QUALITY MANAGEMENT PLAN

FOR

EPA REGION III

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U.S. Environmental Protection Agency
Region III
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Philadelphia, PA 19107

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IDENTIFICATION FORM

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Plan Coverage: This Quality Management Plan (QMP) has been developed to address the Agency quality assurance (QA) requirements and guidelines, and for the data quality needs of Region III. The Plan reflects the overall QA Program framework and management systems necessary to ensure that environmental data generated by or for Region III are of acceptable quality to meet the needs of users and decision-makers. It also describes the delegation of QA responsibilities to the various Divisions and Offices within the Region. Each Regional Division and Program Office is responsible for developing and continuously improving their own QMP.

REGION III QUALITY MANAGEMENT PLAN

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CHAPTER 1 ORGANIZATION AND MANAGEMENT

1.1. REGIONAL QUALITY ASSURANCE POLICY

1.1.1 Background

Region III has maintained the fundamental elements of a quality assurance and quality control program ever since the establishment of the Regional office in the early 1970's. Following issuance of EPA Order 5360.1 in 1984, the Region attempted to more systematically implement quality assurance program requirements, and in 1987 issued its own Regional Order (No. 5360.50) entitled "Region III Quality Assurance Program Policy and Responsibilities". Since then, the Regional Office has implemented its QA responsibilities, through the lead of its Environmental Services Division (now the Environmental Assessment and Protection Division), over an increasingly complex set of environmental programs, monitoring activities, grants and contracts.

1.1.2 Importance of QA/QC within the Region

Managers and staff at EPA Region III make daily decisions which affect the lives and livelihoods of millions of people who reside in the Middle Atlantic states. The quality of air, water and land on which these people depend is the focus of our mission. The quality of decisions made by EPA and its state counterparts depends heavily on the quality of the information used to make those decisions. Everything we do at EPA starts with the environmental information we have at hand. While other factors such as the law, public opinion, and Court direction also influence our decisions, nothing is more fundamental to our daily decisions than environmental data. If that data is not of adequate quality to support its intended uses, then the decisions suffer commensurately.

Environmental data is used for setting priorities, strategic direction, targetting inspections, measuring compliance, identifying enforcement actions, measuring progress and trends, certifying laboratories and for many other uses. This data is often critical because it can impact our programs' direction and emphases, determine whether an enforcement case will be successful, dictate which of several possible cleanup options will be implemented at a hazardous waste site, or demonstrate our progress to the public and Congress.

The consequences of "poor" data (that which does not meet user requirements) are that our individual and collective decisions are not as sound as they could and should be. In the fortunate cases, the consequences of "poor" data can be relatively minor. However, on many occasions, the effects can be significant, such as when an enforcement case has to be withdrawn because our own underlying compliance data is challenged successfully by defendants.

1.1.3 General Goals and Objectives of the Regional Quality System

Region III's Quality System is designed to avoid occasions where environmental data collected falls short of meeting the quality requirements established by the users of the data. The primary goal of this Quality System is to ensure that all environmentally-related data collection and processing activities performed by or for the Region will result in the production of data that are documented and of known quality, and can be used with a high degree of certainty by the intended user to support specific decisions or actions. This includes those monitoring and measurement activities supported by EPA through grants, contracts or interagency agreements. This goal will be achieved by ensuring that appropriate resources are made available and proper procedures followed throughout the process of planning for, collecting, analyzing and interpreting environmental data.

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

o Each Regional program or activity that generates environmental data will be part of an effective Quality Assurance (QA) program, and will document their involvement in such program within the framework of a Program, Division or Office Quality Management Plan (QMP).

o The objectives for generating any new environmental data will be determined prior to data collection activities, so that appropriate resources, and quality assurance and control methods can be applied to ensure a level of data quality commensurate with the intended use(s) for the data.

o Each program or activity that generates environmental data will develop and implement a QA Project Plan (QAPP) and/or Standard Operating Procedures (SOPs) which specifies the detailed procedures required to assure production of quality data. 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 support externally generated environmental data through contracts, grants or interagency agreements will ensure that acceptable QA

requirements are included in the appropriate agreement documents, and that these external parties follow acceptable Quality Management practices as described in the relevant Federal regulations, and in requirements and guidance issued by EPA's Quality Assurance Division (QAD).

o Similarly, any Regional programs or activities that accept externally generated environmental data for use in decision-making, shall ensure that the party supplying the data has followed acceptable Quality Management practices.

o Quality assurance (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 ongoing system of evaluation for Regional QA efforts to ensure that the Quality System is meeting the needs and expectations of data users, and QA requirements and guidelines set forth by EPA Headquarters.

1.1.4 Resources for the QA System

The resources necessary to conduct the various QA and QC activities within the Region are provided by the program customers who require assistance in order to successfully implement their programs. QA is viewed as an integral part of the programs and activities to which QA applies, i.e., any program which deals with environmental measurements and data generation. This includes all monitoring activities. The level of QA resources needed for any given program or project is determined initially by the relevant Regional program or project manager, based on Headquarters' workload models and experience with similar QA efforts.

Most of the Region's QA related positions are located within the Environmental Assessment & Protection Division. Of these, the majority are located within the Office of Analytical Services and Quality Assurance (OASQA) in Annapolis, MD. Since there exists no assigned national program element for Quality Assurance, most resources needed for QA are taken from a variety of program elements which utilize the QA functions and services of EAPD. Included in this mix are resources devoted to general management of the Quality System which are contributed by all benefitting programs.

1.2 SCOPE OF THE QUALITY MANAGEMENT PLAN

The Agency's Quality Assurance policies require that all EPA organizations (national program offices, regional offices, ORD laboratories, etc.) that conduct or

support environmentally-related measurements (as defined in EPA Order 5360.1) will participate in the Agencywide QA program. This participation includes the preparation of an organizational Quality Management Plan (in this case, a Regional QMP). This Plan is intended to establish the foundation for implementing an effective QA program within Region III, covering all intramural and extramural activities which involve the generation of environmental data.

This Quality Management Plan applies to any and all Region III programs, activities, grants, contracts and interagency agreements that generate environmental data which is used to make decisions or support actions related to our defined mission and responsibilities. **Environmental data** is defined as information or measurements resulting from any field data collection activity, laboratory analyses or models involving the assessment of chemical, physical or biological factors relating to the environment. Therefore, any programs, activities, etc. which generate such data are required to comply with the requirements of this QMP.

Since Region III employs a primarily 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.* However, following is a sampling of the types of environmental programs, grants and activities within each Division and Office which are covered by the Region III Quality System.

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

Clean Water Act

- National Pollutant Discharge Elimination System (NPDES) Program
- Water Quality Management (Section 106) Grants Program
- Watershed Protection Program
- Nonpoint Source (Section 319) Grants Program
- Volunteer Monitoring Program
- Clean Lakes Program
- State Revolving Fund Program

- Water Quality Standards Program
- Watershed Grants Program (Section 104(b)(3))

Air, Radiation and Toxics Division

Clean Air Act

- Ambient Air Quality Data (monitoring by states via 105 grants)
- 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)
- Asbestos NESHAP sampling
- Other CAA Compliance Inspections

Toxics, Pesticides and Radon Data

- PCB Sampling
- Pesticide Program (FIFRA)
- Radon measurements in homes (for conditions and trends analyses)
- Surface coating sampling (compliance monitoring)
- Lead (Pb) Program grants (TSCA Title IV, Section 404(g))

Environmental Assessment & Protection Division

- Laboratory Analyses - performed at Annapolis and Wheeling labs
- Ambient air monitoring - per 40 CFR Part 58
- Ambient water monitoring (routine monitoring performed mostly through the states);
- Compliance inspections which generate environmental data
- State Laboratory Inspections
- Ocean Dumping Program
- National Estuary Program coastal waters sampling
- Environmental Monitoring and Assessment Program (EMAP)
- Mid-Atlantic Highlands Assessment Program (MAHA)
- Community-Based Special Studies (e.g., Newton-Chester, Monroe County)
- Fish Tissue Surveys

Hazardous Waste Management Division

Superfund Office

- CERCLA Program, as amended by SARA
- CWA Section 311 Oil and Spill Response Program

RCRA Office

- RCRA Corrective Action Program
  - -Administrative Orders
  - -Permits
- RCRA Enforcement Program - Compliance Monitoring
- Delegated activities through RCRA grants to States
- Underground Storage Tank Program

Chesapeake Bay Program Office

- Mainstem and Tributary Monitoring Program
- Fall Line Monitoring Program
- Ambient Toxicity Monitoring Program
- Atmospheric Deposition Program

1.3 REGION III ORGANIZATIONAL STRUCTURE

Region III employs a decentralized approach to QA management, whereby each Division, Office or program is responsible for deciding how they will specifically implement the general policies and procedures of this QMP. The Regional Administrator has delegated major responsibililty for overseeing the QA System to the Environmental Assessment and Protection Division (EAPD).

Within EAPD, a **Quality Assurance Team (QAT)** in Annapolis serves as Regional QA Program lead, and the Team Leader as the **Regional QA Manager (RQAM).** The RQAM, while located within the Division's Office of Analytical Services and Quality Assurance, has direct access and reporting authority to the Division Director. A **Regional QA Officer (RQAO)** located in the EAPD Philadelphia Office serves as the senior technical QA expert for the Region and assists with a variety of QA functions. Both the RQAM and the RQAO maintain an independence in location and function from any offices or programs which generate environmental data.

