA Region III employs a decentralized approach to quality management. Each Division or Program Office is responsible for determining the specific environmental programs and activities to which the quality system will apply. Listed below are examples of the types of environmental programs, grants and activities within each Division or Program Office which are covered by the Region III Quality System.

1.2.1 Examples of Programs Covered by Region III Quality System

1.2.1.1 Air Protection Division

Clean Air Act

- Ambient Air Quality Data (monitoring by states via 105 grant
- Ambient air monitoring - per 40 CFR Part 58
- Emissions Inventory Data (by states as per 40 CFR Part 51)
- Stack Testing (by company, state or EPA)
- I/M Program statistics (reports by states under 105 grants)
- Environmental data collected as a result of a contract being overseen by an APD Project Manager/Project Officer
- CAA Compliance Inspections

1.2.1.2 Chesapeake Bay Program Office

- Mainstem and Tributary Monitoring Program
- Ambient Toxicity Monitoring Program
- Baywide SAV Aerial Survey Program

1.2.1.3 Environmental Assessment and Innovation Division

- Laboratory Analyses - performed at Ft Meade and Wheeling labs
- Watershed Protection Program

- Water Quality Management (106) Grants Program
- Ocean Dumping Program
- Community-Based Special Studies (e.g., Newton-Chester, Monroe County)
- Fish Tissue Surveys
- Dredging
- Coastal Waters Sampling
- Wetland Grants
- Inspection (NPDES laboratory assessments of State and regulated laboratories, Superfund PRP laboratories, State drinking water laboratories)

1.2.1.4 Hazardous Site Cleanup Division

- CERCLA and the Superfund Amendments and Reauthorization Act of 1986 (SARA).
- SARA Title III Chemical Emergency Preparedness and Prevention (CEPP) program.
- Regional Oil Program pursuant to the Oil Pollution Act (OPA) of 1990.

1.2.1.5 Office of Enforcement, Compliance and Environmental Justice

- Compliance inspections (media specific and multi-media)
- Sample collection
- Facility inspections that support RCRA (Subtitle C and I, NPDES, pretreatment, TSCA/PCB, EPCRA/TRI reporting and asbestos

1.2.1.6 Waste and Chemicals Management Division

Asbestos

- CAA - NESHAPS
- Asbestos enforcement
- Asbestos hazard in schools (AHERA)
- Asbestos Hazard Abatement Act (ASHAA)
- Asbestos enforcement grants

FIFRA

- Pesticide cooperative agreement grants
- Pesticide environmental stewardship grants

RCRA

- Corrective action
- RCRA compliance and enforcement
- RCRA Subtitle C grants

- RCRA Subtitle I grants
- Delisting

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

1.2.1.7 Water Protection Division

Safe Drinking Water Act
- Public Water System Supervision Program
- Sole Source Aquifer Program
- Comprehensive State Ground Water Protection Program
- Underground Injection Control Program
- Wellhead Protection Program
- Source Water Protection Program

Clean Water Act
- National Pollutant Discharge Elimination System (NPDES) Program
- Water Quality Management Planning (Section 604(b)) Grants Program
- Water Pollution Control (Surface/Groundwater Programs)(Section 106) Grants Program
- Watershed Protection Program
- Nonpoint Source (Section 319) Grants Program
- Clean Lakes Program
- State Revolving Fund Program
- Water Quality Standards Program
- Nutrient Criteria Program
- Water Quality Cooperative Agreements (Section 104(b)(3)) Grant Program
- Total Maximum Daily Load (TMDL) Program
- Great Lakes Program
- Ambient water monitoring (routine monitoring performed mostly through the states)
- National Estuary Program
- Beaches

1.2.2 Delegated Programs

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

- RCRA Subtitle C (hazardous waste)
- RCRA Subtitle I (underground storage tanks)

- Air - Clean Air Act Title I permits, Title V permits, and most of Title III air toxics
- Public Water Supply (except District of Columbia)
- Underground Injection Control (except the District of Columbia and Pennsylvania)
- Pesticides
- National Pollutant Discharge Elimination System
- Pretreatment

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

1.3 REGION III ORGANIZATIONAL STRUCTURE

The Region is composed of five Divisions and four Program Offices. The Program Divisions are the Air Protection Division (APD), Environmental Assessment and Innovation Division (EAID), Hazardous Site Cleanup Division (HSCD), Waste and Chemicals Management Division (WCMD) and the Water Protection Division (WPD). The four Offices are the Chesapeake Bay Program Office (CBPO), Office of Regional Counsel (ORC), Office of Enforcement, Compliance and Environmental Justice (OECEJ), and the Office of Policy and Management (OPM). A copy of the Region's organizational chart can be found in Figure 1.

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 this QMP. Division or Program Office QA requirements may be more, but not less stringent than those presented in this QMP. The Regional Administrator has delegated responsibility for overseeing the Region's Quality System to the Environmental Assessment and Innovation Division (EAID). The **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. The **Regional QA Officer (RQAO)** is located in the EAID Environmental Information and Analysis Branch. Within EAID's ASQAB, there is a **Quality Assurance Team (QAT)** which provides technical support to various Regional programs. For additional information about the roles and responsibilities of the RQAM, RQAO and QAT, refer to Section 1.4.

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. An organizational chart which shows the reporting relationships for Region III QA personnel can be found in Figure 2. Additional information about the roles and responsibilities of the Senior Management Representative and the RQC can be found in Section 1.4.

1.4 ROLES AND RESPONSIBILITIES

All individuals in the Region who are directly or indirectly involved with environmental data collection, analyses or use has some responsibility for ensuring data quality. This may include staff level personnel, supervisors, project officers, program managers, senior managers, and personnel specifically assigned to perform QA functions. The following is an overview of the QA responsibilities of some of these Regional personnel:

1.4.1 Regional Administrator and Senior Leadership

The Regional Administrator (RA), Deputy RA, and Senior Managers (Division Directors/Office Directors) have overall responsibility for the Regional QA Program as described in EPA Order 5360.1 A2, dated 5/5/00. Specifically, the RA and Senior Managers are responsible for ensuring that:

- All Regional components and programs comply fully with the requirements of EPA Order 5360.1 A2;
- Quality program management is an identified activity with associated resources adequate to accomplish its program goals and is implemented as prescribed in the Region III QMP;
- QMPs covering Division or Program Office QA operations are developed, updated and effectively implemented. QMPs are not required for the Offices of Regional Counsel, Office of Communications and Government Relations and the Office of Policy & Management;
- All environmental data collection and data compilation activities are covered by the appropriate documentation (i.e., Quality Assurance Project Plans, Sampling and Analysis Plans, Quality Management Plans, Standard Operating Procedures etc.);
- All environmental programs implemented through extramural agreements comply fully with applicable QA/QC requirements;
- Training is available for State, local, and Tribal governments performing environmental programs for EPA in the fundamental concepts and practices of quality management and QA/QC that they may be expected by EPA to perform;
- Internal management assessments are performed to ensure that programs comply with QA requirements. Deficiencies highlighted in the assessments are appropriately addressed;
- Performance Agreements for supervisors, senior managers, and appropriate staff contain performance measures that are commensurate with their assigned quality management responsibilities;
- The Division or Program Office is represented on the Regional QA Council by a

Quality Assurance Coordinator;
- Disputes regarding quality system requirements, QA/QC procedures, assessments or corrective actions are resolved.

1.4.2 Regional Quality Council (RQC)

The RQC oversees the Regional Quality System and ensures the effective implementation of practices and policies defined by the Regional Quality Management Plan. The RQC consists of a Senior Management Representative, RQAM, Regional Quality Assurance Officer and a QA Coordinator from all Division or Program Offices which generate and/or compile environmental data. The primary responsibilities of the RQC are to:

- Review and update the Region's QMP;
- Provide assistance to Regional staff in the organization about QA/QC policies, requirements, and procedures applicable to procurement;
- Identify QA training needs for the Region;
- Participate in assessments of Regional organizations conducting environmental programs to determine the conformance of their mandatory quality systems to their approved QMPs and the effectiveness of their implementation.
- Establish QA priorities for each new fiscal year

1.4.3 Senior Management Representative to the Regional Quality Council

The Senior Management Representative to the RQC serves as a liaison between the Senior Managers and the RQC. The Regional Administrator shall appoint the Senior Management Representative to the RQC. The Senior Management Representative shall serve for a period of two years. Specifically, the Senior Management Representative:

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

1.4.4 Regional Quality Assurance Manager (RQAM)

The RQAM has primary responsibility for the oversight of the Regional Quality System. Specifically, the RQAM is responsible for:

- Facilitating the development of the Region's QMP and preparing updates to the approved QMP;
- Representing the Region at National Quality Meetings, such as the EPA Headquarters' Quality Staff Conference Call, National QA Conference, etc. Also, serves as primary Regional liaison with the Quality Staff in EPA Headquarters and

the State QA contacts;

- Providing expert assistance to Regional staff on QA/QC policies, requirements, and procedures applicable to procurement and technical services;
- Reviewing and approving QMPs submitted by Region III Divisions and Offices and by holders of extramural agreements;
- Performing periodic assessments of Regional organizations conducting environmental programs to determine the conformance of their mandatory quality systems to their approved QMPs and the effectiveness of their implementation;
- Submitting the Annual QA Report and Workplan to Senior Regional Managers and the Office of Environmental Information (OEI) Quality staff;
- Authorizing individuals to review and approve QAPPs;
- Providing and/or scheduling QA training and briefings;
- Distributing Agency QA guidance documents, policies, and procedures;
- Routinely reviewing the QA procedures within the Region and keep the RA and senior managers apprized;
- Facilitating the discussion of disputes regarding quality system requirements, QA/QC procedures, assessments or corrective actions.

1.4.5 Regional Quality Assurance Officer (RQAO)

The RQAO serves as a technical QA expert within the Region. In the RQAM's absence, the RQAO serves as the Region's liaison with the Quality Staff in EPA Headquarters. The RQAO's primary responsibilities are to:

- Provide technical assistance to Regional staff on QA/QC policies, requirements, and procedures applicable to procurement and technical activities;
- Review QAPPs submitted by holders of extramural agreements (EAID's only);
- Provide and/or schedule QA training;
- Review and certify drinking water laboratories;
- Administer the SDWA and NPDES Proficiency Testing (PT) studies;
- Administer the Air Program Performance Evaluation studies; and
- Participate in assessments of Regional and State QA programs to assure that they adhere to their approved QMPs..

1.4.6 Quality Assurance Coordinator (QAC)

Each Division and Program Office, which collects and/or evaluates environmental data has a QAC. QACs are responsible for coordinating the implementation of the quality system within their Division or Program Office. The QAC:

- Disseminates QA information to Division or Program Office staff;
- Conducts QA briefings for Division or Program Office Directors;
- Participates in RQC meetings;
- Facilitates preparation of his/her Division or Program Office's QMP;
- Helps implement the Division or Program Office's QMP;

- Helps Project Managers and/or Project Officers resolve data quality issues with contractors, grant recipients, and recipients of Interagency Agreements;
- Consolidates Division or Program Office's QA information for the QA Annual Report;
- Participates in assessments of Regional and state QA programs to assure that they adhere to their approved QMPs.

1.4.7 Quality Assurance Team (QAT)

The Quality Assurance Team (QAT) is located in the EAID Analytical Services and Quality Assurance Branch (EAID/ASQAB). The QAT provides extensive QA support to the Hazardous Site Cleanup Division. Limited QA assistance is also provided to the Water Protection Division and Waste and Chemicals Management Division. The team's primary responsibilities include:

- Reviewing QAPPs for the Hazardous Site Cleanup Division (HSCD) and other Regional programs defined in EAID/ASQAB negotiated Work Plans;
- Providing technical assistance on QA/QC policies, requirements, and procedures applicable to technical activities;
- Participate in assessments of QA and QC activities within various Regional Programs;
- Develop Program-specific QA Guidance Documents and/or QA Directives;
- Provide or schedule QA training courses.

1.4.8 Program Managers

Program Managers have technical expertise in a specific program area (i.e., TMDL, permits, enforcement, etc.) and serve as the focal lead for environmental program. Program Managers may be Branch Chiefs, Section Chiefs or Team Leaders. In this role, they must ensure that:

- All intramural and extramural projects within their program that involve the collection and/or compilation of environmental data are performed in accordance with the Regional and Divisional QMPs and an approved QAPP;
- Resources required to implement Program QA requirements are identified and provided;
- Adequate procedures are in place to address QA requirements in all applicable program operations, including those delegated to state agencies;
- Cooperate with QA reviews or audits and submit requested information in a timely manner;
- Take appropriate corrective action recommended by audit findings; and
- Discuss any QA concerns with the Divisional QA Coordinator and/or RQAM.

