⊕EPA

Overview of the EPA Quality System for Environmental Data and Technology

Quality

FOREWORD

This document provides a brief summary of EPA's Quality System for environmental data and technology for EPA and non-EPA organizations who are not familiar with the system but are subject to its requirements. It shows where to find detailed information on the requirements and structure, but does not contain in-depth discussions. For example, this document will help an individual identify whether their organization needs a Quality Management Plan, and if so, where to find detailed procedures, specifications, and other information.

EPA's Quality System is a key component in implementing EPA's Information Quality Guidelines released October 2, 2002 (see www.epa.gov/oei/quality/guidelines/index.html). This document provides information on the policies and responsibilities defined in EPA Order 5360.1 A2 (May 2000), *Policy and Program Requirements for the Mandatory Agency-wide Quality System.* This document does not change any existing EPA policies or create any new requirements.

EPA works every day to produce quality information products. The information used in these products are based on Agency processes to produce quality data, such as the quality system described in this document. Therefore, implementation of the activities described in this document is consistent with EPA's Information Quality Guidelines and promotes the dissemination of quality technical, scientific, and policy information and decisions.

This is one of the *EPA Quality System Series* documents that describe EPA policies and procedures for planning, implementing, documenting, and assessing the effectiveness of a quality system. Questions regarding any *EPA Quality System Series* documents should be directed to:

> U.S. EPA
> Quality Staff (2811R)
> 1200 Pennsylvania Avenue, NW
> Washington, DC 20460
> Phone: (202) 564-6830
> Fax: (202) 565-2441
> e-mail: quality@epa.gov

Copies of *EPA Quality System Series* documents may be obtained from the Quality Staff or by downloading them from the Quality Staff Home Page:

<p align="center">www.epa.gov/quality</p>

This document is valid for a period of up to five years from the official date of publication. After five years, this document shall either be reissued without change, revised, or withdrawn from the Quality System Series documentation.

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OVERVIEW OF THE EPA QUALITY SYSTEM
FOR ENVIRONMENTAL DATA AND TECHNOLOGY

1.   BACKGROUND

In order to provide quality products and services, an organization must control its technical, administrative, and human factors that affect quality. A quality system is the means by which an organization ensures the quality of the products or services it provides and includes a variety of management, technical, and administrative elements such as:

- policies and objectives,
- procedures and practices,
- organizational authority,
- responsibilities, and
- accountability.

It provides the framework for planning, implementing, assessing, and improving work performed by an organization and for performing quality assurance (QA) and quality control (QC) activities.

This document summarizes the EPA's Quality System for environmental data and technology for those who are not familiar with the system but are subject to its requirements. It is intended to be a reference guide for EPA managers and staff who implement the EPA Quality System by summarizing the structure (Sections 3.3 and 3.4), requirements (Section 4), responsibilities (Section 5), and tools (Appendix A). This document does not provide detailed information on each subject, instead it shows where to find such information. For example, this document will help an individual identify whether their organization needs a Quality Management Plan, and if so, where to find detailed procedures, examples, and other information. For a description of the topics covered in this document, see Box 1.

Box 1. How to Use this Document

If you are interested in: **see Section(s)**

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This document can also be used by non-EPA organizations (e.g., State, local, and Tribal governments; contractors; etc.) to identify the general requirements for their organization (Sections 3.4.2.2, 4.2, and 5.7) as well as components and tools (Appendix A) that can be used to satisfy these requirements. However, detailed specifications for non-EPA organizations are not described because these specifications can not extend beyond what is contained in the Code of Federal Regulations or in an individual agreement.

2.   GOALS AND BENEFITS OF THE EPA QUALITY SYSTEM

The goal of the Agency-wide Quality System is to ensure that environmental programs and decisions are supported by data of the type and quality needed and expected for their intended use, and that decisions and applications involving environmental technology are supported by appropriate quality-assured engineering standards and practices. Effective implementation of the EPA Quality System leads to several benefits including:

- *Scientific Data Integrity* – EPA will produce data of known and documented quality and non-EPA organizations will submit data of known and documented quality to EPA.