The Region is composed of four major program Divisions - Water Protection, Air, Radiation and Toxics, Hazardous Waste Management, and Environmental Assessment

and Protection - as well as the Offices of Policy & Management, External Affairs, Regional Counsel and the Chesapeake Bay Program. Each Division and Program Office assigns a **Quality Assurance Coordinator (QAC)** to work with the RQAM to implement the QA Program. Figure 1-1 depicts the general Regional QA organizational structure, while Figure 1-2 illustrates the location of the Regional QA Manager within the EAPD.

It should be noted that all of the program Divisions and the Office of Policy & Management have undergone major reorganizations during the past two years in response to streamlining and reinventing government initiatives. As a result, in some Divisions a layer of supervisory management has been eliminated. Thus, **first line supervisors**, who are primarily responsible for ensuring that approved QAPPs and QMPs are implemented, may be Section Chiefs in some organizations, while in others they may be Branch Chiefs. Also, some former supervisors now serve in the capacity of **program managers**, responsible for overseeing functional areas of work (e.g., the Wetlands Program, the NPDES permits program). In this capacity, they may be responsible for ensuring that QA requirements are met within their program's scope of activities.

In addition to the above organizational structure, a **Quality Assurance Council,** consisting of the QA Coordinators from each Division and Office, the RQAM, RQAO, and a rotating management representative, will meet quarterly to discuss QA implementation and common QA issues across the Region (see Section 1.5 of this Chapter, and Chapter 10 for additional discussion about the Council).

1.4 ROLES AND RESPONSIBILITIES

Anyone in the Region who is directly or indirectly involved with environmental data collection or analyses 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:

Regional Administrator

The Regional Administrator (RA) has overall responsibility for the Regional QA Program as described in EPA Order 5360.1, dated April 3, 1984. Specifically, the RA is responsible for ensuring that QA is an identifiable activity with adequate resources allocated for the accomplishment of program and Regional goals, including the collection of the right type, quantity and quality of data for all in-house and extramural projects.

Division and Office Directors (or Designated QA Coordinators)

Division and Program Office Directors have overall responsibility for managing the QA program within their organization, as described in their own QMPs (QMPs are not required for the Offices of Regional Counsel, External Affairs, and Policy & Management). The Directors are specifically responsible for ensuring that:

- QMPs covering Divisional or Office QA operations are developed, updated and effectively implemented;
- Adequate resources are provided to support QA program responsibilities;
- A QA Coordinator is designated to assist with QA implementation;
- All environmental data collection activities are covered by appropriate planning documentation (DQOs, QAPP, SOP, QMP, etc.);
- QAPPs are written, signed, and effectively implemented for all projects which generate environmental data;
- An adequate degree of auditing is performed to determine and achieve compliance with QA requirements;
- Deficiencies highlighted in audits are corrected expeditiously;
- Program specific QA-related training needs are identified; and
- The Division/Office is represented on the Regional QA Council.

Regional Quality Assurance Manager (RQAM) and QA Team

- Maintain and update the Regional QMP;
- Oversee implementation of the Regional QMP;
- Prepare and submit the Annual QA Report and Workplan to Senior Regional Managers and the QAD;
- Review and approve Region III Divisional, Office and State QMPs;
- Serve as primary Regional liaison with QAD in Headquarters and the State QA contacts;
- Authorize individuals to review and approve QAPPs;
- Provide technical assistance to program offices and the states;
- Distribute Agency QA guidance documents, policies, and procedures;
- Routinely review the QA procedures within the Region and keep the RA and senior managers apprised;
- Conduct formal reviews and assessments of QA and QC activities, and prepare reports on such assessments;
- Provide guidance on QA issues for Regional use;
- Maintain a database/tracking system for Regional QA documents; and
- Assess Regional QA training needs, and arrange, develop and/or present training courses on QA topics.

Regional Quality Assurance Officer (RQAO)

- Serve as senior technical QA expert within the Region;
- Serve as secondary liaison with QAD in Headquarters and state QA contacts;
- Assist the RQAM with assessment and provision of QA training needs;
- Perform laboratory audits;
- Review and certify drinking water laboratories;
- Authorize individuals to review/approve QAPPs;
- Provide technical assistance on program or project specific basis;
- Administer the water supply and water pollution Performance Evaluation (PE) studies;
- Administer the Air Program Performance Evaluation studies; and
- Assist with audits of Regional and state QA programs to assure that they adhere to their approved QMPs.

Program Managers

- Ensure that all intramural and extramural projects involving the generation of environmental data are performed in accordance with the Regional and Divisional QMPs and an approved QAPP;
- Ensure that resources needed to implement QA requirments are identified and provided;
- Ensure that adequate procedures are in place to address QA requirments in all applicable program operations, including those delegated to state agencies;
- Cooperate with any 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.

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 catagory includes Superfund Remedial Program Managers (RPMs) and On-Scene Coordinators (OSCs) who are responsible for site specific monitoring projects. For those extramural projects which generate environmentally related data, QA requirements must be followed. In addition to the Regional and Divisional QMPs, the relevant QA requirements for extramural projects are specified in 40 CFR 30 and 31, and 48 CFR 15. Chief among those requirements are that any grant recipient or contractor conducting a project which involves environmental measurements must have in place an acceptable Quality Management

System (as evidenced by a QMP or similar documentation), **and** must prepare an acceptable Quality Assurance Project Plan (QAPP) **prior to** initiating any data collection or analyses. In many cases, in order to document compliance with QA requirements, a Quality Assurance Review Form (EPA Form 1900) must be completed, and approved in writing by the relevant Project Officer and grants or contracts office contact (see Chapter 4 for a description of specific procedures). Because 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.

1.5 COMMUNICATIONS

To be effectively implemented, this QMP must not only be completed, circulated and updated, but **understood** by those responsible for its implementation. Several means will be used to ensure that this occurs. Lines of communication among some of the involved and responsible QA personnel were described earlier in Section 1.3. The Regional QA Manager will keep the EAPD Director and other senior managers apprised of QA issues on a regular basis. The RQAM will also communicate and coordinate with the Division and Office QA Coordinators regularly, and keep them informed of new developments, policies, and other QA procedures. The QAM will also maintain a list of all Region III state QA contacts and provide them with updates and opportunities to exchange QA information as necessary.

The Region will also establish and maintain a standing Quality Assurance Council consisting of the Division and Office QA Coordinators, the Regional QAM and QAO, and a rotating management representative. This group will meet on a quarterly basis to discuss issues of data quality, QMP implementation, and any concerns or suggestions for improving the Quality System. The Council is the primary cross-Divisional Regional group for addressing Regionwide QA topics. The individual Divisions and Offices will establish their own methods of communicating QA issues within their respective organizations.

Finally, QA training will be offered on an ongoing basis in order that personnel responsible for QA functions understand QA requirements and practices related to their responsibilities. The RQAM will be responsible for ensuring that adequate training is provided.

CHAPTER 2 REGION III's QUALITY SYSTEM

2.1 PRINCIPAL COMPONENTS OF THE SYSTEM

The Region III Quality Assurance System consists of the people, functions, tools and procedures used to ensure that an appropriate quality of environmental data is generated for the needs of Regional data users and decision makers.

A Regional Task Force which was established to produce this QMP identified the following elements of an effective QA System:

- Statement of QA Goals and Policy
- List of Applicable QA Requirements and Criteria (EPA Orders, Regulations, Guidelines, Federal Acquisition Regulations, etc.)
- Defined QA Organizational Structure
- Programs and Activities Covered by the QA Requirements
- Roles and Responsibilities of those involved with QA functions
- QA Tools and Procedures
- Resource Assessment and Accommodation
- Communications Processes (internal and external)
- Training Requirements
- Documentation and Record Keeping
- Review and Evaluation Procedures
- Definitions of Key QA Terms
- Methods for Continuous Improvement

As described in Chapter 1, overall QA Program responsibility is delegated to the Environmental Assessment and Protection Division (EAPD). Within EAPD, a **QA Team** (QAT) in Annapolis serves as Regional QA Program lead, and the Team Leader as the **Regional QA Manager (RQAM)**. A **QA Officer (RQAO)** located in Philadelphia serves as the senior technical QA expert for the Region and assists with a variety of QA functions.

The System is largely decentralized, with each Division and Office specifying QA operating procedures in their own QMPs, consistent with this Regional QMP. Divisional requirements many be more stringent than those presented in this QMP, but not less stringent. Each Division and Program Office assigns a **QA Coordinator** to

work with the RQAM and RQAO to support and implement the QA functions. A **Quality Assurance Council** consisting of the Divisional QA Coordinators, the RQAM, RQAO, and a Regional management representative(s), will meet quarterly to review the status and needs of the Regional Quality System. By participating in this forum, each level of the organization acknowledges and accepts responsibility for maintaining and improving the Quality System.

2.2 PRINCIPAL TOOLS AND PRACTICES

Successful implementation of the Region III QA Program requires a consistent and graded approach for QA practices, commensurate with the intended uses of the data and degree of confidence needed in the results. A variety of tools and procedures are employed for planning, implementing and evaluating the Quality System. Managers and staff members are informed of the availability and use of these tools through Regionwide training and through their Divisional Quality Assurance Coordinators.

Primary **QA planning and implementation tools** include Quality Management Plans (QMPs), establishment of Data Quality Objectives (DQOs), Quality Assurance Project Plans (QAPPs), Standard Operating Procedures (SOPs) and, for Superfund, Sampling and Assessment Plans (SAPs). Most of these tools are employed directly by the Program Divisions/Offices, with technical assistance as necessary from the QA Team, RQAM or RQAO.