1.4.9 Project Officers and Work Assignment Managers

Project Officers (POs) and Work Assignment Managers (WAMs) are assigned responsibility for specific projects supported by EPA through contracts, grants or interagency agreements (IAGs). This category includes Superfund Remedial Project Managers (RPMs) and On-Scene Coordinators (OSCs) who are responsible for site specific monitoring projects, as well as Project Officers and Project Managers in WPD, APD, and WCMD. Since POs and WAMs may not be closely familiar with QA procedures, they are encouraged to work with their Divisional QA Coordinator to ensure that QA requirements are addressed. The specific responsibilities of Project Officers and Work Assignment Managers are to ensure that:

- All extramural projects which generate and/or compile environmentally related data, adhere to QA requirements found in Regional and Divisional QMPs;
- All grant recipients or contractors conducting a project which involves environmental data collection and/or data compilation submit a QMP which documents their quality system. The QMP must be approved before grant or contract money is awarded;
- All grant recipients or contractors conducting a project which involves environmental data collection and/or data compilation have an approved QAPP **prior to** initiating any data collection and/or data compilation;
- For contracts, a Quality Assurance Review Form (EPA Form 1900) has to be completed, and approved in writing by the RQAM, Project Officer and Contracting Officer (see Chapter 4 for a description of specific procedures);
- For grants, the decision memorandum has been completed to indicate whether QA requirements should be applied;
- Environmental 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.

1.4.10 ASQAB Lab Quality Assurance Officer (QAO)

The ASQAB Lab QAO is responsible for the design and management of ASQAB's quality system. Specific responsibilities are as follows:

- Assist ASQAB in establishing priorities, annual goals and measures of success;
- Develop annual plans and schedules for internal audits, SOP review and revisions;
- Notify ASQAB management of deficiencies in the quality system and monitor corrective action;
- Serve as the focal point for QA/QC and be responsible for the oversight of quality control data (e.g., trend analysis);
- Coordinate external audits of ASQAB (e.g., triennial SDWA inspection) and track corrective actions;
- Coordinate development of proficiency documentation procedures and protocols including quality control policies, concerning ASQAB's participation in performance sample studies, and analytical method review and validation;

- Coordinate preparation and maintenance of ASQAB QA documents (e.g., Lab QA Plan);
- Develop a QA annual training plan including specific curriculum and provide QA/QC orientation for new employees;
- Assess and improve data review and evidence audits procedures for ASQAB's analytical data including procedures to assure that necessary raw data is archived;
- Review documentation and records for compliance to requirements and consistency with EAID and Region III plans; and
- Assist ASQAB in long-term QA/QC planning.

1.4.11 ASQAB Lab Technical Director (TD)

The ASQAB Lab Technical Director (TD) monitors lab technical operations and conformance to ASQAB quality system components. Specific duties include:

- Negotiate annual Workplan with Regional Clients and monitor progress in meet ing customer needs;
- Participate in yearly organization review including the review of ASQAB's quality system;
- Conduct technical system audits (TSAs) of technical operations (review of SOPs, IDCs, MDLs, and PT sample performance and procedures and documentation relative to the Lab Quality Manual and mandated Agency methods);
- Participate in the development of quality system (data production) policies, and update the Laboratory Quality Manual as necessary;
- Monitor technical operations through conducting TSAs and the routine review of case files;
- Serve as technical mentor by conducting technical sessions to address analytical issues/problems and providing training on the QM; and
- Coordinate SDWA, NPDES and SF laboratory assessments and review of State Laboratory Certification Programs.

1.4.12 Analytical Team

The Analytical Team is located in EAID/ASQAB. The Analytical Team provides analytical services to the air, water and hazardous waste management programs in Region III. The team's primary responsibilities include:

- Analyzing various samples such as water, soils, sediments, hazardous waste, oil, tissue, and air;
- Providing technical assistance and scientific training for state and regulated community inspectors and analysis;
- Conducting laboratory inspections;
- Providing support for criminal investigations and enforcement cases.

1.4.13 Client Services Team

The Client Services Team is located in EAID/ASQAB. The Client Services Team serves as the focal point for procurement of analytical services for environmental data collection activities within the Region. The team's primary responsibilities include:

- Determining the most cost-effective means for acquiring environmental sample analyses;
- Procuring and/or scheduling sample analysis through national or regional contracts.
- Evaluating and assessing environmental data for contract compliance;
- Conducting laboratory inspections for the Superfund Contract Laboratory Program (CLP), and other contract laboratories.

1.4.14 Freshwater Biology Unit

The Freshwater Biology Unit is located in EAID/ASQAB. This unit conducts bioassessments and toxicity testing. The unit's primary responsibilities include:

- Fish and macroinvertebrate field surveys and collections;
- Physical habitat assessments;
- Identification of macroinvertebrates;
- Acute and chronic freshwater toxicity tests

1.4.15 Office of Enforcement, Compliance and Environmental Justice (OECEJ) Field Personnel

The Office of Enforcement, Compliance and Environmental Justice (OECEJ) includes a staff of field personnel located in Fort Meade, Maryland;Wheeling, West Virginia and the Philadelphia, Pennsylvania Regional Office. OECEJ field personnel conduct media specific and multi-media compliance inspections. These inspections are done to support programs, such as the Resource Conservation and Recovery Act (RCRA) Subtitles C and I; National Pollutant Discharge Elimination System (NPDES); Toxic Substances Control Act (TSCA); and the Emergency Planning and Community Right to Know Act (EPCRA). During these inspections, OECEJ field personnel may collect samples to help identify whether a potential violation exists.

1.5 COMMUNICATIONS

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

At a minimum, the RQC meets quarterly to discuss and resolve issues about QMP implementation and its impact on data quality. The RQC will also discuss ways to improve the Region's Quality System. The RQC is the primary cross-Divisional group for addressing QA topics that impact the entire Region. The individual Divisions and Program Offices will establish their own methods of communicating QA issues within their respective organizations.

Finally, each Division or Program Office will identify QA training needs for all Regional personnel in their program who are responsible for environmental data activities. Senior Managers must ensure that adequate resources are available to implement the Region III QA Training Plan. The RQAM, Program Managers, RQAO, RQC and/or the QAT will develop and/or schedule QA training. A list of core QA training courses can be found in Section 3.1.1.

1.6 DISPUTE RESOLUTION

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

CHAPTER 2: QUALITY SYSTEM COMPONENTS

2.1 PRINCIPAL COMPONENTS OF THE SYSTEM

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

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

Quality Management Plans
Laboratory Quality Manuals
Quality Assurance Annual Report and Work Plan
Quality System Status Reports
Quality Systems Assessments
Training Plans
Data Quality Objectives
Quality Assurance Project Plans
Standard Operating Procedures
Technical System Audits
Proficiency Testing Samples
Data Quality Assessments

2.2 QUALITY MANAGEMENT PLANS

2.2.1 Region III Quality Management Plans

The Region III QMP has been prepared by the RQC. This document describes the policies and procedures being implemented to ensure that environmental data being generated by and for the Region are of adequate quality for its intended use. This document complies with the requirements found in the EPA Quality Manual (EPA Order 5360.1 A1) and EPA Order 5360.1 A2. The Region III QMP serves as the "umbrella" document for all Regional programs. This QMP shall be reviewed and approved by all Division and Program Directors and the Regional Administrator. Final approval of the Region III QMP shall be granted by the Director of the EPA Office of Environmental Information (OEI) Quality Staff. The Region III QMP shall be reviewed and updated, as necessary, on an annual basis.

2.2.2 Division/Program Office Quality Management Plans

Each Region III Division and Program Office that conducts projects that involve the use of environmental data shall prepare a QMP. This QMP shall describe the organization's QA management policies, objectives, and internal procedures. These documents shall be consistent with the requirements found in the most recent version of the EPA Quality Manual and EPA Order 5360.1 A2. Division and Program QMP requirements may be more, but not less, stringent than those presented in the Region III QMP. All Division/Program Office's QMPs must be reviewed and approved by the RQAM, or designee. All individuals who conduct QMP reviews must complete the core courses found in Section 3.1.1. These individuals should also have professional knowledge of chemical and biological principles, theories, practices and established methods, statistical techniques commonly used in quality control, data assessments, and data management practices. Extensive knowledge of the principles and practices of quality assurance and the ability to adapt these applications to Agency QA requirements is also required. The most recent version of the OEI Quality Staff QMP Checklist may be used to review these QMPs. When there are organizational or policy changes that impact a Division or Program's quality system, the Division/Program Office QMP shall be updated and submitted to the RQAM for review and approval.

2.2.3 Quality Management Plans for Extramural Projects

Recipients of grants, cooperative agreements, contracts and interagency agreements that involve the use of environmental data must develop and implement QA policies and practices that are sufficient to produce data of adequate quality to meet program objectives. These policies and practices shall be documented in a QMP, or equivalent document. The QMP for grants cooperative agreements and contracts shall be prepared in accordance with the most recent version of EPA QA/R-2: EPA Requirements for Quality Management Plans. The content of the QMP, or equivalent document for interagency agreements shall be negotiated by both parties. The recipient's QMP shall be viewed and updated annually, or as needed.

Should there be multiple programs involved in a grant, cooperative agreement or contract at the recipient's discretion, the recipient may submit a single QMP covering all of the programs in the grant, cooperative agreement or contract or a separate QMP for each program receiving grant, cooperative agreement or contract funds.

The extramural project QMP or combined QMP/QAPP shall be submitted to the RQAM for review. The most recent version of the OEI Quality Staff QMP Checklist may be used to review these QMPs. When applicable, Region III QA Coordinators shall facilitate their organization's review of the technical activities and programs documented in QMP for extramural projects being managed by their Division or Program Office. Prior to environmental data collection or data compilation, the extramural project QMP or combined QMP/QAPP must be approved by the RQAM.

Upon receipt of an extramural project QMP, the RQAM shall update the Region III QMP Status Report. This report contains the name of the organization that submitted the QMP, the

receipt date, the review status and the approval status. The updated Region III QMP Status Report shall be sent to the Region III Office of Policy and Management Grants and Audit Management Branch. The Grants and Audit Management Branch shall distribute the updated QMP Status Reports to all EPA Grant Project Officers. EPA Project Officers shall use this information to ensure that extramural agreements under their purview have fulfilled their EPA QA requirements.

2.3 LABORATORY QUALITY MANUALS

2.3.1 Analytical Services and Quality Assurance Branch

The EAID Analytical Services and Quality Assurance Branch (ASQAB) Quality Management System is based on the requirements of ISO 17025 General Requirements for the Competency of Testing and Calibration Laboratories, and National Environmental Laboratory Accreditation Conference (NELAC) Chapters 2 and 5. Analytical services provided by the EAID Analytical Services and Quality Assurance Branch are documented in the "OASQA Laboratory Quality Manual." This manual describes the laboratory's quality system policies and procedures.

2.3.2 Freshwater Biology Laboratory

The Laboratory Quality Manual for the EAID/ASQAB Freshwater Biology Laboratory describes the management and technical requirements of the bioassessments and toxicity testing laboratory. This manual complies with the requirements found in ISO 17025 General Requirements for the Competency of Testing and Calibration Laboratories. Each person involved in the laboratory's operations shall be familiar with the Freshwater Biology Laboratory's quality system and the technical requirements of the tests being conducted.

2.4 QA ANNUAL REPORT AND WORK PLAN

At least bi-annually, each Division and Program QA Coordinator shall prepare a QA Report that summarizes the QA/QC activities being used to implement their program's quality system. The RQAM consolidates this information into Region III QA reports. These consolidated QA reports shall be distributed to the Senior Management Representative to the RQC and each Region III Division/Program QAC. At the end of each fiscal year, the RQAM shall consolidate the information in the Region's QA reports into a QA Annual Report. The QA Annual Report documents the Region's QA/QC activities (i.e., QA training, technical system audits, quality system audits, QAPP reviews, quality system improvements, etc.) conducted during the fiscal year. The content of the Region III QA Annual Report shall comply with the requirements found in Chapter 4 of the EPA Quality Manual. Prior to the distribution of the QA Annual Report to the Director of the EPA OEI Quality Staff, the report shall be reviewed and approved by the Senior Management Representative to the RQC.

At the beginning of each fiscal year, the RQC shall establish a list of QA priorities for the fiscal year. These QA priorities shall be documented in the QA Annual Report and Work Plan (QAARWP) submitted to the Director of the EPA OEI Quality Staff. The Region III QA Work

Plan shall also include a list of planned training courses, quality system audits and audit responsibilities.

2.5 QUALITY SYSTEM STATUS REPORT

The Quality System Status Report provides a brief summary of the status of the Region's compliance with the QA requirements found in EPA Order 5360.1 A2. This two page report contains a table with a list of EPA QA requirements, the Region's QA activities conducted in the previous year to fulfill these requirements, potential QA vulnerabilities and QA priorities for the current year. A copy of this status report shall be included in the agenda and minutes of all RQC meetings. The RQC shall use this report to monitor the Region's progress in implementation of its quality system. The Council shall review and update the Quality System Status Report at least once per quarter.

2.6 QUALITY SYSTEM AUDITS

The RQAM and the RQC shall evaluate the Region's conformance with the EPA Quality Manual and EPA Order 5360.1 A2 annually. The scope of this audit shall be defined by the RQAM and RQC. At a minimum, an evaluation of the Region's progress on the completion of corrective actions from previous internal and external quality system audits shall be conducted during this evaluation.