- *Reduced or Justifiable Resource Expenditures* – Resource expenditures can be reduced as planned information collection activities are more closely matched to the information needs. For example, through systematic planning, only the appropriate type, amount, and quality of data will be collected by EPA, and those collecting data on behalf of EPA or to satisfy EPA requirements.

- *Effective Management of Internal and External Activities* – The quality system requires documentation of activities and oversight for evaluation purposes. This reduces the potential for waste and abuse.

- *Reliable and Defensible Decisions* – When the quality of data is known, it is possible to determine if the data can be used for a specific decision. This reduces the likelihood of losing challenges to regulations, enforcement actions, permit appeals, etc., resulting from the use of data of uncertain quality.

- *Burden Reduction* – As EPA better defines the data needed for a specific application, the burden on other organizations who are required to collect and/or report these data may be reduced. Our own internal burden may also be reduced as we become more efficient.

- *Continual Improvement* – The continual improvement component of the EPA Quality System leads to the development of a better and more responsive Quality System and technical system which should result in better products and services.

Overall, successful implementation of the EPA Quality System will reduce the Agency's vulnerabilities in decision making and increase EPA's credibility by providing the ability to make reliable, timely, cost-effective, and defensible decisions. The consequences of not having a successfully implemented quality system include the potential to waste time, money, and other resources and increase the uncertainty in EPA's decisions.

3. EPA QUALITY SYSTEM BASICS AND STRUCTURE

3.1 Scope

The EPA Quality System encompasses management and technical activities pertaining to the planning, implementation, assessment, and improvement of environmental programs within the Agency's scope that involve:

- the collection, evaluation, and use of environmental data, and

- the design, construction, and operation of environmental technology.

Box 2 contains definitions that are useful in understanding the scope of this system; Box 3 contains examples of environment programs to which the EPA Quality System applies. The EPA Quality System applies uniformly to EPA organizations and to non-EPA organizations funded by EPA. Section 3.3 describes the organizations that are included within the EPA Quality System.

3.2 Basis

The EPA Quality System is based on ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*. ANSI/ASQC E4 is an American National Standard for quality management practices for environmental programs involving the collection and evaluation of environmental data and the design, construction, and operation of environmental technologies. This standard provides a basis for planning, implementing, documenting, and assessing an effective quality system. EPA requires conformance to this standard through internal Orders and the Code of Federal Regulations (see Section 3.4.2). Copies of the ANSI/ASQC E4 may be purchased from:

> ASQ Quality Press
> P.O. Box 3005
> Milwaukee, WI 53201-3005
> Phone: (800) 248-1946
> www.asq.org

Box 2. Important Definitions[a]

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

Environmental Data - any measurements or information that describe environmental processes, locations, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include both primary data (i.e., information collected directly from measurements) and secondary/existing data (i.e., data that were collected for other purposes or obtained from other sources, including literature, industry surveys, models, data bases, and information systems).

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

Quality Assurance (QA) - an integrated system of management activities involving planning, implementation, assessment, reporting, and improvement to ensure that a process, item, or service is of the type and quality needed. QA is typically applied by managers or technical personnel assigned to a specific oversight role. Example QA activities include technical and management assessments of field and analytical operations.

Quality Control (QC) - an overall system of technical activities that measures the performance of a process, item, or service against defined standards to verify that the performance meets the stated requirements. QC is typically applied by technical personnel. Example QC activities include the use of control samples during sample collection, handling, and analysis, and activities such as data review.

[a]From ANSI/ASQC E4-1994

Box 3: Examples of Environmental Programs

Example environmental programs include but are not limited to:

- Characterize and/or evaluate the states and/or conditions of environmental or ecological systems and the health of human populations;

- Characterize and/or evaluate chemical, biological, physical, or radioactive constituents in environmental and ecological systems, and their behavior and associated interfaces in those systems;

- Establish the ambient conditions in air, water, sediments, and soil in terms of physical, chemical, radiological, or biological characteristics;

- Determine and/or categorize radioactive, hazardous, toxic, and mixed wastes in the environment and to establish their relationships with and/or impact on human health and ecological systems;

- Quantify and/or monitor the waste and effluent discharges to the environment from processes and operations (e.g., energy generation, metallurgical processes, chemicals production), during either normal or upset conditions (i.e., operating conditions that cause pollutant or contaminant discharges);