Primary **QA evaluation and assessment tools** include Management Systems Reviews (MSRs), Technical Systems Audits (TSAs), Performance Evaluations, and Data Quality Assessments (DQAs). Most of these are arranged and/or performed by the RQAM/QAT or RQAO.

Specific procedures for applying these tools are described in the Divisional QMPs; however, some general requirements are specified in this Regional QMP, including a requirement that all QAPPs must be approved, in writing, prior to implementation.

2.2.1 Quality Management Plans

This Regional QMP describes the policies, procedures and systems governing the Region III QA Program. It serves as the "umbrella" document for all Regional QA operations. It was developed through the efforts of a cross-Divisional Regional Task Force. Future revisions and updates to this QMP will be prepared by the Quality Assurance Manager working through the Regional Quality Assurance Council.

Each Region III Division and Program Office shall prepare a separate QMP that describes their organization's QA management policies, objectives, and procedures. These documents will be consistent with the requirements of the Regional QMP and shall be prepared in accordance with EPA QA/R-2, as updated. Divisional requirements may be more, but not less, stringent than those presented in this QMP. The QAT/RQAM will review and approve Division and Program Office QMPs, prior to their incorporation into the Regional QMP. All QMPs shall be reviewed and updated, as necessary, on an annual basis.

QMPs submitted by state agencies and other external organizations as part of extramural agreements will be submitted by the Divisional QA Coordinator to the Regional QA Manager for review and approval. The QAM may request the Regional QA Officer to assist with these reviews depending on the program involved. Approval or disapproval of the QMP, along with any comments, will be returned to the submitter within 15 working days.

2.2.2 Data Quality Objectives Process

Region III is committed to sound science and thus, the generation of environmental data that are technically and legally defensible, and of adequate quality to support decisions. The Data Quality Objectives (DQO) Process is used in the planning phase of all environmental data collection activities. "Guidance for the Data Quality Objectives Process, EPA QA/G-4" is used for the development of DQOs. DQOs are a required element of any Quality Assurance Project Plan (QAPP) submitted to Region III for review and approval. This requirement is applicable to all parties that generate environmental data for use in Region III.

Each program office is responsible for establishing DQOs for its applicable ongoing programs. The Quality Assurance Team will provide technical assistance as warranted in determining the appropriateness of the DQO relative to the intended use of the data. The Quality Assurance Team will review Divisional or Program QMPs to assure that Program offices establish and use DQOs. These reviews will be performed as part of the annual QMP review process by the appropriate QA Coordinator, with assistance from the Regional Quality Assurance Manager (RQAM).

2.2.3 Quality Assurance Project Plans (QAPPs)

The QAPP presents the policies and procedures, organization, objectives, quality assurance requirements, and quality control activities designed to achieve the type and quality of environmental data necessary to support project objectives. In Region III, no data collection or analyses will occur without the approval of the supporting QAPP. All environmental data collection activities are subject to this

requirement. Additionally, all contracts must meet the Quality Assurance requirements of the EPA Acquisition Regulations (EPAAR).

Region III's Quality Assurance Team is responsible for setting policy on format and extent of detail necessary in each QAPP element. Each QAPP must use a document control format that provides its version number and effective date. Currently, EPA Guidance Document EPA QA/R-5, "EPA Requirements for Quality Assurance Project Plan for Environmental Data Operations" is used in preparing QAPPs. Updated QAPP (QA/R-5) guidance is under review and will be implemented upon final approval. Implementation of each QAPP will be evaluated by the respective Division or Program Office. The QAT will provided oversight through audits, Management System Reviews (see Section 2.2.7 below) and other means.

QAPPs will be reviewed by personnel designated by the originating Division or Office. All personnel conducting reviews must have a working knowledge of the Program and/or Divisional Data Quality Objectives, and training in QAPP review (See Chapter 3 on Training). QAPPs are not reviewed as stand alone documents. Rather they are reviewed in the context of the broader project objectives for current and future investigations, and may be reviewed by a team of subject area experts who will provide specific project recommendations. This information, used in conjunction with the Quality Assurance review, allows the Project Manager or Divisional designee to assign an approval status for the QAPP. The Divisions' Quality Assurance Coordinator is responsible for ensuring that all QAPPs receive a quality assurance review, are in approval status prior to sampling, and signed by the Project Officer/Manager.

2.2.3.1 Intramural (In-house) Projects

The Quality Assurance Team will provide technical assistance, as necessary, in the development of the QAPP for each data generation activity. Each QAPP must cite the specific QMP, and its effective date, that it is guided by. The QA Team and the Divisional QA Coordinators will evaluate the implementation of these plans through Technical Systems Audits and Management Systems Reviews.

2.2.3.2 Extramural Projects (Grants, Contracts, Interagency Agreements)

Projects covered in this category are subject to the Quality Assurance requirements described in 40 CFR Parts 30 and 31, 48 CFR part 15 subpart 46.2 and EPA Order 1900.2. The fulfillment of these requirements is the responsibility of the respective Divisions and Program Offices. The oversight and implementation procedures will be described in the Divisional QMPs.

2.2.4 QA Status Reports

Each QAPP for environmental data collection must include a section discussing the frequency, content, and format of the required QA status report(s). These factors are determined by the relevant Project Officer and Region III QA personnel. The status reports are submitted to the Division or Office QA Coordinator and QA Team, and will be used to help track the progress of QAPPs throughout the Region. Each status report must address, as a minimum, the following elements:

- Status of project
- Changes in project activities (sampling, quality control measures, analytical methods)
- Results of performance and systems audits
- Any Corrective Actions taken
- Project Organization changes
- Assessment of data quality indicators (precision, accuracy, completeness, representativeness, and comparability)

Divisional or Office QMPs will contain program/process specifications for QA status reports.

2.2.5 Standard Operating Procedures (SOPs)

The use of Standard Operating Procedures (SOPs) in Region III serves as one mechanism to ensure comparability across programs and individual environmental data collection projects. SOPs must be incorporated either in full or by reference in the QMPs and QAPPs. SOPs developed for use in Region III must be peer reviewed and receive approval by the QA Team or Divisional designees as appropriate. SOPs are tracked and maintained by the QA Team and designated Divisional contacts as described in the respective Division's QMP.

2.2.6 Technical Systems Audits (TSA)

All programs that employ environmental sample collection and analyses are subject to a TSA. The TSA involves a thorough review of the facilities, equipment, sampling and analysis procedures, documentation, data validation and management, training procedures and reporting aspects of the technical system for collecting or processing environmental data. TSAs may be routinely planned by the QA Team, specifically requested by a program, or result from other audit or review findings. The QA Team is responsible for scheduling the TSA, assembling the audit team, and participating in the TSA. Results will be reported to the audited organization in the form of a written report. See Chapter 9 for a further discussion of TSAs.

2.2.7 Management System Reviews (MSR)

Management System Reviews (MSRs) will be performed for each major Region III Division and Program Office at least once every three years. The MSR will qualitatively assess a program's organization and data collection procedures to determine if the quality system in place is adequate to ensure the quality of the program's data. The Quality Assurance Team is responsible for assembling the audit team and coordination of audit activities. The RQAM, DQACs, and representatives from outside the audited program's division will conduct the audit using current Quality Assurance Division Guidance. Results of any MSRs conducted will be promptly shared with the Division or Program's senior management upon completion of the review (but prior to a final written report). The senior management of the organization reviewed is responsible for taking any necessary corrective actions and determining whether additional audit activities are required.

2.2.8 QA Annual Report and Workplan

At the beginning of each fiscal year, the Regional Quality Assurance Manager will develop, after consulting with the Divisional QA Coordinators and the QA Council, a QA status Report and Workplan (QAARWP). This combined report shall be submitted to Regional Management and to the Director of the QAD. The QAARWP shall reflect the implementation status of the Region III QA Program. The Work Plan shall describe major planned QA activities for the coming fiscal year, including specific planned audits and audit responsibilities.

The QA Report/Work Plan shall contain the following information as a minimum:

- Implementation Status of the Regional QA Program.
- Revisions to the Regional Quality Management Plan.
- Significant QA related needs, i.e., new policies, changes to existing policies, guidance documents, audit protocols, etc.
- Data Quality Objectives.
- Status of QA Programs/Projects and Standard Operating Procedures.
- Audits conducted or planned.
- Resource changes.
- Training plans and needs.

In addition to the regular communication/reporting activities described above, the RQAM shall participate in monthly QAD conference calls and Annual Management/Technical meetings.

CHAPTER 3 PERSONNEL QUALIFICATIONS AND TRAINING

3.1 POLICY FOR QA RELATED TRAINING

The purpose of this Chapter is to explain the processes used by Region III to ensure that staff and managers working in the various environmental programs are trained and qualified to perform their required QA responsibilities . This includes project managers, laboratory staff, field personnel, members of the Regional QA Team, Division and Office QA Coordinators, data processors, modelers and the individuals who manage and supervise these personnel.

3.1.1 Responsibilities

First line supervisors are responsible for ensuring that each staff member involved with collecting or analyzing environmental data has the necessary technical, quality assurance and project management training and certifications required for their assigned tasks and functions. Supervisors are also responsible for ensuring that technical staff maintain the necessary level of proficiency to effectively meet QA responsibilities. QA training and additional development needs will be identified as part of the mid-year and annual performance discussions, and during preparation of Individual Development Plans (IDPs).

Maintaining staff proficiency in critical technical disciplines (e.g., laboratory microbiologist, toxicologist, environmental engineer) is the joint responsibility of the individuals filling those positions and the responsible program manager and/or supervisor.

The individual Divisions and Program Offices, through their Quality Assurance Coordinators, and with necessary assistance from the Regional QA Manager or Officer, are responsible for identifying needed QA training within their organizations. The RQAM is responsible for arranging or providing for the training needs so identified.