An in-depth quality system audit of each Division and Program Office in the Region's quality system shall be conducted at least once every three years. This audit shall evaluate all of the applicable elements of the organization's quality system. The RQAM shall be responsible for assembling the audit team and coordinating audit activities. At a minimum, the audit team shall consist of the RQAM or designee and at least one member of the RQC. The audit team may also include a member of the EAID/ASQAB Quality Assurance Team and a representative from outside the audited program. All members of the audit team shall be familiar with the QA requirements found in EPA Order 5360.1 A2.

2.7 TRAINING PLANS

The Region is committed to ensuring that all personnel have the necessary skills to effectively accomplish the tasks that have been assigned. To facilitate this process, it is imperative that all individuals that participate in the Region's Quality System obtain information about EPA QA requirements and understand their QA roles and responsibilities. Each Region III Division and Program Office QAC shall receive information about QA requirements from the Region III QA Manager and/or National Program Offices.

QA Coordinators shall assist their Division/Program Office in the identification of QA training needs for the members of their organization. These QA training requirements shall be documented in each Division/Program Office QMP. When QA responsibilities have been defined, they shall be incorporated into performance standards.

The implementation of QA requirements for extramural agreements is a critical component of the Region's Quality System. Therefore, the RQC shall establish QA Training requirements for Project Officers, Work Assignment Managers, etc. responsible for implementing these tasks. The procedures found in the most recent version of EPA QA/G-10: Guidance for Developing a QA Training Program may be used to develop these training plans.

Additional information about generic QA training requirements for all Region III personnel can be found in Chapter 3 of this QMP.

2.8 DATA QUALITY OBJECTIVES PROCESS

The Region is committed to the generation of environmental data that is of adequate quality for its intended use. All parties that generate environmental data for the Region shall use a systematic planning process, such as the Data Quality Objectives (DQO) Process found in the most recent version of EPA QA/G-4: Guidance for the Data Quality Objectives Process. The results of the systematic planning process shall be documented in the project's QAPP.

When appropriate, each Division or Program Office may establish data quality objectives for its ongoing programs. The EAID/ASQAB Quality Assurance Team may provide technical assistance as warranted in determining the appropriateness of the DQO relative to the intended use of the data. The RQAM, or designee, shall ensure that internal and extramural project QMPs require the use of the systematic planning process.

2.9 QUALITY ASSURANCE PROJECT PLANS (QAPPs)

The QAPP is the document that provides comprehensive details about the quality assurance/quality control requirements and technical activities that must be implemented to ensure that project objectives are met. The QAPP must be approved prior to any environmental data collection or compilation. The only exception to this requirement shall be for environmental projects that require immediate action to protect human health and the environment or operations conducted under police powers.

The Region has embraced the "graded approach" found in Section 2.4.2 of EPA QA/R-5: EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations. The level of detail found in the QAPP shall be commensurate with the nature of the work being performed and the intended use of the data. For some environmental programs, a generic QAPP may be acceptable. However, for all environmental projects conducted in the Region, the applicable elements of EPA QA/R-5 shall be included in the QAPP.

For extramural projects, recipients of grants, cooperative agreements and Interagency Agreements must submit a QAPP that conforms with the requirements found in the most recent version of EPA QA/R-5. The QAPP must be submitted to the EPA Project Officer at least 30 days prior to the initiation of data collection or data compilation. The EPA Project Officer is responsible for the approval of QAPPs. The decision to approve or reject a QAPP is based on the Project Officer's technical expertise and the comments received from QAPP reviewers. As

noted above, the QAPP must be approved prior to environmental data collection or data compilation.

The title(s) of the individual(s) responsible for the review of QAPPs shall be documented in all Division/Program Office QMPs. All individuals assigned responsibility for QAPP reviews shall be knowledgeable of EPA QA/R-5. These individuals should also have professional knowledge of chemical and biological principles, theories, practices and established methods, statistical techniques commonly used in quality control, data assessments, and data management practices. Extensive knowledge of the principles and practices of quality assurance and the ability to adapt these applications to Agency QA requirements is also required. The QAPP Checklist developed by the ASQAB Quality Assurance Team may be used for this review. To date, the RQAM has not delegated the review and approval of QAPPs to any grant or cooperative agreement recipient.

2.10 Standard Operating Procedures (SOPs)

A Standard Operating Procedure (SOP) is a set of written instructions that document a routine or repetitive activity that shall be followed. The use of SOPs serves as a mechanism to ensure comparability across programs and individual environmental data collection projects. SOPs can describe both technical and administrative operational elements.

The information contained in the most recent version of EPA QA/G-6: Guidance for the Preparation of Standard Operating Procedures (G-6) may be used to provide guidance on the development and use of SOPs. Additional information about the development and use of SOPs can be found in each Division or Office QMP. The RQAM or designee shall ensure that all QMPs include the title(s) of the individual(s) responsible for the review and approval of SOPs.

2.11 Technical Systems Audits (TSA)

A technical systems audit is a systematic and objective examination of the facilities, equipment, personnel, training, procedures, record-keeping, data validation, data management and analysis, and reporting aspects of an environmental measurement system. 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. Technical audits may also be used as an investigative tool when problems are suspected.

All programs in the Region that employ environmental sample collection and analyses are subject to a TSA. The most recent version of EPA QA/G-7: Guidance on Technical Audits and Related Assessments may be used as a resource for planning, conducting, evaluating and documenting technical systems audits and related assessments. The RQAM, or designee shall ensure that all QMPs include the title(s) of the individual(s) responsible for conducting TSAs.

2.12 Proficiency Testing Samples

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

2.13 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-9: Guidance for Data Quality Assessment may be used during the DQA. At a minimum, all environmental data shall be reviewed to ensure that the analytical measurement criteria specified in the approved QAPP has been achieved. Data shall be qualified in accordance with the data validation criteria specified in the approved QAPP.

After the data has been subjected to this initial data review process, it shall 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 (i.e., t-tests, quantile tests, etc.) may also be conducted to help draw conclusions about the data.

CHAPTER 3: QUALIFICATIONS AND TRAINING

It is Region III's policy to provide the QA and QC training necessary to ensure that all persons involved in handling environmental data understand Region III's Quality System. All Regional personnel involved with environmental data generation or use shall be required to have the appropriate QA Training. It shall be the responsibility of the Directors of all Region III Divisions and Program Offices to ensure that the individuals in their organizations meet the minimum QA training requirements for their assigned activities. QA responsibilities are not currently incorporated into performance standards, however, the emphasis on QA training should have a greater impact on implementing the Region's QA policy statement and achieving the Region's stated mission. The following sections describe Region III's QA training program and the requirements for Regional personnel involved with environmental data use and generation.

3.1 REGION III's QA TRAINING PROGRAM

Each Region III Division or Program Office shall determine their organization's QA training needs in accordance with the procedures specified in their Division/Program QMP. EPA QA/G-10: Guidance for Developing a QA Training Program may be used as a tool. Annually, the RQC shall review these QA training needs to determine if the training needs for Divisions and Programs are similar. When similar QA training needs have been identified, the RQC shall determine the feasibility of offering a Region-wide QA training course(s). The RQC shall then identify the most cost-effective method(s) to obtain Region-wide QA training. These Region-wide QA training courses may be given by the Region's Environmental Services Division, another Region, other Federal Agencies, contractors or the OEI Quality Staff.

This section describes the core Region-wide QA training courses, the program logistics, and the associated documentation.

3.1.1 Courses

Region III has identified below, the core QA courses that shall be offered to Region III personnel and Region III state and local government agencies. More courses may be developed as additional training needs are identified.

Orientation to the EPA Quality System: This course shall provide an overview of the EPA Quality System, basic QA concepts, and a description of the application of these concepts to environmental programs involving the collection or use of environmental data.

Introduction to Quality Management Plans: This course shall provide an overview of the ten QMP elements found in QA/R-2. During this course, EPA's graded approach to QMP development will also be emphasized.

Introduction to the Data Quality Objectives: This course shall provide an overview of the Agency's systematic planning process. During this course, participants will not only learn the seven steps of the Data Quality Objectives Process, but also the benefits of using the DQO process for environmental projects.

Introduction to Quality Assurance Project Plans: This course shall provide an overview of twenty-four QAPP elements found in QA/R-5. During this course, the need for systematic planning and EPA's graded approach to project plan development shall be emphasized. Based on the training needs of the audience, the course may either focus on how to write a QAPP or how to review a QAPP.

How to Prepare Standard Operating Procedures: This course shall provide information about the purpose of a Standard Operating Procedure (SOP) and the recommended formats for administrative and technical SOPs. Participants will also learn about the recommended process for review and approval of SOPs.

3.1.2 Logistics

The Region III QA training program shall be administered through a collaborative effort between the Region's [illegible] and the RQC. Additional training support for non-routine topics may be provided by the OEI Quality Staff, other Regions, local universities, contractors and professional organizations. The Region III's Office of Policy and Management (OPM) shall arrange for training announcements and training rooms.

3.1.3 Documentation of Training

After completion of each QA training course, attendees shall receive a certificate of completion from the organization providing the training. For this reason, attendance at the courses shall be recorded. The Office of Policy and Management (OPM) shall maintain a record of all QA training taken by all personnel. This record shall be maintained in OPM's training data base. Upon request, OPM shall provide Division and Program Office Directors with a list of individuals within their Division/Program Office who have completed core QA training courses. The Regional Division and Program Office Directors shall use this information to determine whether appropriate members of their staff meet the minimum training requirements for their assigned activities. At the end of each fiscal year, the RQAM or designee shall provide senior management with a summary of the QA training courses that have been offered in the Region. This information shall also be included in the Annual QA Report and Work Plan. This summary shall include, but is not limited to the courses offered, the number of attendees (both EPA and non-EPA), and a listing of all non-EPA participating organizations.

3.2 Training Requirements

One of the goals of the Region III training program is to ensure that the Region's Quality System is being effectively implemented in a consistent manner throughout all Regional programs and organizations. To accomplish this goal, all Region III personnel must have the

appropriate knowledge of quality assurance policies, principles and procedures. Staff members who are directly involved in the generation and/or use of environmental data are the primary focus of the Region's QA training program. However, all individuals who are active participants in the Region's Quality System shall be knowledgeable of the basic elements of the EPA Quality System. Region III's training program incorporates a graded approach relative to the functions performed by the various groups of personnel. This section outlines the minimum QA training requirements for the various groups of personnel.

3.2.1 Regional Administrator and Senior Managers

Senior Managers are responsible for ensuring that the Region III Quality System is implemented as described in this QMP and the resources are available to achieve these QA requirements. Therefore, Senior Managers shall be knowledgeable of the QA requirements described in the Region's "Orientation to the EPA Quality System" training course. Senior Managers shall receive information about these QA requirements from the Region's Quality System Status Report or during the RQC's Senior Management briefings.

3.2.2 Program Managers

Program Managers must ensure that all intramural and extramural projects within their program that involve the collection and/or compilation of environmental data are performed in accordance with the Regional and Divisional QMPs and an approved QAPP. Consequently, they must be knowledgeable of the elements of the EPA Quality System. Program Managers are required to attend an "Orientation to the EPA Quality System" training course or briefing. Additional training may be required depending on the specific duties and responsibilities of the individual. When additional QA training is required, Program Managers shall forward this training request to their Division or Program Office QA Coordinator. These QA training requests will be included in the Division or Program Office's annual QA training needs survey.

3.2.3 Project Officers and Work Assignment Managers

Project Officers (POs) and Work Assignment Managers (WAMs) are assigned responsibility for specific projects supported by EPA through contracts, grants or interagency agreements (IAGs). Project Managers and WAMs must be knowledgeable of the elements of the EPA Quality System. They shall be required to attend an "Orientation to the EPA Quality System" training course or briefing. Additional training may be required depending on the specific duties and responsibilities of the individual. An orientation to the EPA quality system shall also be included in the Project Officer Certification Training. When additional QA training is required, Project Managers and WAMs shall forward this training request to their Division or Program Office QA Coordinator. These QA training requests will be included in the Division or Program Office's annual QA training needs survey.

3.2.4 Regional Quality Assurance Manager (RQAM)

With respect to QA training, the RQAM shall ensure that a summary of training offered during the fiscal year is provided to senior management at the end of the fiscal year. Training needs identified by EPA management and States shall be given consideration. At a minimum, the RQAM must have successfully completed all of the core QA courses listed in Section 3.1.1. In addition, the RQAM must complete a quality system audit training course.

3.2.5 Regional Quality Assurance Officer (RQAO)

The RQAO serves as a technical QA expert. In this role, the RQAO provides technical assistance to Regional staff on QA/QC requirements and reviews QAPPs submitted by holders of extramural agreements. In order to accomplish these roles, the RQAO must complete all of the core QA courses listed in Section 3.1.1. In addition, the RQAO must complete a quality system audit training course.

3.2.6 Quality Assurance Coordinators (QACs)

QACs are responsible for coordinating the implementation of the quality system in their Division or Program Office. QACs shall also consolidate their program's QA training needs and present this information to the RQC on an annual basis. At a minimum, QA Coordinators shall complete the Orientation to the EPA Quality System, Introduction to Quality Management Plans and Introduction to Quality Assurance Project Plans training courses. Additional training may be required depending on the specific duties and responsibilities of the individual. When additional QA training is required, these training requests will be included in the Division/Program Office's annual QA training needs survey.