- Develop and/or evaluate environmental technology for waste treatment, storage, remediation, and disposal; pollution prevention; and pollution control and the use of the technology to generate and/or collect data (e.g., treatability and pilot studies);

- Map environmental processes and conditions, and/or human health risk data, etc. (e.g., geographical information system);

- Support enforcement and/or compliance monitoring efforts;

- Develop or evaluate methods for use in the collection, analysis, and use of environmental data;

- Develop and/or evaluate models of environmental processes and conditions and use models to characterize environmental processes or conditions;

- Develop, revise, or use of information technology and management system operations that impact the quality of the results of environmental programs (e.g., electronic databases with environmental information including data entry, handling, transmission and analysis, and laboratory information management systems); and

- Monitor or address concerns over the occupational health and safety of personnel in EPA facilities (e.g., indoor air quality measurements) and in the field (e.g., chemical dosimetry, radiation dosimetry).

3.3   Organizational Structure of the EPA Quality System

3.3.1 *EPA Organizations*

Because of the diversity (and dispersion) of programs within EPA, the Agency-wide Quality System is decentralized so organizations have individual quality systems that specifically address their needs. As a result, the EPA Quality System is composed of individual quality systems developed and implemented by the various EPA Regions, National Program Offices, and the National Centers and Laboratories in the Office of Research and Development. These individual quality systems are supported by the quality systems of non-EPA organizations who receive funding from, and provide data and information to, EPA.

Figure 1[1] shows the organizational structure for quality management in EPA. Overall, there are more than 40 EPA organizations that maintain quality systems. These organizations are usually at the Regional Office level, at the level immediately below each National Program
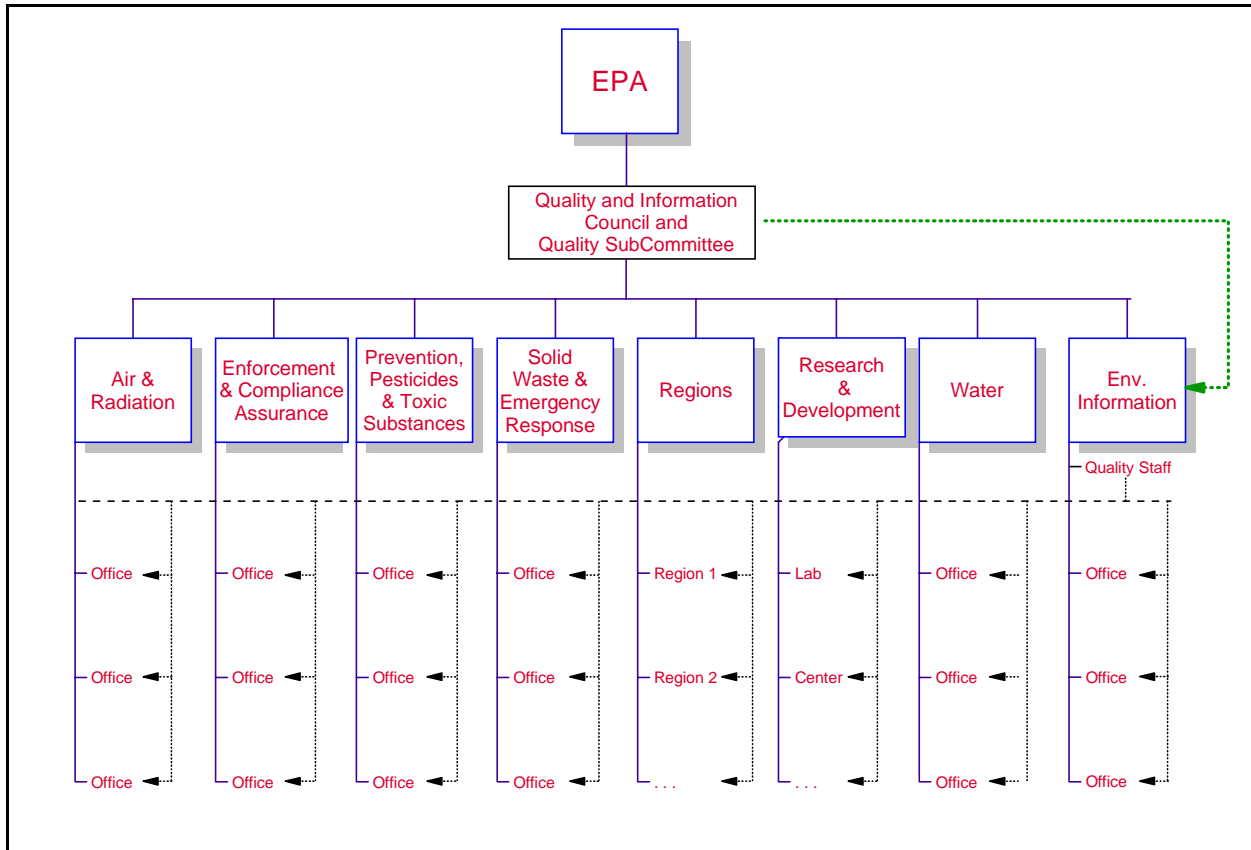
Figure 1. Example EPA Organizations within the EPA Quality System