3.1.2 Identification of Training Needs

Generally, QA related training needs are assessed by first estimating which personnel within each organization (Division or Program Office) have QA related responsibilities, what specific types of QA functions they perform, and with what

frequency. These estimates are conveyed by the organization's QA Coordinator to the Regional QA Manager, who develops an appropriate training program in response. First line supervisors will identify program specific training needs, including those for critical technical disciplines.

3.1.3 Implementation of Training Requirements

Staff are encouraged by supervisors to draw upon their educational background, experience, professional symposia, and on-the-job training to enhance their understanding and performance of QA related procedures.

The Regional QA Manager and QA Team will coordinate QA training with the Region III Training Institute and Quality Assurance Division (QAD) staff. The QA Team will arrange or make known the following courses at a schedule and frequency suited to meet the needs of Region III and state employees with QA responsibilities.

1. Orientation to Quality Assurance Management
2. Data Quality Objectives
3. Preparing Quality Assurance Project Plans
4. Reviewing Quality Assurance Project Plans

The first two courses will be offered regularly throughout the year and will be open to anyone responsible for QA functions. The QA Team will also work with the Division QA Coordinators to schedule additional training for staff preparing or reviewing QA Project Plans on an as-needed basis.

Members of the QA Team, the Regional QA Manager and Officer, and Division and Program Office QA Coordinators are expected to take, or have taken, all of the above courses, or their equivalent, within two years from the effective date of this QMP. In addition, they are encouraged to to attend meetings and seminars, and to take formal training, to enhance their understanding of the technical programs and procedures they work with.

All staff and managers responsible for implementing QA and QC procedures must attend "Orientation to Quality Assurance Management" as a minimum. Project Officers who review QMPs and/or QAPPs must complete, in addition to the Basic Project Officers training, courses 1, 2, and 4 above (within two years from the effective date of this QMP). Individuals who review and approve QAPPs must be authorized to do so by their QA Coordinator. The Regional QA Manager will set forth requirements for such authorization. Individuals who are preparing QMPs or QAPPs should complete courses 1, 2, and 3 above as a minimum.

3.1.4 Assurances for Grants and Contracts

Project Officers/Managers and Work Assignment Managers (WAMs) are responsible for ensuring that all grant recipient or contract personnel involved with data generation have the necessary QA training to successfully complete their granted or contracted tasks and functions. Minimum QA training requirements should be described in Requests for Proposals (RFPs), all specific Statements of Work (SOWs) or similar documents, and in grant applications and/or conditions.

In addition, the Regional QA Manager will work with the Region III Training Officer to ensure that fundamental training courses for grants and contracts include segments addressing QA requirements and responsibilities for Project Officers and WAMs.

3.1.5 Documentation of Training

The QA Team will keep a record of all QA training taken by staff and managers responsible for environmental data generation. This list will also be kept on file with the Regional Training Officer. Plans for upcoming Regionwide QA training will be described annually in the QA Report and Workplan.

CHAPTER 4 PROCUREMENT OF ITEMS AND SERVICES

It is Region III policy that all Extramural Agreements and Procurement involving environmentally related measurements or data generation require suppliers (i.e., contractors, subcontractors, or financial assistance recipients) to have a Quality Management System in accordance with EPA requirements (EPA QA/R-2). Procurement, Contracts, Grants, Interagency Agreements (IAGs) and their related actions are covered by this policy. In general, a Quality Assurance Management Plan must be reviewed and approved by the Region before the formal execution of any agreement or related action. Subsequently, the organization must submit a Quality Assurance Project Plan (QAPP) for the Region's review and approval before any environmental measurements or data collection activities can be performed.

4.1 CONTRACTS

The Office of Superfund conducts and oversees assessment, remedial, and removal activities at hazardous waste sites in Region III. For some of these activities, the Region contracts directly for environmentally related measurements or data generation. The Region also utilizes existing contracts placed by Headquarters or other EPA organizations for Superfund and other programs (e.g., Air, Water). Work Assignments, Delivery Orders, etc. are then issued by the Region for services under these contracts.

Where contracts and related actions involve the collection of environmental data, the Regional Quality Assurance Manager (RQAM) or his/her designee shall be involved in the contract development and execution process as follows:

Statement of Work--QAM reviews statement of work and provides QA tasks where required.

Acquisition Plan--QAM and Project Officer define QA oversight role in acquisition process.

RFP Development--QAM incorporates QA activities into evaluation as needed, including QA in sample work assignment, Quality Management Plan, and Quality Assurance Project Plan.

RFP Evaluation--QAM serves on selection board (over $500,000) to score specified QA submissions.

Contract Award--QAM participates in debriefing.

Work Assignments and Delivery Orders--QAM monitors work assignments which require QAPP and monitors QA activities.

In order to document compliance with the above policy, the Project Officer and the RQAM will jointly prepare a Quality Assurance Review Form (EPA Form 1900) for each new contract, contract modification, work assignment or delivery order. If the action involves environmental measurements, Part III of the Form will be completed stipulating the Quality Assurance Requirements addressing functions such as (1) procurement source evaluation and selection, (2) evaluation of objective evidence of quality furnished by the supplier, (3) source inspections, (4) supplier audits, and (5) examination of deliverables. Both the Project Officer and QA Manager or QA Officer will sign the Form and attach it to the Procurement Request for the applicable action. The Regional Contracting Officer will assure that a completed Form accompanies the Procurement Request (Monetary Actions). For Non-monetary actions (e.g., time or scope changes having no dollar impact), a Quality Assurance Review Form will also be completed and forwarded to the Contracting Officer. The Contracting Officer will also assure that there is a stipulation in the contract action that a Quality Assurance Project Plan will be submitted by the contractor and approved by the Quality Assurance Manager or Officer before any environmental measurements or data collection activities are performed.

All procurement of services involving Federal Information Processing Standards resources must meet the requirements of the FAR, the Federal Information Resources Management Regulations (FIRMR), Delegation 1-84 (1200 TN310), OIRM Delegation 1-10A (September 27, 1991), OARM's EPA Acquisition Regulations, Chapters Four and Six OIRM's Information Resources Management Policy Manual (July 1987) and Region III Order 5361.5 Site Location Identification Policy and Responsibilities.

4.2 SMALL PURCHASES

Procurement of environmentally related measurements or data generation which qualify for small purchases under the FAR will be subject to Quality Assurance requirements. In Region III these actions are generally for analytical services obtained under an existing Headquarter's contract. The Project Officer from the applicable Division and the QAM or QAO will jointly prepare a Quality Assurance Review Form for

each procurement. If the action involves environmental measurement, Part III of the form will be completed stipulating the Quality Assurance Requirements. Generally, a Quality Assurance Program Plan (or similar documentation) has previously been provided and approved as required in the original contract award. The Regional Contracting Specialist will assure that a completed Form accompanies the Procurement Request. Also, the Contracting Specialist will assure that there is a stipulation in the Procurement Action that a Quality Assurance Project Plan will be submitted and approved by the Quality Assurance Officer before any environmental measurement or data collection activities are performed.

Procurements qualifying as small purchases must meet established administrative and QA requirements of the FAR, FIRMR, Delegation 1-84 (1200 TN310), 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 and cooperative agreements under which environmental measurements or data generation are performed must have an approved Quality Management Plan before an award can be made. If the applicant already has an EPA approved Quality Management Plan and it covers the project than the applicant need only reference that plan in their application. Before any environmental measurements or data collection activities can be performed, the grantee, in addition, must submit a Quality Assurance Project Plan for review and approval according to the applicable Region III Division, Office or Program QMP procedures.

In order to document compliance with the above policy, for grant or cooperative agreement actions (including amendments), the Project Officer will indicate in the Program Decision Memorandum (Program Office Authorization for the Award) if Quality Assurance Requirements apply. If yes, then a Quality Assurance Review Form signed by the Project Officer and the Regional Quality Assurance Manager or Officer indicating that a Quality Assurance Management Plan has been approved must be included in the award package. Awards cannot be made without such approval. In addition, the Review Form will indicate if a Quality Assurance Project Plan (QAPP) has been approved. If not, then a condition will be included in the grant or cooperative agreement stating that a QAPP must be submitted and approved before environmental measurement or data collection activities can be performed.

The Grants Specialist will assure that a completed Quality Assurance Review Form is included in grant award packages where QA requirements apply and also will include a condition in grant awards requiring a QAPP. This policy applies to all grant and cooperative agreements awards and amendments.

The requirements for QA are contained in 40 CFR Part 30.54 for universities and other non-profits, 40 CFR Part 31.45 for States, tribal, and local governments, Regional Order 5360.50 Quality Assurance Program Policy and Responsibilities and Regional Order 5361.5 Location Identification Policy and Responsibilities.

4.4 INTERAGENCY AGREEMENTS (IAGs)

All IAGs with environmental measurement activities which Region III funds, or participates in, will require an approved Quality Management Plan before an IAG is executed. Where Region III is providing funds to another organization, that organization is responsible for preparing the QMP. If the external organization has equivalent requirements to EPA's for Quality Management Systems and Plans, then their procedures may be acceptable. If there are not comparable QA procedures, the QA procedures agreeable to both parties must be negotiated prior to execution of the IAG. Before any environmental measurements or data collection activities can be performed, the external organization must submit and have a Quality Assurance Project plan approved or successfully negotiated and acceptable to both parties.