3.2.7 Quality Assurance Team

The EAID/ASQAB Quality Assurance Team provides extensive QA support to the Hazardous Site Cleanup Division. Limited QA support is also provided to other Divisions and Program Offices. This QA support includes reviewing QAPPs; providing technical assistance and providing QA training. In order to accomplish these roles, all members of the Quality Assurance Team must complete all of the core QA courses listed in Section 3.1.1. In addition, a quality system audit training course must also be completed. Additional training may be required depending on the individual's assigned duties and responsibilities. When additional QA training is required, these training requests shall be forwarded to the EAID/ASQAB Associate Director. These QA training requests may also be included in the Division or Program Office's annual QA training needs survey.

3.2.8 Analytical Team and Freshwater Biology Staff

Members of these organizations conduct chemical and biological analyses and field studies that support our Regional programs. Training requirements for individuals that conduct these analyses are found in the laboratory's Quality Manual. When additional QA training is

required, these training requests shall be forwarded to the appropriate Laboratory Director. These QA training requests may also be included in the Division or Program Office's annual QA training needs survey.

3.2.9 Client Services Team

The EAID/ASQAB Client Services Team serves as the focal point for the procurement of analytical services for environmental data collection activities within the Region. At a minimum, individuals on this team must complete an Orientation to the EPA Quality System training or briefing. Additional training may be required depending on the individual's assigned duties and responsibilities. When additional QA training is required, these training requests shall be forwarded to the EAID/ASQAB Associate Director. These QA training requests may also be included in the Division or Program Office's annual QA training needs survey.

3.3 Recertification

All persons who are actively involved in the Region's Quality System shall be required to attend QA refresher courses every four years. The contents of these QA refresher courses shall be determined by the year 2004.

CHAPTER 4: PROCUREMENT OF ITEMS & SERVICES

4.1 ACQUISITIONS BY US GOVERNMENT CONTRACTING OFFICERS

EPA requires that all recipients of funds for work involving environmentally-related measurements comply with the American National Standard ANSI/ASQC E4-1994. The EPA Procurement Policy Notice: Guidance for Use of Higher-Level Contract Quality Requirements in Acquisitions (March 2001) shall be used to develop a Region III QA form for defining the contract quality requirements.

Contracting Officer's Representative (i.e., Project Officers, Deputy Project Officers, Regional Project Officers, Zone Project Officers, Delivery Order Project Officers, Work Assignment Managers, Task Order Managers, Technical Program Managers) and the RQAM will use the Region III QA form to identify the appropriate QA requirements for the acquisition. The QA form shall then be distributed to the Contracting Officer. The Contracting Officer shall use the information on the Region III QA form to determine the appropriate QA clause from the Integrated Contract Management System (ICMS) to include in the contract. This QA clause shall require contractors to provide documentation of the organization's quality system and the project's QA/QC requirements. The documentation of a contractor's quality system shall comply with the most recent version of QA/R-2: EPA Requirements for Quality Management Plans. The documentation of a contractor's project QA/QC requirements shall comply with the most recent version of QA/R-5: EPA Requirements for Quality Assurance Project Plans.

Prior to the initiation of environmental data activities, the contractor's QMP and QAPP must be approved. The QMP must be approved by the RQAM or designee. The RQAM shall ensure that all Division/Program Office QMPs include the title(s) of the individual(s) responsible for the approval of the contractor's QAPP.

For contracts consisting of a single project or task, a combined QMP/QAPP that describes the organization's quality system and the application of the quality system to the work being conducted in the contract may be submitted. The decision to use a combined QMP/QAPP can only be made by the Contracting Officer's Representative (COR) and the RQAM or designee. The RQAM, or designee shall identify the QA elements that must be addressed in the combined QMP/QAPP. The combined QMP/QAPP must be approved by the RQAM or designee and the COR prior to the initiation of environmental data activities.

For contracts or solicitations that cover similar activities being conducted at multiple locations or over a long period of time, a Program QAPP may be submitted. The decision to require a Program QAPP shall be made by the COR and the RQAM. The Program QAPP shall describe common activities that are not site-specific, but those that are being applied throughout the program. Site-specific QA activities shall be included in a site-specific Sampling and Analysis Plan (SAP). The Program QAPP and the SAP must be approved before environmental data activities are initiated. The RQAM shall ensure that each Division/Program Office QMP

includes the title(s) of the individual(s) responsible for the approval of the contractor's Program QAPP and SAP.

If a contractor submits a Statement of Work (SOW) that involves environmental data activities, the COR shall submit the SOW to the RQAM for review. The RQAM, or designee shall review the draft SOW to ensure that the applicable QA requirements necessary to achieve the project's data quality objectives have been included in the SOW. The results of this review will be distributed to the COR. When applicable, the RQAM or designee shall also serve on formal source selection technical panels. For an acquisition that involves Information Technology hardware or software, the COR shall obtain the concurrence of Computer Services Branch in the Region III OPM.

4.2 SMALL PURCHASES

Procurement of environmentally related measurements or data generation which qualify for small purchases under the Federal Acquisition Regulations (FAR) will be subject to QA requirements. In Region III these actions are generally for analytical services obtained under the regional Delivery of Analytical Services (DAS) Brokerage and by existing Headquarter's non-Routine Analytical Services (non-RAS) contract for dioxin analysis.

Generally, an approved QAPP or similar documentation such as a SAP are used to create an analytical services request for the procurement of analytical services. The requirement for a QAPP and/or SAP should be included in the original contract award to study a site. Under the direction of an EPA On Scene Coordinator (OSC), Regional Program Manager (RPM), or other Project Manager/Project Officer, a request for analytical services is created by the contracted field contractor and submitted to the Project Manager/Project Officer for approval.

The EAID DAS Brokerage Project Officer and the OSC or RPM of the Hazardous Site Cleanup Division (HSCD) shall jointly prepare and review the analytical services request for each procurement. This joint preparation and review consists of selecting the most cost effective Field and Analytical Services Training Advisory Committee (FASTAC) contracting mechanism, administrative site information component review, number of samples to be analyzed, methods selected to characterize the site, parameters of interest, reporting limits, and stipulating the QA Requirements as per the QAPP or SAP.

Once the joint review is completed, the DAS Brokerage Project Officer creates a bid form for the solicitation of analytical services. Each bid form consists of the number of samples to be analyzed, methods selected to characterize the site, parameters of interest, contract deliverables and agreements, reporting limits, and Quality Assurance Requirements stipulated in the QAPP or SAP. These bids are sent to regional participating commercial labs for price solicitation. All commercial laboratories that receive this bid shall provide a copy of their laboratory's Quality Manual. The EAID/ASQAB Client Services Team shall review this manual to ensure that the laboratory's quality system conforms with the requirements found in the most recent version of

ISO 17025, NELAC Chapter 5 or ANSI/ASQC Q2-1991. If the laboratory's documented quality system is acceptable, the laboratory's solicited bid will be considered.

All acceptable bids shall be compiled and reviewed by the DAS Brokerage Project Officer. Bids are reviewed to ensure that the laboratory's analytical procedures and QC acceptance criteria meet the requirements found on the analytical request form. The DAS Brokerage Project Officer will assure that a Procurement Request Package is complete and provide it with a recommendation to the Procurement Contracting Officer for review and award.

Procurements qualifying as small purchases must meet established administrative and QA requirements of the Federal Acquisition Regulations (FAR) , Federal Information Resources Management Regulations (FIRMR), Delegation 1-84 (1200 TN310), Office of Information Resource Management (OIRM) Delegation 1-10A (September 27, 1991), ARM's EPA Acquisition Regulations, and Chapters Four and Six of OIRM's Information Resources Management Policy Manual, July 1987 and Region III Order 5361.5 Site Location Identification Policy and Responsibilities. The purchase of computer hardware must also conform with the April 1, 1993 Executive Order Number 12845 titled Requiring the Agency to Purchase Energy Efficient Computer Equipment.

4.3 GRANTS AND COOPERATIVE AGREEMENTS

All applicants for grants or cooperative agreements involving environmental data collection or data compilation shall submit a QMP prepared in accordance with the specifications provided in the most recent version of EPA QA/R-2: EPA Requirements for Quality Management Plans, which describes the quality system implemented by the applicant. The EPA Project Officer will indicate on the Funding Recommendation whether the project includes the taking of environmentally related measurements or data generation. If it does, EPA will include a term and condition in the assistance agreement. This term and condition requires the recipient to submit the QMP within a specified time and notifies the recipient that they may not begin work involving environmental data collection or compilation until the QMP has been approved by the EPA RQAM.

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

The Grants Specialist will assure that the terms and conditions are included in the assistance agreements where QA requirements apply. The EPA Project Officer will assure that the grantee complies with the conditions.

The requirements for QA are contained in 40 CFR 30.54 for universities and other non-profits, 40 CFR Part 31.45 for States, tribal, and local governments, and Regional Order 5361.5 Location Identification Policy and Responsibilities.

4.4 INTERAGENCY AGREEMENTS (IAGS)

All IAGs with environmental measurements activities which Region III funds, or participates in, shall require an approved QMP, or equivalent document. The content of the QMP, or equivalent document for interagency agreements shall be negotiated by both parties. When Region III is providing funds to another organization, that organization is responsible for preparing the QMP, or equivalent document. If the external organization's documented quality system meets the requirements found in the most recent version of QA/R-2: EPA Requirements for Quality Management Plans or the Intergovernmental Data Quality Task Force: Uniform Federal Policy for Implementing Environmental Quality Systems (when implemented), their QMP, or equivalent document shall be acceptable. If there are no comparable QA procedures, the QA procedures agreeable to both parties must be negotiated for the IAG. Before any environmental measurements or data collection activities can be performed, the external organization must submit and have a QMP, or equivalent document and a QAPP approved or successfully negotiated and acceptable to both parties.

In order to document compliance with the above policy, the EPA Project Officer shall indicate in the IAG Program Decision Memorandum (Program Office Authorization for the Award) if QA Requirements apply. If yes, the EPA Grants Specialist will include a special condition in the IAG. The special condition notifies the other Federal agency that they must submit to the EPA Project Officer a QMP and that EPA will review and concur on the QA documents (e.g. QAPPs, SAPs and Workplan), which reflect environmental sampling and laboratory analysis and Health and Safety Plans (HASPs).

After the IAG is executed by both parties it is the responsibility of the EPA Project Officer to assure that the recipient of the IAG is in compliance with the QA condition(s). These QA requirements shall be prepared in accordance with the specifications provided in the most recent version of QA/R-2: EPA Requirements for Quality Management Plans or the Intergovernmental Data Quality Task Force (IDQTF): Uniform Federal Policy for Implementing Environmental Quality Systems and the IDQTF Uniform Federal Policy for Quality Assurance Project Plans or QA/R-5: EPA Requirements for Quality Assurance Project Plans.

CHAPTER 5: DOCUMENTATION AND RECORDS MANAGEMENT

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

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

It is Region III's plan to adopt and implement all Agency-approved records management policies and guidance developed by the Office of Administration and Resources Management, Office of Environmental Information (formerly the Office of Information Resources Management). Region III adheres to the most recent version of the following guidance and policies:

- Records Management Manual (2160), U.S. Environmental Protection Agency, OIRM IRM Policy Manual (2100), Chapter 10, Records Management, U.S. Environmental Protection Agency, OIRM
- IRM Policy Manual (2100A16), Chapter 8, Information Security, U.S. Environmental Protection Agency, OIRM
- Managing Cartographic and Architectural Records (Instructional Guide Series), National Archives and Records Administration (NARA)
- Managing Electronic Records (Instructional Guide Series), NARA
- Federal Records Management Laws and Regulations, NARA
- Disposition of Federal Records: A Records Management Handbook, NARA,
- Personal Papers of Executive Branch Officials: A Management Guide (Management Guide Series)
- Records Disposition Schedules, U.S. Environmental Protection Agency

Project level quality-related documents and records (both printed and electronic) will be identified by the EPA Project Manager/Project Officer. Regional quality-related documents and records will be identified by the RQAM. It is the responsibility of the person identifying quality-related documents and records to manage and control those documents and records (or cause them to be managed and controlled), in accordance with the guidance and policies listed above.

The RQC is responsible for preparing, issuing and revising the Region III QMP. The Region III QMP shall conform with the requirements found in the EPA Quality Manual for Environmental Programs (5360.1 A1). Prior to the dissemination of this QMP, it will be reviewed and approved by Region III Senior Managers, the Region III Administrator and the Director of the EPA OEI Quality Staff or designee. When a revised Region III QMP is approved, a notice will be sent to all Senior Managers for distribution to their staff. The obsolete version of the Region III QMP posted on the Region III website will be removed and the current version of the Region III QMP will be posted.