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[1]Note, not all EPA Offices are shown on Figure 1. See www.epa.gov/epahome/organization.htm for a current list of EPA Offices.

Office, and at the National Center and Laboratory level. Specialized, complex, large, or highly-visible programs (for example, EPA's Great Lakes National Program) also may have their own quality systems. Typically, such programs cut across organizational lines and have their own organizational infrastructure. The Assistant Administrator for Environmental Information is responsible for developing and coordinating the EPA Quality System in addition to directing its implementation within EPA. This role is performed by the Quality Staff. See Section 5 for a discussion of the specific responsibilities of each of these organizations.

3.3.2   *Non-EPA Organizations*

Non-EPA organizations are required to develop and implement quality systems to support their environmental programs and projects funded or regulated by EPA. This quality system may be part of an existing system for the organization as long as it addresses all of EPA's requirements. Organizations that may be affected by the EPA Quality System requirements include: other Federal departments and agencies; State, local, and Tribal governments; academic and other non-profit organizations; and commercial business enterprises. Quality management requirements are either defined through the Federal Regulations that specify, in general, what an organization must do to comply with EPA policy, or are negotiated into agreements that are not covered by the Federal Regulations. See Sections 3.4.2.2 and 4.2 for discussions on the specific regulations and requirements for non-EPA organization.

3.4   Structural Components of the EPA Quality System

Figure 2 illustrates the components to consider when developing an individualized Quality System. There are 3 types of components in the EPA Quality System:

1. **Policy** – These components address quality-related policies and regulations that EPA organizations and non-EPA organizations must address.

2. **Organization/Program** – These components address the management and implementation component of the individual Quality System. The components are applied across an entire organizations (e.g., a Regional Office or a National Research Laboratory) or to a specialized, complex, large, or highly-visible programs (for example, EPA's Great Lakes National Program).

3. **Project** – These components address the project-specific components that are applied to individual projects (within an organization or program) to ensure that the project objectives are achieved.