In order to document compliance with the above policy, the Project Officer will indicate in the Program Decision Memorandum (Program Office Authorization for the Award) if Quality Assurance Requirements apply. If yes, than a Quality Assurance Review Form, signed by the Project Officer and the Regional Quality Assurance Officer, indicating that a Quality Assurance Management Plan has been approved must be included in the award package. Awards cannot be made without such approval. In addition, the Review Form will indicate if a Quality Assurance Project Plan (QAPP) has been approved. If not, then a condition will be included in the IAG stating that a QAPP must be submitted and approved before environmental measurement or data collection activities can be performed.

The Grants Specialist will assure that a completed Quality Assurance Review Form is included in IAG packages where QA requirements apply and also will include a condition in the IAG requiring a QAPP. This policy applies to all IAGs and amendments.

CHAPTER 5 DOCUMENTATION AND RECORDS MANAGEMENT

Maintaining important QA documents and records is a continuous process at EPA Region III. 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. QA documents and records are maintained as follows:

5.1.1 National QA Documents

Copies of national guidance or requirements documents issued by the Quality Assurance Division for QMPs, QAPPs, SOPs and other specific quality practices are maintained by Region III's QA Manager, the Regional QA Officer, QA Team members and Divisional Quality Assurance Coordinators. They are distributed by these individuals to appropriate regional staff, states, grant recipients and support contractors. National QA documents specific to one program area (e.g., Superfund or the Office of Water QMPs) are maintained by the Quality Assurance Coordinator of the Division or Office responsible for that program.

5.1.2 Routine QA Operating Documents

Project or site specific QA documents and records generated as part of the Regional Quality System are used and stored in the various program offices within Region III. Records and documents associated with a given project are the responsibility of the Division that has primary responsibility for that project. Hard copies of site or project specific information such as sample field sheets, chain-of-custody records, laboratory notes, field notes, and instrument readings shall be maintained by the responsible program office. These records provide support to the validity of the environmental data for making decisions. [However, this information will not be included within a central database]. Projects involving the generation of environmental data shall include, as a minimum, the QAPP and final report, which should be stored together, allowing a subsequent analyzer or investigator to understand the full context of the data produced and the conclusions reached. Division and Office QA Coordinators shall be responsible for maintaining QA documents for a period specified in their Divisional QMP.

5.1.3 In-House QA Guidance Documents

Quality guidance documents developed in-house are peer reviewed by QA staff personnel and the appropriate program office. Most of the in-house quality guidance documents are formatted as SOPs covering specific environmental monitoring activities such as field inspections; sample collection/handling; analytical protocols; and data review/validation. The QA Team has developed an extensive list of SOPs which have been peer reviewed and approved for Regional use. QA directives have also been developed by this group. These documents are on file at OASQA and the Regional Office library and specific program offices.

5.1.4 Other QA Documents

QMPs developed by Region III Divisions and Program Offices or by state agencies are reviewed by Regional QA Team staff and program officers of the respective program office. Copies are retained by both the QA Team and the relevant program office. QAPPs submitted to Region III are also peer reviewed by the respective program manager/project officer, appropriate EAPD staff and Region III QA staff. Copies are retained by the Project Officer and QA reviewers.

5.1.5 Peer Review

On June 7, 1994, the EPA Administrator issued a Policy requiring mandatory peer review of major scientific work products. As a result, Region III established a Standard Operating Procedure (SOP) which formalizes peer review. The SOP establishes the Region III Peer Review Group and specifies an annual reporting cycle which must be completed under the Regional Administrator's signature. Criteria for identifying major scientific and technical work products subject to this SOP include:

- Supports major regulatory decisions or policy/guidance of major impact
- Establishes a significant precedent, model, or methodology
- Addresses controversial issues
- Focuses on significant emerging issues
- Has significant cross-Agency/inter-Agency implications
- Involves a significant investment of Agency resources
- Considers an innovative approach for a previously defined problem/process/methodology
- Satisfies a statutory or other legal mandate for peer review

5.1.6 Document Tracking

A database of all Regional QMPs, QAPPs and other important quality

documents shall be maintained by the Quality Assurance Team. This database will include information similar to that required by the QTRAK system used by several EPA organizations for tracking quality documents. All QMPs submitted to the QA Team for review and approval will be entered into this system. QAPPs are not required to be submitted to the QA Team, however basic information regarding the QAPPs must be provided to the QA Team so that these documents can also be tracked. Division and Office QA Coordinators will provide QAPP information to the QA Team. QMPs and QAPPs are not considered to be approved unless they are entered into the Regional quality database. All QMPs and QAPPs, regardless of approval status, must be tracked to assure timely review, approval or re-submission, and to be able to inform internal and external customers of the status of any QA document at any time.

5.1.6 Disposition of Documents and Records

The Quality Assurance Team in conjunction with Division Quality Assurance Coordinators ensures that all QMPs and QAPPs are current. Should one of these documents become outdated, the Regional QA Manager or QA Officer shall determine the status of the plan, and initiate appropriate action. All quality assurance documents or copies thereof which are sent to, generated by, and/or sent from the Quality Assurance Team will be filed after action in a central EAPD file room. These documents will be maintained under the supervision of a file clerk. Short and long term storage shall be maintained in a place and for a period of time to be decided by each Division/Office Director (with advice from the QA Coordinators) in accordance with the EPA's Records Management Manual (Classification Number 2160; OIRM, 1984) and similar governing policies. The Director represents the final custodian of that information.

5.1.7 Maintaining Document Integrity

Following all appropriate action, the file clerk will take special care to preserve the integrity of sensitive documents such as audit reports and performance evaluation reports. This special care includes such precautions as locking these files in the absence of the file clerk. If sensitive documents are to be used at a work station, due care will be used there, too, in order to maintain the integrity of the data.

CHAPTER 6 COMPUTER HARDWARE AND SOFTWARE

In order to ensure the effective and efficient use of the Regional 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 Enterprise Technology Systems Division (ETSD) Guidance on Hardware and Software Standards. These standards address Compatibility, Hardware, Operating Systems, Communication, Database Management, User Interface/Printer Interface, Application Development and Applications.

Region III will procure Agency-approved hardware and software that conforms with Agency-wide information management architecture. In some cases the Region will buy or develop hardware or application software that is not on the Agency contract. All such purchases will be evaluated to ensure that they comply with Agency standards in the ETSD Guidance on Hardware and Software Standards. Prior to any purchases, the PC Site Coordinator will evaluate software or hardware to determine it's performance capabilities and impact of the change.

6.2 SYSTEM DEVELOPMENT

All Region III Information Resource Management (IRM) system development, enhancement and modernization efforts will comply with OARM's System Design and Development Guidance. 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 the OARM Operation and Maintenance Manual. Compliance with applicable IRM Standards will ensure that all hardware and software configurations are tested.

For proper implementation and maintenance of the ADP system, the appropriate Divisions 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.

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 (Draft). 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. For a comprehensive, Region-wide security program to safeguard the Region's information resources, all information resources shall be safeguarded as specified in the EPA Security Manual.

CHAPTER 7 QUALITY ASSURANCE PLANNING

A major goal of Region III's Quality System is to promote effective planning for the collection, analyses 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 upon which all programmatic priorities and corresponding environmentally related data collection and use activities are based. 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 (Division and Office Directors) usually meet early during the fiscal the year to discuss and set Regional priorities. These priorities are then reflected in the Regional Strategic Planning process, which establishes overarching goals, directions, resource utilization policies 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 environmentally-related data generation activities that will occur, for what decisions they are designed to support, and the corresponding requirements for quality assurance and quality control procedures.

7.1.2 External Data Coordination

The Region must also coordinate the collection and use of environmentally related data across numerous government agencies, and also academic and private organizations. Close coordination and planning is essential to ensure that data are of sufficient quality to support decision-makers or otherwise meet the intended uses, and can be shared where Data Quality Objectives (DQOs) are similar. The Region encourages data sharing wherever possible, provided adequate data descriptors are available so that the quality of the data is sufficiently known to support the applicable decision(s).

7.1.3 Annual QA Plan

During October of each year, the QA Team will prepare a QA Report and Workplan which summarizes past fiscal year accomplishments, and outlines planned QA actions for the upcoming year. Included in this Report will be a description of specific audits and evaluations to be performed. The Report will be submitted to the QA Council and to the Region's senior managers, and shared with personnel who are involved with QA activities in the Region.

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 (the Volunteer Monitoring Program). Any of the Regional environmental programs which generate environmental data are covered by this QMP, though not all require the same level of quality assurance. Generally, program managers (their grades and titles vary by Division/Office) are responsible for program level planning, which includes the responsibility to ensure that there is agreement between the customer and the data supplier as to expected data quality.

Developing Data Quality Objectives (DQOs) when initiating a new program or incorporating major statutory changes is a mandatory component of QA planning at the program level. The Quality Assurance Division guidance document Guidance for The Data Quality Objectives Process (EPA QA/G-4) is available to assist users in developing these objectives. DQOs at the program level include all sources of error (i.e., design, sampling, measurement, or indicator error) that will accumulate and affect the interpretation of data for status and trends. Program-level DQOs are defined by their ability to meet Regional program objectives discussed with desired certainty. Data Quality Objectives are used as performance criteria for assessments of data quality for their adequacy in determining status and trends.

For many ongoing environmental monitoring programs, the National Program Offices at EPA Headquarters have already developed DQOs. In these cases, Region III simply uses the national guidance and DQOs, and incorporates them by reference into the applicable QAPP.