Each Division and Program Office that is responsible for environmental data activities shall prepare a QMP. The Division or Program Office QMP shall conform with the requirements found in the EPA Quality Manual for Environmental Programs (5360.1 A1). Division and Program Office QMPs are reviewed by the RQAM or designee. After these QMPs are approved by the RQAM, they are returned to the Division or Program Office QA Coordinator. The QA Coordinator maintains the QMP in accordance with the procedures specified in the approved QMP. When a revised Division or Program Office QMP is approved, the older version of this document is removed from circulation.

QMPs for extramural projects are reviewed and approved by the RQAM. After these QMPs are approved, they are returned to the Project Officer. Information about the review, approval, distribution, retention and disposition of approved QAPPs and other QA-related documents (i.e., chain of custody and evidentiary records, etc.) can be found in each Division/Program Office approved QMP.

The Project Officer is responsible for managing all project level quality-related documents and records, including transmittal, distribution, retention, access, preservation (including protection from damage, loss, and deterioration), traceability, retrieval, removal of obsolete documents, and disposition, in accordance with the procedures specified in their Division/Program Office QMP. The Project Officer is also responsible for ensuring that records and documents accurately reflect completed work. The RQAM is responsible for managing all regional quality-related documents and records, including transmittal, distribution, retention, access, preservation (including protection from damage, loss, and deterioration), traceability, retrieval, removal of obsolete documents, and disposition, in accordance with the policies and guidance listed above. Each Division and Program Office is responsible for managing the custody and confidentiality of evidentiary quality-related documents and records in accordance with applicable regulations. Regional Records Center staff and resources are available to assist in carrying out these responsibilities.

CHAPTER 6: COMPUTER HARDWARE AND SOFTWARE

In order to ensure the effective and efficient use of the Regional Automated Data Processing (ADP) systems, including hardware and software system design, development, implementation and maintenance, Region III will comply with all EPA standards and regulations pertaining to hardware, software, system development, and data. It is a Region III goal to achieve consistency in the way data are generated, compiled, stored and disseminated across all Regional programs.

6.1 COMPUTER HARDWARE/SOFTWARE REQUIREMENTS

Region III managers and staff will 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.

Region III will procure Agency-approved hardware and software that 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.

Installation and maintenance follow Agency guidelines, with emphasis being on security issues. We assess the impact on the user community by staying in touch with them and noting their complaints and requests. System performance is monitored continually. If a system change adversely impacts performance, we make any necessary adjustments or undo the change.

6.2 SYSTEM DEVELOPMENT

All Region III Information Resource Management (IRM) system development, enhancement and modernization efforts will comply with EPA Directive 2100, Information Resources Management Policy Manual. This compliance should include a systematic and comprehensive dialogue between the data providers, data/system users and system developers, prior to the design of the system in order to ensure extensive user participation and a systematic approach to the design.

All software systems shall be operated and maintained according to EPA Directive 2100. Compliance with applicable IRM Standards as outlined in Region III's System Design and Development Guidance documentation will ensure that all hardware and software configurations

are tested. For proper implementation and maintenance of the ADP system, the appropriate Divisions/Program Offices shall provide:

- A written description of the computer system(s) hardware and written operating procedures for routine maintenance operations. Documentation should be developed to include a written description of the computer system(s) hardware and written operating procedures which describe the routine operation, maintenance and testing, to ensure that both the hardware and software in use is accurately performing the intended functions;

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

- Standard Operating Procedures which describe the routine operation, maintenance and testing, to ensure that both the hardware and software in use is accurately performing the intended functions.

These documents should be readily available in the areas where these procedures will be performed. Changes in any part of the operating procedures shall be properly authorized, reviewed and accepted in writing by the designated responsible person.

The Information Services Branch (ISB) in the Office of Policy and Management documents procedures and maintains those systems which it develops. It is anticipated that by January 2003, SOPs will be formalized and distributed to ISB and Division software developers. Divisions that develop systems using their own staff or contractors are responsible for documenting procedures and maintaining their systems. For example, the Chesapeake Bay Program Office has developed a Chesapeake Information Management System (CIMS) development protocol to improve development, review, testing, and acceptance of new hardware, software or procedural systems or subsystems being used by the CBPO. This protocol is comprised of fourteen steps. A description of this protocol can be found in the Chesapeake Information Management System Major Project 14 Point Development Protocol (Bahner, 1999).

6.3 DATA STANDARDS

To take full advantage of the Region's growing technological and data resources, there needs to be an increased emphasis on improving compatibility of data among the systems. For consistent definition of data, and to facilitate cross-media use of data, all data produced or collected by the computers shall be managed as specified in the Agency IRM Policy manual. Region III will incorporate Agency data standards as listed in the Agency Catalogue of Data Policies and Standards. This catalog will summarize Federal data policies and standards which are the definitive list of data standards that Agency personnel, contractors, grantees, and other governmental organizations must meet when developing information systems. Critical standards that will be followed include:

Chemical Abstract Service Registry Number Data Standard, EPA Order 2180.1, June 26, 1987;

- Data Standards for the Electronic Transmission of Laboratory Measurement Results, EPA Order 2180.2, December 10, 1987;
- The Minimum Set of Data Elements for Ground Water Quality, Policy Order 74500.IA, September 11, 1989;
- Facility Identification Data Standard, U.S. EPA Office of Administration and Resources Management, Information Management and Services Division, April 9, 1990;
- Policy on Electronic Reporting, U.S. EPA Office of Administration and Resources Management, July 30, 1990;
- Site Location Identification Policy and Responsibilities, Region III Order 5361.5, September 14, 1988;
- Locational Data Policy, IRM Policy Manual, Chapter 13, April 1991;
- Locational Data Policy Implementation Guidance - Guide to the Policy, U.S. EPA Office of Information and Resources Management, March 1992.

EPA's data-related policies apply to all EPA organizations and personnel, including contractors, grantees and other governmental organizations who design, implement, and maintain information management systems for Region III. The Region will incorporate Agency data standards into all data collection activities and into new or modernized information management systems.

6.4 INFORMATION SECURITY

It is important that the Region's information resources are protected from potential loss and misuse from a variety of accidental and deliberate causes. To ensure this, the Region will safeguard all information resources as specified in the EPA Security Manual. Technical staff will assure that all servers meet the Office of Environmental Information's security standards and that all virus programs are kept current and virus definition files are deployed in a timely manner to servers and workstations.

The Region will continue to expand the Regional Security Program. An Information Security Officer (ISO) has been named and tasked with this responsibility as well as maintaining a Regional Security Plan. Security awareness training and information will be provided to all employees on a regular basis and all new employees are now required to take the Agency's security awareness training.

6.5 GEOGRAPHIC INFORMATION SYSTEMS (GIS)

QA issues within the Geographic Information Systems team are concentrated into three distinct areas: project management, primary data, and secondary use products. Each of these areas will be addressed individually.

6.5.1 Project Management

The GIS Team is currently comprised of one EPA Team Leader, seven on-site contractor GIS analysts and one contractor GIS analyst assigned to the Wheeling, WV office. The contractor employees are funded through an Interagency Agreement with the General Services Administration (GSA). The internal hiring processes of the contractor ensure only individuals who possess the necessary skills are brought on board. GSA ensures that very specific requirements have been established to ensure candidates have received the proper academic and, where applicable, on-the-job training prior to being accepted as candidates. Once hired, each person is educated on EPA procedures by the on-site contractor task leader. Additionally, ample opportunities for continuing education and training are afforded all members through EPA-sponsored meetings, vendor training courses, and contractor-induced incentives.

Each GIS project is given a project number and, if user requirements are such that written instructions or reference information are included, a project file folder is created and all pertinent documents filed. Once a project is completed, it is archived using programs written to compress the electronic files and copy them to CD or tape for off-line storage. Projects can be "un-archived" if necessary.

6.5.2 Primary Data

The GIS Team in EPA Region III "creates" very little data. Virtually all primary data has been obtained from outside sources. These sources include other federal agencies, state, county, and local governments, non-profit groups, and academic institutions. Primary data is defined as "general base map" information (roads, railroads, streams and rivers, political boundaries, etc.) and "specific map" information (state game lands, historic places, soil types, etc.). With few exceptions, Region III relies on these groups to ensure the quality of their data prior to distribution.

Additionally, the GIS Team's quality assurance concern is focused primarily on the "spatial" component rather than the "descriptive" attributes. The spatial component is the X-Y location values in two-dimensional space. These values can be in many forms, including several varieties of geographic coordinates (degrees+minutes+seconds, decimal degrees, decimal minutes), individual state plane coordinate systems, and a host of other map projections in both the English and metric systems.

While the Region III GIS Team generates very little data on its own, EPA as an agency maintains several databases that are used in environmental mapping projects. These include CERCLIS, RCRAInfo, TRIS, SDWIS, PCS, and several others. Historically, the spatial

component of these databases has been poor. Created prior to the introduction of computer mapping software, collecting geographic coordinate information for sites and facilities was not given a high priority. Most of EPA's databases have place holders for coordinates but for a variety of reasons have been either left blank or been populated with easily identified surrogate information such as the latitudes and longitudes of nearby post offices or county and zip code centroid. The historical QA/QC is also suspect. When placed on maps, many sites and facilities appear in the ocean, in Europe, Asia, and on occasion, the north and south poles. A closer inspection of the coordinates reveals transposed values (latitude values in the longitude field and vice versa), impossible values (latitudes greater than 90 degrees), negative values where positive values should appear, zero values and other similar problems.

This "oversight" has led to several efforts to improve the quality of the coordinate information in these databases. The most recent is the Locational Data Improvement Project or "LDIP." The Region III GIS Team is participating in this project by using aerial photography, address-matching software, and telephone calls to facilities. The new information, if it is deemed "better" than what already exists, is forwarded to EPA headquarters where it is incorporated into the Locational Reference Table, a temporary holding area for coordinate information until mechanisms are put in place to update the main EPA databases. The update process is slow because there is still much debate about what is the actual location of sites and facilities. The answer seems to be "it depends on the intended use."

Metadata, or "data about data", is an important part of the total data set. It is here that information about collection methods, dates, scales, responsible parties, etc. are listed. The GIS Team maintains a searchable web presence of all metadata records which is freely usable over the EPA Intranet. It is the intention of the GIS Team to eventually make all the metadata Federal Geographic Data Committee-compliant. However, this is a slow and tedious process requiring many hours of labor. Initially a "scaled-down" set of metadata is kept on each electronic data file providing users the bare-bones facts about that particular data set.

A general disclaimer about the quality and reliability of each data layer is posted on the web site under the "Data Catalog" section. However, other than this disclaimer, qualifications in the metadata on the GIS Team web page, and verbal correspondence with the individual clients there is not much effort put into identifying data problems with the descriptive attributes. It is assumed to be the responsibility of the individual clients to understand their data, its appropriate use and any inherent limitations.

6.5.3 Secondary Use Products

Paper maps and programmed applications make up the bulk of the what are considered "secondary use products." There are several quality assurance initiatives in place that ensure that only accurate products leave the GIS Team shop. All maps are reviewed and checked by the author and two other GIS Team members for spelling, map element positioning (scale bars, north arrows, etc.), colors, and overall readability. Maps are then reviewed by the client before final delivery.

Because map production is part science and part art, liberal latitudes are given to the GIS analysts to develop their own styles within the boundaries of sound cartographic principles. Based on the intended audience for the map and the message the client is trying to impart, sizes, shapes, colors, fonts, line weights, labels, etc. are left to the discretion of the analyst.

6.5.4 Summary

The Region III GIS Team creates very little data. It is, however, heavily involved in efforts to correct existing latitude and longitude value problems with EPA databases. Secondary use products are checked by several trained individuals before being handed over to clients. Project folders and archives are kept for each GIS project. Only qualified individuals are hired as GIS Analysts.

CHAPTER 7: PLANNING

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

7.1 REGION-WIDE PLANNING

7.1.1 Internal Strategic Planning

The Regional Strategic Plan is the foundation for all programmatic priorities and for all environmental data collection and use. Using the projected annual budget for the Region, and guidance from the various program offices in EPA Headquarters, the Regional Administrator and the senior managers meet early in the fiscal year to set Regional priorities. These priorities are then reflected in the Regional Strategic Plan, which establishes program goals, resource utilization plans and budget allocations. Yearly action plans developed by the individual Divisions, tied to the Strategic Plan and budget distribution process, further specify the types of environmental data generation activities that will occur and the corresponding requirements for QA and QC procedures.

7.1.2 External Data Coordination

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

7.1.3 Annual QA Report and Work Plan

During October of each year, the RQAM will prepare a QA Report and Work Plan (QAARWP). The Report will summarize the past fiscal year accomplishments and the Work Plan will outline planned QA actions for the upcoming year. Included in the Report will be a description of specific audits and evaluations. The QAARWP will be submitted to the QA Council and to the Region's senior managers for their review and approval.

7.2 PROGRAM-SPECIFIC PLANNING

Programs are functional areas of work authorized by Statutory reference (e.g., the Air Toxics Program) or by Executive or Agency direction (i.e., the Volunteer Monitoring Program). All of the Regional environmental programs that generate environmental data are covered by this QMP, though not all require the same level of QA. When initiating a new program or incorporating major statutory changes, the program shall establish the minimum quality system components required to achieve the program requirements.