Figure 2 also shows some of the quality management tools EPA has developed to assist in developing and implementing a quality system. These tools are described in Appendix A.
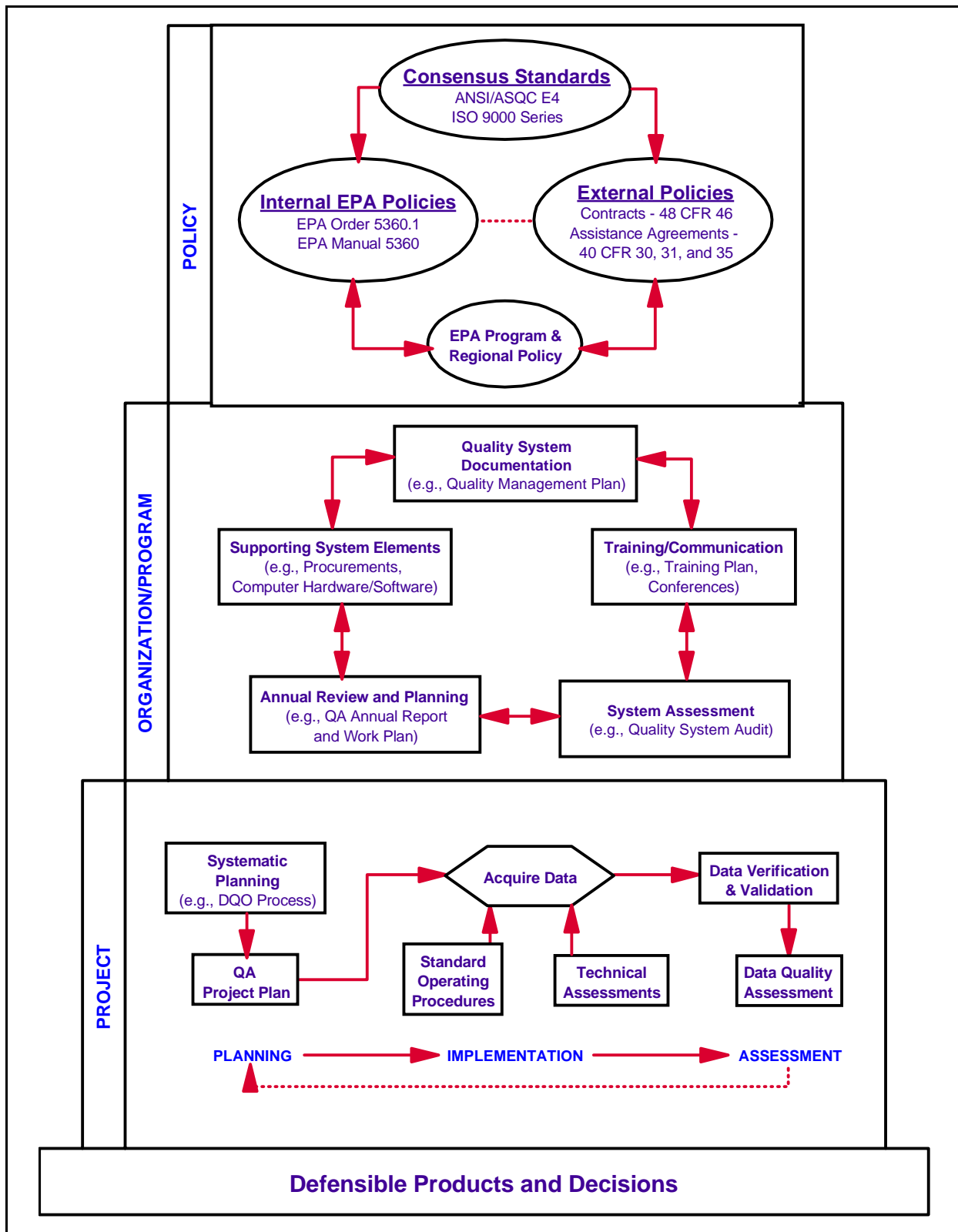
Figure 2. EPA Quality System Components and Tools

3.4.1 Graded Approach

The development and implementation of a quality system should be based on a "graded approach." This means that the components and tools of a quality system (Figure 2) are applied according to the scope and nature of an organization, program, or project and the intended use of its products or services. This approach recognizes that a "one size fits all" approach to quality management is not appropriate and that the quality system of different organizations and program should (and will) vary according to the specific needs of the organization. For example, the quality expectations of a research program are different from that of a regulatory compliance program because the intended use of the products differs.

3.4.2 Policy Components

The policy components of the EPA Quality System consist of:

✓ Agency-wide policies specific to EPA organizations,

✓ Agency-wide policies for non-EPA organizations that perform environmental programs on behalf of EPA, and

✓ Organization and program-specific policies for both EPA and non-EPA organizations. These policies are consistent with one another and are based on the national consensus standard ANSI/ASQC E4.

3.4.2.1 Agency-wide Internal Policy

Agency-wide policies for EPA organizations are contained in EPA Order 5360.1 A2 and EPA Manual 5360 A1. Together, these documents define the Agency-wide Quality System. Copies of these documents are available at www.epa.gov/quality/tools-pol.html.