It is critical to consider this QMP as part of the planning process when modifying existing programs or designing new programs. Although this QMP outlines the minimum QA requirements for the Regional programs, it is likely that most of the programs covered by this QMP will need more QA specificity and detail for implementing their programs. In these cases, supplemental QA components and

procedures should be developed and described in the Division or Office QMP. They will also be referenced in future revisions to this QMP. The QA Team will serve as technical advisors in the development of these procedures and documents. All programs covered by this QMP should review their program needs within the next year to determine whether this QMP adequately covers their QA needs, and develop supplemental procedures as necessary.

7.3 PROJECT LEVEL PLANNING

A project is an organized set of activities within a program. The Quality Assurance Project Plan (QAPP) is the primary vehicle for ensuring adequate data quality at the project level (see Chapter 2, Section 2.2.3 for a more complete discussion of the QAPP development and review process). QA activities will be described as a well-defined component of any project plan involving the collection or use of environmental data.

The key to good quality planning at this level is to link the data collection or analyses to be performed directly to the environmental decision to be made, so that the Region is not collecting mounds of data for which it has no use or purpose. Achieving this key requires a dialogue between the decision maker (the "customer") and the data supplier. Again, QAD document EPA QA/G-4, Guidance for The DQOs Process, can be invaluable in establishing the desired data certainty requirements based on the decision to be supported.

The use of statistical methods to quantify data acceptability measures is highly recommended. Members of the QA Team in Annapolis can provide assistance with statistical applications. In addition, EPA Region III recently offered a graduate level training course on statistical analyses tools which is being taken by approximately 30 Regional employees. The individuals completing this course are expected to possess enough knowledge necessary to assist with QA project level planning and data review, as well as design of DQO processes. In cases where special expertise is needed, the Region will consider use of available QAD contract support for statistical analyses.

Since the Region employs a decentralized QA system, the Regional Quality Assurance Manager is not directly involved in the Data Quality Objectives (DQO)/QAPP planning process or data quality assessment. However, the QA Team is involved with training and provides assistance with QAPP development as requested. Also, technical expertise is typically available from a variety of personnel within the Region for such subject areas as sampling protocols, analytical methods and QA and QC procedures.

Planning documentation should identify the personnel responsible for all components of the QAPP described therein. Project Officers or Managers will normally be responsible for the development of these QA components, which will adhere to the requirements of EPA QA/R-5, EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations. As part of the project planning, Project Officers/Managers will adhere to the procedures specified within each Division or Office QMP for the development, review and approval of the QAPP. Division or Office QA Coordinators, with assistance as necessary from the RQAM or RQAO, will be involved in the project planning process, and will approve in writing each QAPP developed within their organization.

CHAPTER 8 IMPLEMENTING QA PROCEDURES

This Chapter of the QMP describes the processes used in the Region for ensuring that the QA plans and procedures which comprise the Quality System are effectively implemented. As with QA planning described in the previous Chapter, implementation of QA procedures takes place at Regional, program and project levels.

8.1 REGION-WIDE IMPLEMENTATION

Region III utilizes a decentralized approach to ensure that environmental data is of sufficient quality for its intended purpose. This Regional QMP requires each Division and Program Office in the Region that generates environmental data to develop its own specific Division or Program QMP which will address, at a minimum, the requirements set forth by EPA's Quality Assurance Division as outlined in EPA QA/R-2 (and future updates). Any revisions to this QMP or the Division/Office QMPs will be processed in the same manner as the original documents. The QA Team, Regional QA Manager, and Regional QA Officer will provide general oversight of implementation of the Regional Quality System. The Divisions and Program Offices will provide technical oversight for implementing environmental data operations. The Divisional QA Coordinators are responsible for determining the need for written QA procedures within their organizations.

8.1.1 Division and Office QMPs

Each Division or Office QMP will contain specific implementation procedures that identify those first line managers with direct implementation responsibilities. Each Divisional QMP will address the process for implementing environmental data operations according to the approved planning documents.

Additionally, each Division or Office QMP will identify those specific activities that will ensure the generation of quality data by:

- o Identifying mission elements and/or programs generating or using data for environmental decisions;

- o Identifying criteria for collecting or selecting data sufficient to support environmental decisions;

o Describing procedures for the preparation, review and approval of QAPPs;

o Outlining procedures to ensure that the work described in the QAPP is being performed according to the Plan, including evaluation activities;

o Ensuring that individuals with QA responsibilities have been properly trained; and

o Defining the level of management oversight and inspection to be provided that will be commensurate with the importance of the particular project and the intended use of the project results.

8.2 PROGRAM LEVEL IMPLEMENTATION

8.2.1 Operating Policies and Procedures

Any Regional program which generates or uses environmental data will document their responsible QA policies and procedures, and will develop and/or use appropriate policy and procedures manuals for their programs (the Annapolis laboratory already has such procedures documented within its Facilities Plan). The QAD document "Guidance for the Preparation of Operating Procedures for Quality-Related Operations", QAD/G-6, November, 1995, should be consulted by Regional programs for developing procedures manuals for administrative and technical QA operations. Having these procedures available will ensure that program personnel are knowledgable about their operations, and will also serve as a training guide for new staff members.

The Regional QA Manager will work with the Regional programs to ensure that operational QA policies and procedures developed by the programs are consistent with the Regional QMP. This responsibility includes defining procedures for appropriate routine, standardized, special, or critical operations, including the policies and procedures that address, but are not limited to:

- identification of operations needing standardized procedures;

- the process for preparation of procedures, including form, content, and applicability; and

- review and approval of the adequacy of the SOPs.

Any QA procedures manuals developed by Regional programs will be made

available to all personnel involved in program implementation. If implementation of the program is delegated, the manuals will be referenced in any assistance or delegation agreement. Where a program uses data generated by external sources, it must develop criteria and a process by which to evaluate the acceptability of the data supplied, in the context of the environmental decision(s) to be made. The data quality assessment process described in Chapter 9.4 can be useful here.

8.3 PROJECT LEVEL IMPLEMENTATION

8.3.1 QAPP Implementation

All environmental data operations will be implemented in accordance with an approved QAPP. Any changes to the QAPP will be documented and approved in writing through an amended QAPP. Amendments will be reviewed and approved by the original approving officials, including the Division or Office QA Coordinator. The Project Officer should include identifiable QA milestones and target dates in the project timeline so that progress and completion of the QA and QC activities can be effectively tracked.

For contracts and grants involving environmental data generation, the Project Officer and Division QA Coordinator shall ensure that the applicable Work Assignment, Task/Delivery Order or similar document includes specific requirements for reports on the QA of products or services to be supplied.

8.3.2 Standard Operating Procedures (SOPs)

Many repetitive procedures that are routinely used can be standardized and documented in writing as standard operating procedures (SOPs). SOPs can be prepared for routinely conducted sampling, analytical, and quality control procedures. Once established, the SOPs can be cited in QAPPs, contract proposals, grant agreements, and other similar documents, thus saving time and paper by avoiding the need to write out the specific procedures in each document. Regional SOPs relating to QA shall be reviewed and approved by the Regional QA Manager and maintained by the appropriate program office. Any substantive changes in the SOPs will be likewise approved by the QAM.

Tasks or functions that may be effectively addressed within a SOP include:

- Sampling network design.
- Sampling site selection.
- Sampling and analytical procedures.

- o Sample collection methods and devices, containers, preservatives, holding times, handling and transportation methods.
- o Documentation and chain-of-custody procedures.
- o Calibration and maintenance of instruments and equipment.
- o Quality control procedures.
- o Data review, reduction and validation.
- o Safety procedures.
- o Inspection and audit procedures.

8.4 IMPLEMENTATION SCHEDULE

The Quality Assurance Task Force will initially coordinate the schedule for completion of the Divisional or Program Office QMPs. Following their completion and approval, the Quality Assurance Team (QAT) will track their implementation, and will report progress and any concerns to EAPD senior management at least quarterly. Where implementation problems are encountered, the Team will work with the Divisional QA Coordinator to resolve. Program and project level implementation are primarily the responsibility of the Divisions and Program Offices.

The schedule for major Region III QA efforts over the next several months is as follows:

Timeline for Implementing the Region III QA System

Activity	Target Date	Lead
R3 QMP Final Completed	August 15, 1996	QA Task Force
R3 QMP Authorization	August 20, 1996	DDs/OHs/DRA/RA
Submittal to QAD	August 23, 1996	RA/DRA
R3 QMP Approval	September 30, 1996	QAD (HQ)
Establish QA Council	September 30, 1996	DRA
Annual QA Report and Workplan	November 1, 1996	QA Team
Division/Office QMPs (Draft)	October 15, 1996	Divisions and Offices
Review Div./Off. QMPs	December 1, 1996	RQAM, RQAO
Identify Regional QA Training Needs	December 15, 1996	QA Team
Division/Office QMPs (Final)	January 1, 1997	Divisions and Offices

QAPP Reviews	Ongoing	Divisions/Offices
Review Program Needs	August 1, 1997	QA Manager/Team
Revise R3 QMP	September 30, 1997	QA Manager/Team
Review Data Generating Programs	August 30, 1998	QA Manager
Complete QA Training	September 30, 1998	QA Manager/Team

CHAPTER 9 QUALITY ASSESSMENT AND RESPONSE

This Chapter of the QMP describes how Region III will assess the effectiveness of its Quality System. The Region will use a variety of internal management and technical reviews, performance evaluations and audits to make sure that the procedures in this QMP are implemented successfully. The Region will also use independent reviews by personnel from other Regions and/or EPA offices to periodically evaluate the systems and procedures described in the QMP. This Chapter will also describe the Region's commitment to using the results of these evaluations to make any necessary operational adjustments to the Region's data collection and analytical procedures, as well as to the Quality System itself.