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

7.3 PROJECT LEVEL PLANNING

A project is an organized set of activities within a program. The QAPP is the primary vehicle for ensuring adequate data quality at the project level (see Chapter 2, Section 2.9 for a more complete discussion of the QAPP development and review process). All projects and tasks involving the generation or use of environmental data that are conducted by or for Region Project Level Planning (PLP) shall have an approved QAPP in place prior to the start of data generation or use. The Project Manager/Project Officer is responsible for ensuring that a systematic planning process is used and documented. Guidance and technical support in using a systematic planning process may be provided by the EAID/ASQAB Quality Assurance Team as requested.

The key to good quality planning at this level is to link the data collection directly to the environmental decision to be made. Achieving this connection requires a dialogue between the decision maker and the data supplier. Consequently, all stakeholders shall be involved in the systematic planning process. Division or Program Office QA Coordinators, with assistance as necessary from the RQAM, RQAO or EAID/ASQAB Quality Assurance Team may be involved in the systematic planning process. The most recent version of EPA QA/G-4: Guidance for the Data Quality Objectives Process may be used to assist in the development of the project goals, objectives, type and quantity of data needed to support the decision and the acceptance and performance criteria for measuring quality. The results of this systematic planning process shall be documented in a QAPP.

7.3.1 Quality Assurance Project Plan Preparation, Review, and Approval

QAPP shall be prepared in accordance with the most recent version of QA/R-5: EPA Requirements for Quality Assurance Project Plans. At a minimum, the QAPP shall include the project objectives; project organization; data generation and acquisition procedures; assessment and oversight procedures and data validation and usability criteria. This requirement applies to all QAPPs prepared for projects or tasks involving environmental data to be performed by Regional staff or through grants, cooperative agreements (40 CFR Parts 30, 31, and 35), and contracts (48 CFR Chapter 15, Part 1546) and Interagency Agreements. The Region uses the "graded approach" to determine the level of detail required.

EPA QA/G-5: Guidance on Quality Assurance Project Plans may also be used during the QAPP development process. In addition, the QAPP Checklist developed by the EAID/ASQAB Quality Assurance Team may be used as a tool in the development and/or review of QAPPs. Project Managers/Project Officers shall ensure that QAPPs are developed for all projects under their jurisdiction. Project Managers/Project Officers are responsible for approval of QA Project

Plans. The decision to approve or reject a QAPP is based on the Project Manager/Project Officer's technical expertise and the comments received from QA Project Plan reviewers

The title(s) of the individual(s) responsible for the review of QAPPs shall be documented in all Division/Program Office QMPs. All individuals assigned responsibility for QAPP reviews shall be knowledgeable of EPA QA/R-5. These individuals should also have professional knowledge of chemical and biological principles, theories, practices and established methods, statistical techniques commonly used in quality control, data assessments, and data management practices. Extensive knowledge of the principles and practices of quality assurance and the ability to adapt these applications to Agency QA requirements is also required. The QAPP Checklist developed by the ASQAB Quality Assurance Team may be used for this review.

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

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

Once all critical issues have been addressed, the Project Manager/Project Officer shall approve the QAPP, sign it and include it in the project file. The decision to approve or reject a QAPP is based on the Project Manager/Project Officer's technical expertise and the comments received from QAPP reviewers. Revisions to the approved QAPP shall be documented in a second or subsequent revision or an addendum. However, sometimes the scope of a project can change which may have the potential to affect the quality of the data. If these changes are significant (as determined by the Project Officer or Project Manager) and affect the scope and objectives of the project, data use, or data quality, the revised QAPP or addendum must be reviewed and approved in the same manner as the original QAPP. For continuous projects, the Project Manager/Project Officer shall ensure that the approved QAPP is updated every three to five years. The Project Manager/Project Officer is responsible for ensuring all appropriate personnel receive a copy of the revised QAPP or addendum once it is approved.

7.3.2 Generic Quality Assurance Project Plans

For multiple projects or sites with the same objectives and environmental decision(s), a generic QAPP may be prepared. A generic QAPP shall adhere to the QAPP requirements specified in Section 7.3.1. The generic QAPP shall include the elements which remain constant among the different projects or sites. Most generic QAPPs will be supported by a site-specific or project-specific plan which address the QA elements that are unique to each site or project. The generic QAPP shall include the procedures being used for the preparation, review, and

approval of the site-specific or project-specific plan. The appropriateness of a generic QAPP is determined on case-by-case basis by the Project Manager/Project Officer in cooperation with the RQAM, RQAO or EAID/ASQAB Quality Assurance Team. The Project Manager/Project Officer is responsible for the approval of generic QAPPs. The decision to approve or reject a QAPP is based on the Project Manager/Project Officer's technical expertise and the comments received from QAPP reviewers

The title(s) of the individual(s) responsible for the review of QAPPs shall be documented in all Division/Program Office QMPs. All individuals assigned responsibility for QAPP reviews shall be knowledgeable of EPA QA/R-5. These individuals should also have professional knowledge of chemical and biological principles, theories, practices and established methods, statistical techniques commonly used in quality control, data assessments, and data management practices. Extensive knowledge of the principles and practices of quality assurance and the ability to adapt these applications to Agency QA requirements is also required. The QAPP Checklist developed by the ASQAB Quality Assurance Team may be used for this review.

The Project Manager/Project Officer is responsible for the approval of site-specific and project-specific plans. The decision to approve or reject a site-specific and project-specific plan is based on the Project Manager/Project Officer's technical expertise and the comments received from QAPP reviewers. If the site-specific or project-specific plan contains analytical and/or sampling procedures that are not found in the generic QAPP, the site-specific or project-specific plan must be reviewed in accordance with the procedures documented in the appropriate Division/Program Office QMP.

7.3.3 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/ASQAB 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.

CHAPTER 8: IMPLEMENTATION OF WORK PROCESSES

The implementation of the procedures specified in this section shall ensure that all environmental data activities being conducted within the Region conform to the requirements found in this QMP, EPA Quality Manual and the EPA Order 5360.1 A2. These procedures are currently being implemented at the program and project level.

8.1 PROGRAM IMPLEMENTATION

Annually, the Region III QMP shall be reviewed by the RQC to ensure that the documented QA policies and procedures are accurate. The Region III QMP shall also be reviewed whenever there is a major reorganization or there are significant changes that impact the Region's Quality System. In addition, every three years, based upon the original approval date, the Region III QMP will undergo a more in-depth review. If revisions are required, the RQC shall revise the QMP and distribute it to Senior Managers for review and comment. After Senior Management approval of the revised QMP, the document shall be distributed to the Regional Administrator for review and comment. After the QMP has been approved by the Regional Administrator, it shall be distributed to the Director of the OEI Quality Staff for review and approval. After final approval has been received, the approved QMP shall be distributed to EPA Senior Managers and the RQC. An e-mail announcement about the newly approved Region III QMP shall be sent from the Senior Management Representative to the RQC. The obsolete version of the Region III QMP shall be removed from the Region's QA website and the newly approved version shall be added.

Annually, each Division or Program Office QA Coordinator shall review their organization's QMP. Division or Program Office QMPs are also reviewed whenever there is a major reorganization or a significant organizational change that impacts the Division or Office quality system. Every three years, Division and Program Office QMPs undergo a more thorough review. If revisions are required, the QA Coordinator shall revise their organization's QMP and distribute it to the RQAM for review and comment. The RQAM is responsible for the approval of the Division and Program Office QMPs. After the QMP has been approved, it shall be distributed to managers and supervisors. Older versions of Division and Program Office QMPs shall be removed from circulation.

Approved QMPs for extramural projects shall be updated every three years, or whenever there are major organizational changes that impact the documented quality system. Grantees and contractors are required to review their QMP annually. If revisions are required, the revised QMP shall be submitted to EPA Region III for review and approval in accordance with the procedures specified in Section 2.2.1.3. The State QMP Status Report is used to document the approval status of QMPs for extramural projects.

Annually, the Region shall submit a QAARWP to the Director of the OEI Quality Staff. The QA report will summarize the QA management resources, training, quality system-related accomplishments (i.e., innovative practices, technical assessments, QMP revisions, QA guidance, technical assistance, etc.) and quality system audits that have been conducted in the previous

fiscal year. The QAARWP will include a list of QA activities planned for the upcoming fiscal year. Each Division or Program Office that is a part of the Region's Quality System shall provide information for the Region III QAARWP. Prior to submission to the OEI Quality Staff, the QAARWP shall be reviewed by the Regional Administrator or his designee.

8.2 PROJECT IMPLEMENTATION

8.2.1 Quality Assurance Project Plans

EPA Region III shall conform to the requirements found in EPA Order 5360.1 A2. More detailed information about the implementation of this project requirement can be found in Chapter 2. Whenever there is a major project reorganization or there are significant changes that impact the QA/QC procedures documented in the QAPP, the QAPP shall be revised. In addition, every three to five years, based upon the original approval date, the QAPP must be reviewed to ensure that the documented procedures are still accurate. If a revision is required, the revised QAPP shall be submitted to the Project Manager/Project Officer for review. The EPA Project Manager/Project Officer is responsible for the approval of QAPPs. The decision to approve or reject a QAPP is based on the Project Officer's technical expertise and the comments received from QAPP reviewers. As noted above, the QAPP must be approved prior to environmental data collection or data compilation.

The title(s) of the individual(s) responsible for the review of QAPPs shall be documented in all Division/Program Office QMPs. All individuals assigned responsibility for QAPP reviews shall be knowledgeable of EPA QA/R-5. These individuals should also have professional knowledge of chemical and biological principles, theories, practices and established methods, statistical techniques, commonly used in quality control, data assessments, and data management practices. Extensive knowledge of the principles and practices of QA and the ability to adapt these applications to Agency QA requirements is also required. The QAPP Checklist developed by the ASQAB QA Team may be used for this review.

After final approval has been received, the Project Managers/Project Officers shall ensure that all project personnel have a copy of the newly approved QAPP. The Project Manager/Project Officer shall also ensure that obsolete versions of the QAPP are removed from work areas. Verification of the changes to the QAPP shall be determined during the project's technical system audit that occurs after the changes have been implemented.

8.2.2 Standard Operating Procedures

SOPs can describe both technical and administrative operational elements. It is recommended that SOPs have a control documentation notation that includes the SOP title and identification number, the revision number and the revision date. In order for SOPs to accurately reflect current procedures, it is further recommended that SOPs be reviewed every three years. The RQAM shall ensure that the procedures each Division or Program Office uses to develop, review, approve and implement SOPs is found in the Division or Program Office QMP. Additional information about SOPs can be found in Section 2.10.

The Office of Enforcement, Compliance and Environmental Justice (OECEJ) Field Inspection Program has developed SOPs that describe the procedures for ambient monitoring and the collection of outfall (wastewater) samples. OECEJ field personnel have also developed SOPs that describe the procedures to be used to conduct opportunistic sampling during a compliance and/or multi-media inspection. A list of these SOPs can be found in the Appendix of this document. The Program Manager for the OECEJ Field Inspection Program is responsible for the review and approval of these SOPs.

8.2.3 EPA Region III Users' Guide for Acquiring Analytical Services

The EAID/ASQAB Client Services Team has developed a users' guide for acquiring analytical services. This guide includes a list of analytical services available and the various acquisition mechanisms for obtaining these services. A detailed description of the procedures to be followed for requesting and scheduling these services is also provided. The Users' Guide also includes detailed procedures for completing field and shipping documentation. A copy of this document is available from the EAID/ASQAB Client Services Team.

8.2.4 Region III OASQA Sample Submission Guidelines

These guidelines have been prepared to document the procedures that are to be followed when submitting samples to the ASQAB Laboratory located at Ft. Meade, Maryland. The use of the procedures specified in these guidelines help ensure that the field and laboratory aspects of the sampling event produce data of known quality. The appendix of this document contains information about sample requirements, nominal quantitation limits and chain of custody requirements. A copy of this document is available from the EAID/ASQAB Analytical Team.

8.2.5 Inspections

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

The vast majority of sampling conducted during compliance inspections would be consider "opportunistic" sampling. These sampling activities are not planned. The inspector makes a decision to collect samples as a result of observations made during the course of the inspection. If sampling is required, samples are collected in accordance with SOPs developed by OECEJ Field Inspection Program. For inspections being conducted to support criminal investigations, the Criminal Investigation Division (CID) investigator in charge of the case

manages the sampling activities. CID investigators often rely on the technical expertise of the OECEJ field inspectors to help determine where to sample and how many samples to collect.

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

In addition to compliance related sampling, OECEJ field personnel routinely collect samples to support ambient water quality monitoring projects, such as TMDL and water quality standards investigations. For these type of sampling activities, the Region uses a generic SAP developed by the PA Department of Environmental Protection (PADEP) for ambient water quality monitoring projects. This SAP was reviewed by OECEJ field personnel and approved by the EPA Project Officer. Data analysis and preparation of the final report shall be conducted by the EPA Project Officer.

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

CHAPTER 9: ASSESSMENT AND RESPONSE

The Region uses a variety of tools (i.e., quality system audits, technical audits, etc.) to ensure that the procedures documented in this QMP are being implemented. These independent reviews and assessments evaluate the conformance of the Region's Quality System with the procedures described in this QMP. The Region is committed to using the results of these assessments to make operational changes that improve our existing quality system.

9.1 QUALITY SYSTEM ASSESSMENTS (QSA)

9.1.1 Internal Quality System Assessments

An annual assessment of the Region's Quality System shall be conducted by the RQAM, or designee and the RQC. The scope of this annual assessment shall be determined by the RQAM and RQC. The results of this annual assessment shall be documented in the Region's QA Status Report. The RQC shall use this information to determine the QA priorities for the following year.

In addition, 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.

All members of the QSA team must complete the Orientation to the EPA Quality System training course described in Section 3.1.1. In addition, members of the audit team are encouraged to attend a quality system audit training course. The RQAM and RQC may request assistance from the EAID/ASQAB Quality Assurance Team to supplement the experience and technical knowledge of the QSA review team.

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 QA Coordinator 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. If there is a dispute about the audit findings, it shall be resolved in accordance with the dispute resolution procedures specified in Section 1.6 of the Region III QMP. 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. If concurrence with the formal comments can not be achieved, dispute resolution procedures shall be used to achieve consensus on the content of the final audit findings report. 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. The QSA team shall review and approve the Division or Program Office's Corrective Action Plan. The Division or Program Office's QA Coordinator and the RQAM shall periodically review the status of approved Division or Program Office Corrective Action Plans. The QAAWRP will summarize the findings of each QSA conducted during the previous fiscal year. A summary of corrective actions initiated as a result of these QSA shall also be included.

9.1.2 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. This information will be included in the audit file, which is maintained by the RQAM, or designee. 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.

The QAARWP will summarize the findings of each QSA conducted during the previous fiscal year. A summary of corrective actions initiated as a result of the OEI QSA shall also be included.

9.2 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.

The procedures being used to conduct TSAs of program activities (i.e., State laboratories, PM 2.5, NPDES facilities, PRP laboratories, etc.) can be found in each Division or Program Office QMP. These QMPs shall also include the title(s) of the individual(s) responsible for ensuring that these TSAs are conducted. Information about TSAs being conducted by State Agencies shall be included in their approved QMP. The RQAM, designee shall ensure that a description of TSAs is included in all QMPs.

9.3 LABORATORY ASSESSMENTS

The EAID/ASQAB Technical Director in conjunction with members of the ASQAB Analytical Team, Client Services Team and Quality Assurance Team conduct assessments of laboratories that support the National Pollution Discharge Elimination System (NPDES) program and the Safe Drinking Water Act (SDWA) program. EAID/ASQAB also conducts assessments of several laboratories being used by Superfund Potentially Responsible Parties (PRP). The EAID/ASQAB Client Services Team conducts assessments of laboratories in Region III that participate in the Contract Laboratory Program and the Delivery of Analytical Services procurement process. EAID/ASQAB also performs inspections under the National Environmental Laboratory Accreditation Program (NELAP) for the review of Accrediting Authorities(AA)

9.3.1 National Pollution Discharge Elimination System (NPDES)

EAID/ASQAB conducts laboratory assessments of NPDES permittee laboratories and commercial laboratories analyzing compliance samples. Inspections are routinely performed in partnership with the State Authority and may be announced or unannounced to the facility. The goal of these assessments are to improve Discharge Monitoring Reports Quality Assurance (DMRQA) performance; to provide technical assistance to States that have limited expertise in

certain analytical methodology; to improve analytical QA/QC procedures; and to improve documentation procedures.

During the DMRQA laboratory assessments, a review of analytical procedures; sampling procedures; equipment; instrumentation; record keeping; documentation; analytical data and Proficiency Testing (PT) sample results are conducted. A Data Audit Inspection (DAIs) is also conducted. This audit is conducted by recalculating the results from unprocessed instrument results and comparing them to the results reported on the Discharge Monitoring Reports (DMRs). If routine problems are found in the Proficiency Testing (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). The EAID/ASQAB Technical Director is responsible for tracking 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", Fall 1994, EPA-903-R-94-043 (currently in revision).

9.3.2 Safe Drinking Water Act (SDWA)

ASQAB 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). The procedures for the Data Audit Inspections are similar to those described in Section 9.3.1. 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/ASQAB Technical Director is responsible for tracking corrective actions. ASQAB also performs reviews of the Region III State SDWA Laboratory Certification Programs as per the Laboratory Certification Manual. Ever three years, the assessments and program are reviewed by the Office of Ground Water and Drinking Water through yearly questionnaires and on-site inspection.

9.3.3 Superfund Program: Laboratories used by Potentially Responsible Parties (PRP)

ASQAB conducts inspections of laboratories being used by Region III Superfund PRP. The Region III Hazardous Site and Cleanup Division (HSCD) selects the PRP laboratories that will be inspected. These laboratory inspections are conducted in accordance with the procedures found in the Standard Operating Procedure for On-site Inspection of Superfund PRP Monitoring Procedures (December 2000). The procedures for the Data Audit Inspections are similar to those described in Section 9.3.1. The PRP laboratory inspections include the review of PT sample results; the site's QAPP and/or SAP; and the site's third party data validation reports. Prior to distribution of the Laboratory Inspection Findings Report to the appropriate HSCD Project Officer, the report shall be reviewed by the EAID/ASQAB Quality Assurance Team. The

EAID/ASQAB Technical Director is responsible for tracking the corrective actions for PRP laboratories.

9.3.4 Contract Laboratory Program (CLP)--Routine Analytical Services (RAS):

The EAID/ASQAB Client Services Team conducts annual on-site audits of CLP laboratories located in Region III. These audits are conducted in accordance with procedures found in the applicable CLP Statement of Work. The EPA Office of Solid Waste and Emergency Response (OSWER), Office of Emergency and Remedial Response (OERR), Analytical Operations/ Data Quality Center (AO/DQC) conducts a contract compliance screening (CCS) of all CLP analytical data packages. The primary goal of the CCS is to ensure that the laboratory adheres to the applicable CLP contract documentation requirements The EAID/ASQAB Client Services Team in conjunction with the Region III Environmental Services Assistance Team (ESAT) also conducts evidentiary audits of CLP laboratory analytical deliverable packages. These evidentiary audits evaluate the documentation for chain-of-custody and sample handling procedures.

The results of the on-site audit, the contract compliance screening, Quarterly blind Proficiency Testing samples, data validation and monthly laboratory visits are used to assess a CLP laboratory's performance. Corrective actions from these laboratory assessments are monitored by the Region III CLP Project Officer. If there are significant contract non-conformances, the Region III CLP Project Officer forwards this information to the National CLP Program Manager and Contracting Officer for appropriate action. This action may include the rejection of data and/or a reduction in payment.

9.3.5 Delivery of Analytical Services (DAS):

For the analysis of samples for non-CLP methods, the Region contracts laboratories via the DAS procurement process. Whenever possible, the Region will use CLP laboratories for DAS analytical services. The use of a CLP laboratory, provides the Region with access to information about a laboratory's performance (i.e., quarterly blind Proficiency Testing sample results, on-site audit reports, etc.). Prior to sample receipt, all DAS laboratories must provide a statement of qualifications. At a minimum, this statement of qualifications shall contain the laboratory's quality policy; a description of the laboratory facilities; a list of personnel with qualifications; measurement and calibration procedures; procedures for data review and corrective action procedures. For non-routine methods, the laboratory must also submit an initial demonstration of capability (IDC) for the non-routine method. The EAID/ASQAB Client Services Team evaluates each of the proposed laboratory's statement of qualifications and IDC results (if applicable) to assess a laboratory's capability to conduct analyses for the DAS program.

The EAID/ASQAB Client Services Team also conducts on-site audits of DAS laboratories located in the Region. The procedures found in the applicable CLP Statement of Work may be used to conduct these on-site audits. If applicable, the CLP on-site audit checklist is used for specific analytical fractions (i.e., volatiles, semivolatiles, pesticides, metals, cyanide, etc.). The EAID/ASQAB Client Services Team in conjunction with the Region III ESAT also conducts a contract compliance screening and evidentiary audits of DAS laboratory analytical deliverable packages. The results of the on-site audit, the compliance screening and data validation are used to assess a CLP laboratory's performance. Corrective actions from these laboratory assessments are monitored by the Region III DAS Project Officer. If significant contract non-conformance is found, the Region III DAS Project Officer may reject the data and/or initiate a reduced payment.

9.3.6 National Environmental Laboratory Accreditation Conference (NELAC)

EAID/ASQAB performs inspections under the National Environmental Laboratory Accreditation Program (NELAP) for the review of Accrediting Authorities (AA). The procedures for conducting these inspections are documented in the National Environmental Laboratory Accreditation Conference (NELAC) Chapter 6 (Accrediting Authority). The results of the inspections are documented in a 23 page checklist. Findings are resolved with the AAs and the final reports are sent to the NELAP Director for final review and approval. The program's procedures, assessments and accreditation are reviewed yearly by the AA Review Board (described in Chapter 6 of the NELAC standards).

EAID/ASQAB has completed an inspection of the program being conducted by the PADEP. In addition, EAID/ASQAB has completed a preliminary review of the program planned for the Virginia Division of Consolidated Laboratory Services. EAID/ASQAB will also be participating in NELAC accreditations of Region III State Laboratories and will serve on assessment teams to accredit EPA Regional Laboratories.

The Quality System being implemented by the EPA Program for the Accreditation of Laboratories (EPAL) is documented in a Quality Manual and detailed SOPs (rev., 2002). This documentation has been reviewed by representatives from Florida, New York and Texas and found compliant with Chapter 6. NELAP conducts a detailed program review (Management System Review) of EPAL every 2 years. Every three years, NELAP will also conduct a TSA of EAID/ASQAB. This TSA will include interviewing EAID/ASQAB assessors and reviewing files of on-site inspections.

9.4 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.

CHAPTER 10: QUALITY IMPROVEMENT

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

10.1 APPROACH TO IMPROVEMENT

At the beginning of each fiscal year, the RQC shall review the information included in the previous year's QAAWRP, Quality System Status Report and QSA reports. This information will be used to establish the Region's QA priorities for the upcoming fiscal year. These priorities will be documented in the upcoming year's Quality System Status Report. A more detailed description of the Region's Quality System Status Report can be found in Section 2.5. Throughout the year, the report shall be updated by the RQAM, or designee when QA activities are completed. The Quality System Status Report shall also be attached to the agenda and minutes of all RQC meetings. This process helps ensure that all Division or Program Offices are routinely made aware of the Region's progress in implementing its QA priorities. In addition, the RQC schedules quarterly QA briefings with Senior Managers to discuss the status of the Region's Quality System.

All Regional personnel are encouraged to raise issues that impact the quality of data and information being generated or used by the Region. These issues should be raised to the designated Division or Program Office QA Coordinator. One issue that has been identified is the need to develop a formal process to conduct QSA of State programs. If these issues impact more than one Division or Program Office, the QA Coordinator will facilitate a discussion of the issue during the scheduled RQC meeting. Based on these discussions, the RQC will make a recommendation to Senior Management about ways to resolve the issue and improve the Region's Quality System.

If the issue requires immediate action, it will be forwarded to the Senior Management Representative to the RQC. The Senior Management Representative to the RQC will then determine the appropriate mechanism to resolve the issue. Whenever possible, the RQC will be involved in discussions about issues that impact the Region's Quality System.

10.2 IMPROVEMENT LEADERS

10.2.1 Program Level

All individuals who are active participants in the Region's Quality System have the opportunity to serve as an improvement leader. As noted in the previous section, all Regional personnel are encouraged to offer suggestions about ways to improve the Region's Quality System. The members of the Senior Management Representative to the RQC, the RQAM, the RQAO and each of the members of the RQC serve as the Region's quality champions. These individuals promote the use of Quality System tools within their organization. A list of these

tools can be found in Chapter 2.0.

10.2.2 Project Level

At the project level, the information obtained from technical system audits, data quality assessments, conference calls and project meetings will be used to determine if there are opportunities for quality improvements. If it is determined that quality improvements should be implemented to ensure that the quality of data being generated is of adequate quality for its intended use, the proposed changes to the project's existing sampling and analysis procedures must be submitted to the Project Manager/Project Officer for review and approval. These proposed QAPP changes must be reviewed and approved in accordance with the procedures specified in each Division or Program Office approved QMP. The approved changes must be included in the project files. In addition, the final project report will document the rationale for the proposed changes and the results of the quality improvements that were implemented. The Project Manager/Project Officer shall ensure that all project personnel obtain copies of the project's revised sampling, analytical or data quality procedures. Older versions of the revised procedures shall be removed from all work areas.