9.1 ANNUAL REVIEW OF THE REGIONAL QUALITY MANAGEMENT PLAN

The QA practices and procedures described in this QMP will be assessed annually and revised or updated as necessary. The Regional QA Manager is responsible for coordinating this assessment, arranging for appropriate personnel to assist with the review, and for incorporating any recommended changes into the document. Minor changes in the QMP will be reported to QAD and senior Regional management through the QA Annual Report and Workplan. Any major changes may require a formal resubmittal of the Plan to QAD.

9.2 REGIONAL AUDITS

Region III employs several assessment tools designed to provide an increased understanding of the components of its quality system, and to provide a basis for improving the system. Internal and external audits are one of the principal tools for determining the effectiveness of the QA components described in the Regional or Divisional QMPs. Audits of Region III QA programs and activities will be conducted in accordance with established QAD or other appropriate protocols. Audit frequency and scheduling varies with the type of audit conducted. Following is a description of some of these evaluation tools.

9.2.1 Management System Reviews (MSRs)

An MSR is an independent assessment of an organization's QA management practices. MSRs address the effectiveness of management controls in achieving and assuring data quality, the adequacy of resources and personnel devoted to QA functions, the effectiveness of training and assessments, and the applicability of data quality requirements. MSRs can identify significant QA concerns and areas of needed improvement, but also point out noteworthy accomplishments.

Organizational MSRs are generally conducted by an *external* party (typically ORD/QAD or a QAD directed team) and focus on the organization's adherence to its approved QMP. QAD attempts to conduct an MSR for every major Agency organization (including the Regional Offices) once every three or four years (an MSR was last conducted on Region III's QA System in August, 1994). The organizational MSRs focus on the overall structure and procedures for accomplishing the QA program.

Program MSRs are generally performed by an *internal* review team and focus on implementation of QA practices within a single program area. These MSRs will typically be performed by a Review Committee authorized by the Director of EAPD. The Review Committee will include representatives of the QA Team, and those with knowledge of the Regional program under review, and may include staff members, supervisors and managers.

Most MSRs will examine the following elements:

- An assessment of the overall effectiveness of the QA management system, as measured by its adherence to the approved QMP;
- Procedures for developing Data Quality Objectives (DQOs);
- Procedures for developing and approving QAPPs;
- The effectiveness of existing QAPP guidance and QAPPs;
- Procedures for developing and approving SOPs;
- Procedures, criteria and schedules for conducting audits;
- Tracking systems for assuring that the QA program is operating and that corrective actions disclosed by audits have been taken;
- Responsibilities and authorities of various line managers and QA personnel for implementing the QA program;
- The degree of management support;
- The level of financial and other resources committed to implementing the QA program;

MSRs performed or arranged by Region III will be conducted in accordance with *Guidance for the Management Systems Review Process, EPA QA/G-3* (now available

in draft form), the related Requirements Document, EPA QA/R-3, when it is finalized, or future updates.

The Region may also make occasional use of independent, outside reviews of its quality assurance practices. When electing to use an outside source, the Regional QA Manager will make arrangements for such a review by selecting, in conjunction with the appropriate Divisional QA Coordinator(s), an appropriate team of qualified reviewers from other EPA Regions and/or Headquarters. The goals and objectives of this type of review will be the same as if the assessment were conducted internally.

9.2.1.1 Review of Division and Office QA Programs

The Region will conduct internal assessments of individual Divisions' quality assurance programs as described in their QMPs. All major data generating programs within the Region will be reviewed not less than once every two years. These programs include Air Quality, Toxics and Radiation, Water Quality, Drinking Water, the Chesapeake Bay Program, Superfund and RCRA. Included in these reviews will be the QA practices and QMPs of States, contractors, and other agencies that collect data for EPA-supported activities.

These reviews will be authorized by the Director of the Environmental Assessment and Protection Division (EAPD) and will be coordinated by a QMP Review Committee arranged by the Regional QA Manager. The results of the evaluations will be transmitted to the relevant Division Director in a written memorandum from the Review Committee Chairperson. Program-specific recommendations will be provided to the Divisional QA Coordinator for incorporation into the organization's QMP.

The reviews are intended to accomplish the following objectives:

- Identify any data quality problems.
- Identify benchmark practices that could be used in other Regional programs.
- Propose recommendations for resolving quality problems.
- Confirm implementation and effectiveness of any recommended corrective actions.

The reviewed program will normally have 30 days to prepare a written response to the review memorandum. The response should include an evaluation of the Review Committee's findings and recommendations. If the Review Committee recommended corrective actions, the reviewed Division or Office should address those recommendations and include a schedule for making any appropriate changes in its quality assurance procedures.

These reviews will be used by senior Regional managers to gauge the effectiveness of the Regional QMP and of individual programs' approaches to data quality management.

9.2.2 Technical Systems Audits (TSAs)

A Technical Systems Audit is conducted to assess the sampling and analytical quality control procedures used to generate environmental data. Region III will use TSAs to evaluate laboratory and field procedures used by EPA and state personnel, contractors and grantees. TSAs may entail a comprehensive, on-site, evaluation of facilities, equipment calibration, personnel qualifications and training, record keeping procedures, data validation, data management and reporting of field and laboratory activities. Both laboratory and field TSAs are performed.

9.2.2.1 Laboratory TSAs

TSAs will be conducted for State laboratories and for contract laboratories in Region III that prepare environmental data for use in EPA-sponsored programs. TSAs will also be conducted for other Federal agency laboratories that perform sample analysis under Interagency Agreements with Region III. The Region's EAPD Annapolis laboratory will also be examined on a regular basis.

The primary goals of these audits will be to review the laboratory organization, operation, and capabilities, determine the reliability of data, and note corrective action for any apparent deficiencies. Auditors for TSAs will be selected by the Regional QA Manager based on their technical proficiency in the subject area, and will be responsible for planning and conducting the audit, and reporting the findings to the laboratory manager.

9.2.2.2 Field TSAs

Oversight of field operations is an important part of the quality assurance process, and Region III will conduct audits of field sampling activities, both for its own field operations, and for those of States, contractors and other federal agencies that collect samples for programs sponsored by EPA. The Divisional QMPs will specify frequency and procedures for conducting field TSAs within specific program areas. The Regional QA Manager will determine the adequacy of field TSAs when QMPs are reviewed, and also during any MSRs or other audits.

9.3 PERFORMANCE EVALUATIONS

Performance Evaluations (PEs) are conducted to assess the ability of a laboratory or field measurement system to obtain reliable data. PEs will normally be accomplished at laboratories providing analytical services directly or indirectly for the Region. The evaluation consists of providing a reference, or "blind", sample to the laboratory for analysis. This PE sample contains known concentrations of chemical constituents, or pollutants, of interest and will normally be in the appropriate media (e.g., soil, water, air). The analytical results obtained by the laboratory are compared to the known concentrations of the specific parameters contained in the PE sample(s) as a means of determining if the laboratory demonstrated its ability to properly identify and quantify pollutants within established or calculated control limits.

PEs will be scheduled at a frequency specified by program requirements, or on an as-needed basis depending on the laboratory and program involved. Some national programs, such as the Public Water Supply Supervision (PWSS) and National Pollutant Discharge Elimination System (NPDES) programs, have regularly-scheduled PE studies in which participation is mandatory for designated laboratories. For the PWSS program, PE evaluations are required twice a year for all laboratories who wish to be certified for drinking water analysis. Other national programs have regularly scheduled evaluations, but participation is optional. In addition, PE samples of specific parameters may be obtained from appropriate EPA ORD laboratories or prepared locally.

All PEs performed within the Region, whether required on a regular basis or performed on a one time basis, will be coordinated through or requested from the RQAM or designee. In the case of the PWSS program, PEs will be coordinated by the RQAO. The RQAM, or designee, will track and monitor the conduct of PEs and upon completion, will provide the results to the requestor and the participant, as appropriate. The results of PEs provide a means for assessing overall data integrity, and may be used as the criteria for selecting candidates for on-site evaluations.

9.4 DATA QUALITY EVALUATIONS

Data quality requirements and evaluation methods are included in each Divisional QMP and also in specific QA Project Plans. Each Division and Office QMP will describe the methods by which data quality evaluations will be conducted and utilized and how these evaluations relate to the Data Quality Objectives.

9.4.1 Data Quality Assessments (DQAs)

A Data Quality Assessment (DQA) refers to the process used to determine whether the quality of a given data set is adequate for its intended use, using appropriate statistical tools. DQAs can be performed on all or selected projects involving data collection. The purpose of this type of evaluation is to determine whether the data collected are acceptable to the decision-maker or user for their intended use, since the data are ultimately meaningful only in this context. A DQA involves a statistical comparison of the collected data with the Data Quality Objectives (DQOs) for the project. The intended use of the data is established by the project's Data Quality Objectives (see Chapter 7). This evaluation and comparison will result in the determination that the data are useable or not useable for their intended purposes. Guidance for this procedure is provided in *EPA QA/G-9, Guidance for Data Quality Assessment,* July, 1996.

The Regional laboratory in Annapolis routinely reviews and validates data generated in-house and by contract laboratories for the Superfund program. These activities use standard operating procedures and standardized qualification codes to indicate data quality.

9.4.2 Data Quality Audits

A related evaluation tool involving data review and assessment is the data quality audit which is used to evaluate the documentation of the quality of data generated for a given project. This assessment primarily involves an evaluation of the completeness of the documentation of field and analytical procedures and quality control results; and usually involves tracing the paper trail accompanying the data from sample collection and custody to analytical results and entry into a data base. It is commonly used to verify the process involved in entering data residing in large regulatory data bases.

Results of both DQAs and data quality audits can be used in a number of ways. First, they can be used in making recommendations for changes in the design and performance of data collection efforts, and in the use and documentation of QC procedures. Secondly, they can be used as a guide for the planning and acquisition of supplemental data for the project and potentially for other related projects. Problems identified through DQAs may trigger the need for an MSR to determine management deficiencies, or a TSR to identify technical problems.

LIST OF REFERENCES

EPA Order 5360.1, *Policy and Program Requirements to Implement the Mandatory Quality Assurance Program*, U.S. Environmental Protection Agency, April, 1984.

EPA Requirements for Quality Management Plans (Draft Interim Final), EPA QA/R-2, U.S. EPA, Quality Assurance Management Staff, August, 1994.

Standard Operating Procedure for Quality Management Plan Reviews, QAD/96-1, U.S. EPA, Quality Assurance Division, January, 1996.

EPA Information Security Manual (Draft), U.S. EPA Office of Information and Resources Management, June, 1994.

U.S. EPA Acquisition Regulations, U.S. EPA Office of Administration and Resources Management.

EPA 1900 -- Contracts Management Manual, U.S. EPA Office of Administration, January 31, 1991.

U.S. EPA Grant Regulations, QA Requirements, 40 CFR Part 30.54 for Universitites and Other Non-Profits, and 40 CFR Part 31.45 for States, tribal, and local governments.

Managing Your Financial Assistance Agreement, U.S. EPA Office of Administration and Resources Management, EPA 202-B-94-001, May, 1994.

Region III Order 5361.5, Location Identification Policy and Responsibilities, U.S. EPA Region III, Office of Policy & Management.

APPENDIX A

TERMS AND DEFINITIONS

Acceptable Quality Level - a limit above which quality is considererd satisfactory and below which it is not. In sampling inspection, the maximum percentage of defects or failures that can be considered satisfactory as an average.

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

Assessment - the evaluation process used to measure the performance or effectiveness of a system and its elements. In this document, 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 - a planned and documented investigative evaluation of an item or process to determine the adequacy and effectiveness, as well as compliance with established procedures, instructions, drawings, QAPPs, and other applicable documents.

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

Computer Program - a sequence of instructions suitable for processing by a computer. Processing may include the use of an assembler, a compiler, an interpreter, or a translator to prepare the program for execution. A computer program may be stored on magnetic media, and be referred to as "software", or may be stored permanently on computer chips, and be referred to as "firmware". Computer programs covered by this document are those used for design analysis, data acquisition, data reduction, data storage (data bases), operation or control, and data base or document control registers when used as the controlled source of quality information.

Contractor - any organization or individual that contracts to furnish services or items or perform work.

Corrective Action - measures taken to rectify conditions adverse to quality and, where necessary, to preclude their recurrence.

Customer - any individual or organization for whom items or services are furnished or work performed in response to defined requirements and expectations.

Data Quality Assessment (DQA) - a **process** for performing statistical analysis to determine whether the **quality** of a data set is adequate for its intended use.

Data Quality Objectives (DQOs) - qualitative and quantitative statements of the overall level of uncertainty that a decision-maker is willing to accept in results or decisions derived from environmental data. DQOs provide the statistical framework for planning and managing environmental data operations consistent with the data user's needs.

Data Usability - the process of ensuring or determining whether the quality of the data produced meets the intended use of the data.

Design Review - a documented evaluation by a team, including personnel other than the original designers, the responsible designers, the customer for the work or product being designed, and a QA representative to determine if a proposed design will meet the established design criteria and perform as expected when implemented.

Engineered Environmental Systems - 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 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 pollutant reduction or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

Environmental Conditions - the description of a physical medium (e.g., air, water, soil, sediment) or biological system expressed in terms of its physical, chemical or biological characteristics.

Environmental Data - any information or measurements resulting from field data collection activity, laboratory analyses or modelling involving the assessment of chemical, physical or biological factors related to the environment, and that describe environmental processes or conditions, or the performance of engineered environmental systems.

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

Environmental Monitoring - the process of measuring or collecting environmental data.

Environmental Processes - manufactured or natural processes that produce discharges to or impact the ambient environment.

Environmental Programs - an all-inclusive term pertaining to any 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 engineered environmental systems; and laboratory operations on environmental samples. In this document, also refers to functional areas of work performed by groups or teams of people within the organization.

Environmentally Related Measurements - the data collection or analyses activity or investigation involving the assessment of chemical, physical or biological factors in the environment which affect human health or the quality of life.

Extramural - Relating to activities performed for EPA but not by EPA employees, usually by contracts, grants or cooperative agreements. Used in reference to QAPPs and QMPs.

Financial Assistance - the process by which funds are provided by one organization (usually government) to another organization for the purpose of performing work or furnishing services or items. Financial assistance mechanisms include grants, cooperative agreements, and government interagency agreements.

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 results and the degree of confidence needed in the quality of the results.

Hazardous Waste - any waste materials that satisfies the definition of "hazardous waste" as given in 40 CFR Part 261, "Identification and Listing of Hazardous Waste".

Independent Assessment - an assessment 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.

Inspection - examination or measurement of an item or activity to verify conformance to specific requirements.

Intramural - Term used to describe activities performed by EPA employees, usually used in relationship to QAPPs, QMPs, contracts or grants.

Item - an all-inclusive term used in place of the following: appurtenance, facility, sample assembly, component, equipment, material, module, part, product, structure, subassembly, subsystem, system, unit, documented concepts, or data.

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.

Management System Review (MSR) - the qualitative assessment of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained.

Method - a body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification) systematically presented in the order in which they are to be executed.

Mixed Waste - hazardous waste material, as defined by 40 CFR part 261 (RCRA), mixed with radioactive constituents.

Peer Review - a documented critical review of work generally beyond the state of the art or characterized by the existence of potential uncertainty. The peer review is conducted by qualified individuals (or organization) who are independent of those who performed the work, but are collectively equivalent in technical expertise (i.e., peers) to those who performed the original work. The 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 assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them. Peer reviews provide an evaluation of a subject where quantitative methods of analysis or measures of success are unavailable or undefined, such as in research and development.

Performance Evaluation (PE) - 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.

Procedure - a documented set of steps or actions that systematically specifies or describes how an activity is to be performed.

Process - an orderly system of actions that are intended to achieve a desired end or result. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

QTRAK - is a computer program that contains database information on Quality Management Plans and Quality Assurance Project Plans for the Program Managers, Project Officers, and the QA Team for planning and assessment of the status of Regional quality documents.

Qualified Data - any data that have been modified or adjusted as part of statistical or mathematical evaluation, data validation, or data verification operations.

Quality - the sum of features and properties/characteristics of a process, item, or service that bears on its ability to meet the stated needs and expectations of the user.

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

Quality Assurance Council - an interdivisional organization with representatives from all major Region III Divisions and Offices which provides a forum for discussion of Quality Assurance activities and issues within Region 3, and provides advice to the senior managers and the Quality Assurance Team.

Quality Assurance Division (QAD) - the EPA Headquarters office within the Office of Research and Development that establishes and promulgates Quality Assurance Policy for the Agency. Formerly the Quality Assurance Management Staff (QAMS).

Quality Assurance Manager (QAM) - the designated Region III lead for oversight of the Regional QA Program. Also serves as Team Leader of the QA Team located within the Office of Analytical Services and Quality Assurance (OASQA).

Quality Assurance Officer (QAO) - serves as the senior technical QA expert for the Region and assists with a variety of QA functions, including performance evaluations for drinking water laboratories and review of QAPPs.

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

Quality Assurance Team (QA Team) - the designated Region III team whose function consists exclusively of QA that comprise the directed work team led by the Region 3 QA Manager. The QA Team reports to the Director of the Office of Analytical Services and Quality Assurance.

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.

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 Indicators - measurable attributes of the attainment of the necessary quality for a particular environmental decision. Indicators of quality include precision, bias, completeness, representativeness, reproducibility, comparability, and statistical confidence.

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, and assessment) pertaining to the quality system.

Quality Management Plan (QMP) - a formal 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 QA 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, and assessing work performed by the organization and for carrying out required QA and QC procedures.

Readiness Review - a systematic, documented review of the readiness for the startup or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work.

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

Self-Assessment - Assessments of work conducting by individuals, groups, or organizations directly responsible for overseeing and/or performing the work.

Service - the category of economic activity that does not produce manufactured items. In environmental data operations or engineering projects, such activities include design, inspection, laboratory and/or field analysis, repair, and installation.

Significant Condition - any state, status, incident, or situation of an environmental process or condition of an engineered environmental system in which the work being performed will be adversely affected in a manner sufficiently serious to require corrective action to satisfy quality objectives or specifications and safety requirements.

Software Life Cycle - the period of time that starts when a software product is conceived and ends when the software product is no longer available for routine use. The software life cycle typically includes a requirements phase, a design phase, an implementation phase, a test phase, an installation and check-out phase, an operation and maintenance phase, and sometimes a retirement phase.

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.

Supplier - any individual or organization furnishing items or services or performing work according to a procurement document or financial assistance agreement. This is an all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant.

Surveillance - the act of monitoring or observing a process or activity to verify conformance to specified requirements.

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

Validation - an activity that demonstrates or confirms that a process, item, data set, or service satisfies the requirements defined by the user.

Verification - the act of authenticating or formally asserting the truth that a process, item, data set, or service is, in fact, that which is claimed.

APPENDIX B

EPA Order 5360.1

Policy and Program Requirements to Implement the Mandatory Quality Assurance Program

April 3, 1984