Figure 1: Organizational Chart: EPA Region III

Figure 2: QA Chart

APPENDIX A

STANDARD OPERATING PROCEDURES

Subject	Revision	Date
Chesapeake Bay Program Office		
Managing Non-Point Source Data	0	June 14, 2002
Blind Audit Program	0	June 21, 2002
Managing Point Source Data	0	June 21, 2002.
Assumptions and Procedures for Calculating Water Quality Status and Trends In Tidal Waters of the Chesapeake Bay and its Tributaries		January 2002
Environmental Services Division[1]		
Freshwater Biology Laboratory		
Macroinvertebrate Sample Receiving and Handling	2	July 2001
Macroinvertebrate Sample Subsampling and Sorting	2	July 2001
Identification of Macroinvertebrates	2	July 2001
Bioassessments Information & Data Management Systems	2	July 2001
Bioassessments Document Handling	2	July 2001
Handling, Storage and Disposal of Toxicity Samples	0	July 2001
Data Review/Reporting/Retention Process for Toxicity Testing	0	July 2001
Analysis of Total Residual Chlorine for Toxicity Testing	0	July 2001
Amber Science Digital Conductivity Meter - Model 604	0	July 2001
Standard Operating Procedure (SOP) for the YSI	0	July 2001
Hanna pH Meter - Model 9023	0	July 2001
Cole Palmer Conductivity Meter - Model 01481-61	0	July 2001
Fathead Minnow, *Pimephales Promelas* Larval Survival & Growth Test,	0	July 2001

Dissolved Oxygen Meter - Model 50B	0	July 2001
Cladoceran, Ceriodaphnia Dubia Survival & Reproduction Test	0	July 2001
Acute Toxicity Test	0	July 2001

[1]A list of Standard Operating Procedures used by the Environmental Services Division, Analytical Services and Quality Assurance Branch Laboratory (ASQAB) may be obtained from the ASQAB Director.

Subject	**Revision**	**Date**
Office of Enforcement, Compliance and Environmental Justice		
Field Operations	0	April 1982
RCRA Sampling Procedures for Drums/containers	1	August 1, 2001
RCRA Sampling Procedures for Tanks	1	August 1, 2001
RCRA Sampling Procedures for Soil	1	August 1, 2001
RCRA Groundwater Sampling Procedures	1	August 1, 2001
RCRA Sampling Procedures for Waste Piles[2]		
PCB Wipe Sampling Procedures		July, 1999
Sampling of Residential Drinking Water		
Residential Well Sampling		
QA/QC Guidance and Sop for NPDES Sampling		Summer 1999
Lamotte - Dc1100 Chlorine Analyzer		
Ysi Model 58 DO Meter		
Beckman Model 11 Ph Meter		
GPS Pro Instructions		August 1999
Niton Xl309 Lead Detector		
Hydrolab Calibration Procedure		

[2] Cannot Be Finalized at Present Time. Awaiting promulgation of Revised SW846 manual.

APPENDIX B

REFERENCES

Quality System Documents

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EPA Quality Manual for Environmental Programs; EPA Order 5360.1 A1, U.S. Environmental Protection Agency, Washington, DC, 2000.

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*EPA Requirements for QA Project Plans (R-5);*EPA/240/B-01/003; U.S. Environmental Protection Agency, U.S. Government Printing Office; Washington, DC, 2001.

Guidance for the Data Quality Objectives Process (G-4); EPA/600/R-96/055; U.S. Environmental Protection Agency, U.S. Government Printing Office; Washington, DC, 2000.

Guidance on Quality Assurance Project Plans (G-5); EPA/600/R-02/009; U.S. Environmental Protection Agency, U.S. Government Printing Office; Washington, DC, 2002.

Guidance for Preparing Operating Procedures (G-6); EPA/240/B-01/004; U.S. Environmental Protection Agency, U.S. Government Printing Office; Washington, DC, 2001.

Guidance on Technical Audits and Related Assessments (G-7); EPA/600/R-99/080; U.S. Environmental Protection Agency, U.S. Government Printing Office; Washington, DC, 2000.

*Guidance on Environmental Verification and Validation (G-8);*EPA/240/R-02/004; U.S. Environmental Protection Agency, U.S. Government Printing Office; Washington, DC, 2002.

Guidance for Data Assessment: Practical Methods for Data (G-9); EPA/600/R-96/084; U.S. Environmental Protection Agency, U.S. Government Printing Office; Washington, DC, 2000.

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Guidance for Use of Higher-Level Contract Quality Requirements in Acquisitions; Procurement Policy Notice; U.S. Environmental Protection Agency, Office of Environmental Information; Washington, DC, 2001.

Information Management

Chemical Abstract Service Registry Number Data Standard, EPA Order 2180.1, U.S. Environmental Protection Agency, Office of Environmental Information, Office of Technology Operations and Planning, Information Technology Policy and Planning Division; Washington, DC, 1987. (Web Site: http://www.epa.gov/irmpoli8/casstandard/index.html)

Chesapeake Information Management System Major Project 14 Point Development Protocol; U.S. Environmental Protection Agency, Region III, Chesapeake Bay Program Office, Annapolis, MD, 1999.

Data Standards for the Electronic Transmission of Laboratory Measurement Results; EPA Order 2180.2. U.S. Environmental Protection Agency, Office of Environmental Information, Office of Technology Operations and Planning, Information Technology Policy and Planning Division; Washington, DC, 1987. (Web Site: http://www.epa.gov/irmpoli8/labmeas/index.html)

Facility Identification Data Standard; EPA Order 2180.3; U.S. Environmental Protection Agency, Office of Environmental Information, Office of Technology Operations and Planning, Information Technology Policy and Planning Division; Washington, DC, 1990. (Web Site: http://www.epa.gov/irmpoli8/facilid/index.html)

Information Resources Policy Manual; EPA Directive 2100; U.S. Environmental Protection Agency, Office of Environmental Information, Office of Technology Operations and Planning, Information Technology Policy and Planning Division; Washington, DC, 1991. (Web Site: http://www.epa.gov/irmpoli8/polman/index.html)

Minimum Set of Data Elements for Ground Water Quality; EPA Order 74500.IA, U.S. Environmental Protection Agency, Office of Environmental Information, Office of Technology Operations and Planning, Information Technology Policy and Planning Division; Washington, DC 1992. (Web Site: http://www.epa.gov/irmpoli8/gwstnd/index.html)

One Stop Reporting; U.S. Environmental Protection Agency, Office of Environmental Information; Washington, DC, 1998. (Web Site: http://www.epa.gov/OEI/onestop/blocks/blocks.htm)

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12845; Washington, DC, 1993. (Web Site: http://hydra.gsa.gov/pbs/pt/call-in/eo12845.htm)

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Program Documents

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EPCRA Section 313 Data Quality Inspection Manual; 68-C8-0066, 68-DO-0020; U.S. Environmental Protection Agency, Office of Water; Washington, DC, 1992.

Generic Quality Assurance Project Plan Guidance for Programs Using Community Level Biological Assessment in Wadable Streams and Rivers; EPA 841-B-95-004; U.S. Environmental Protection Agency, Office of Water; Washington, DC, 1995.

Graves, J., *Metadata Tools Manual for EPA Region III (Draft);* U.S. Environmental Protection Agency, Office of Environmental Data; Philadelphia, PA, 2001.

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NPDES Self-Monitoring Data and Data Inspections DAIs; EPA-903-R-94-043; U.S. Environmental Protection Agency, Office of Wastewater Management; Washington, DC, 1994.

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APPENDIX C

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.

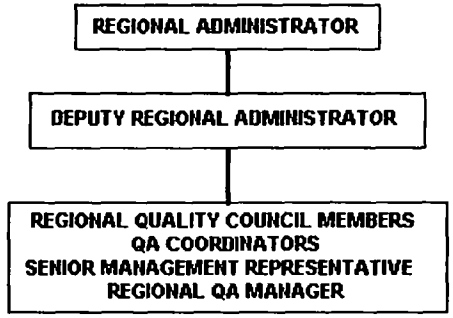
Technical review - a documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed 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.

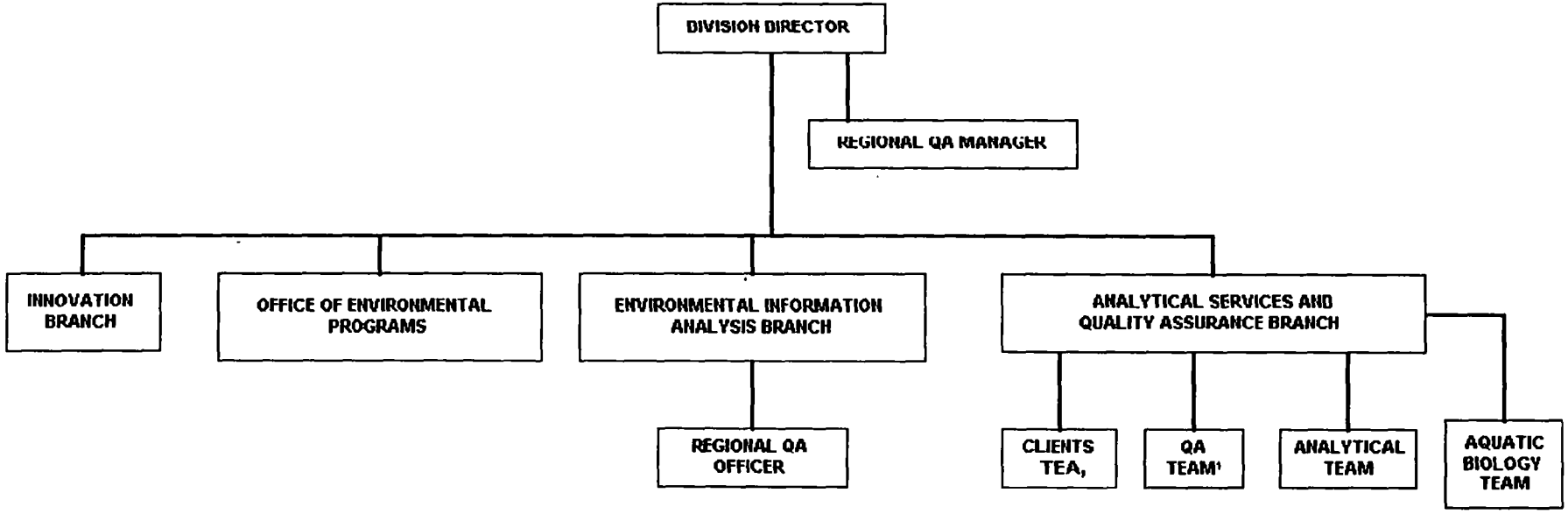
Figure 2

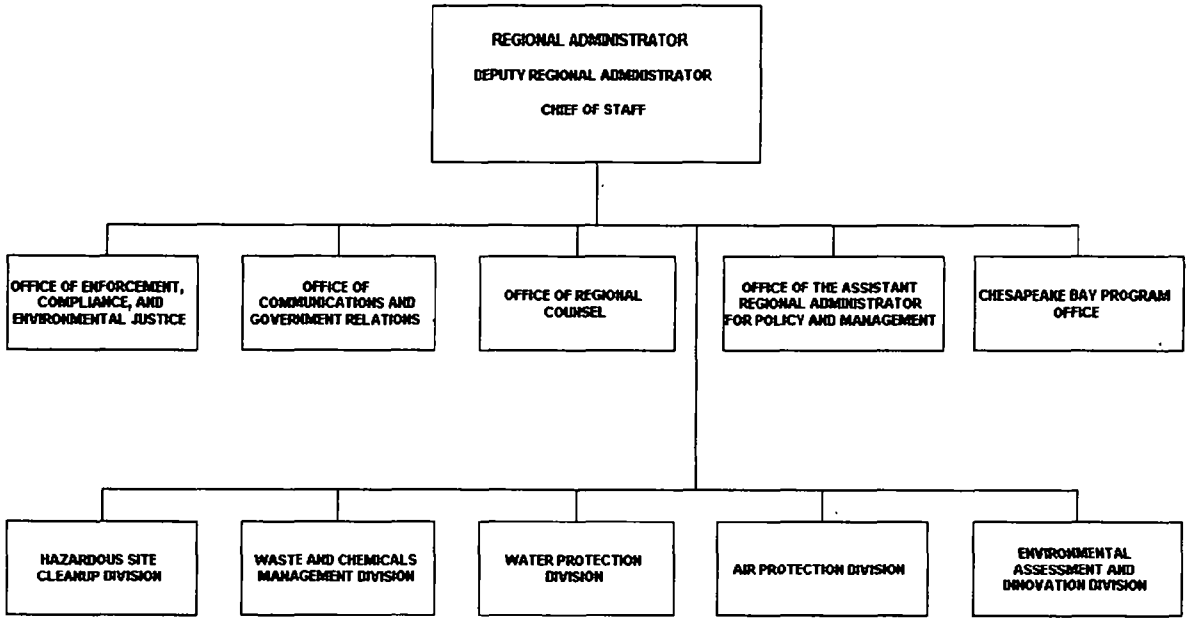
QA FUNCTIONS

Regional Quality Council



Environmental Services Division



[1]The Regional QA Manager (RQAM) is located in the Division's Immediate Office. The RQAM is independent of direct environmental generation, model development, or environmental technology development. On issues relative to the Region's quality system, the RQAM reports to the Senior Management Representative of the Regional Quality Council.

PROPOSED REGION III ORGANIZATION CHART