EPA Order 5360.1 A2 (May 2000), *Policy and Program Requirements for the Mandatory Agency-wide Quality System* – Establishes the minimum requirements for EPA organizations covered by the mandatory Agency-wide Quality System including conformance to ANSI/ASQC E4-1994. Contains requirements specific to EPA such as developing Quality Management Plans, ensuring adequate resources, providing training, etc. Describes responsibilities for EPA management, staff, and quality management personnel.

EPA Manual 5360 A1 (May 2000), *EPA Quality Manual for Environmental Programs* – Known as the Quality Manual. Provides implementation requirements for EPA organizations covered by the mandatory Quality System defined in EPA Order 5360.1. Addresses the implementation of quality management activities, including inherently governmental functions (i.e., the limitations on the use of non-EPA organizations for

quality-related activities); reporting requirements; requirements for organizations funded by EPA; requirements for reporting results from applicable environmental programs; Quality System requirements and guidance documents; user-specific quality-related guidance; and dispute resolution. Provides details on documenting compliance with EPA Order 5360.1.

3.4.2.2 Agency-wide External Policy

Quality System policies and requirements for non-EPA organizations funded by EPA are contained in the Code of Federal Regulations (CFR). There are four basic regulations that apply to extramural agreements (i.e., contracts, grants, and cooperative agreements, as well as any work assignments, delivery orders, or tasks orders that are contained in the above). Box 4 contains information on which requirement applies to an individual or organization. Each regulation is described below and the full text is available at www.epa.gov/quality/exmural.html.

48 CFR 46, *“Quality Assurance”* – Contains requirements for contracts, work assignments, delivery orders, and task orders. Allows Federal agencies to select a national consensus standard as a basis for their quality requirements. EPA uses ANSI/ASQC E4 as its basis and requires that offerors/contractors submit a Quality Management Plan (or equivalent) and a QA Project Plan (or equivalent) to demonstrate conformance to the standard.

40 CFR 30, *“Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations”* – Contains requirements for organizations identified in title. Requires that grantees comply with ANSI/ASQC E4. EPA requires that grantees submit a Quality Management Plan (or equivalent) and a QA Project Plan (or equivalent) to demonstrate conformance.

40 CFR 31, *“Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments”* – Contains requirements for grants and cooperative agreements to State, local, and Tribal Governments. Requires that grantees develop and implement quality-related practices to produce data of adequate quality to meet project objectives. EPA has issued clarifying language to require grantees to comply with ANSI/ASQC E4-1994 and submit a Quality Management Plan and QA Project Plans (or equivalents) to demonstrate conformance. This clarifying language is available at www.epa.gov/ogd/ quality_ assurance_ requirements.htm and is consistent with 40 CFR 30.

40 CFR 35, “State and Local Assistance” – Contains program-specific requirements for financial assistance agreements to State, local, and Tribal governments. Requires that grantees comply with 40 CFR 31.

**Box 4. Regulations containing Quality-Related Requirements
for non-EPA Organizations**

	Contract	Cooperative Agreement	Grant*	Inter-Agency Agreement	Agency Mandates
Contractor	48 CFR 46	N/A	N/A	N/A	N/A
Consultant	40 CFR 46	N/A	40 CFR 30	N/A	N/A
Federal Agency	N/A	N/A	N/A	Negotiated into each agreement	Contained in the individual Federal Regulation
Hospital	48 CFR 46	40 CFR 30	40 CFR 30	N/A	Contained in the individual Federal Regulation
Institute of Higher Education	48 CFR 46	40 CFR 30	40 CFR 30	N/A	Contained in the individual Federal Regulation
Local Government	48 CFR 46	40 CFR 30, 31, 35	40 CFR 30, 31, 35	N/A	Contained in the individual Federal Regulation
Non-profit Organization	48 CFR 46	40 CFR 30	40 CFR 30	N/A	Contained in the individual Federal Regulation
Permittees	N/A	N/A	N/A	N/A	Contained in the Federal Regulation under which the permit was issued as well as the specific requirements contained in the permit
Regulated Entity	N/A	N/A	N/A	N/A	Contained in the individual Federal Regulation
State Government	48 CFR 46	40 CFR 30, 31, 35	40 CFR 30, 31, 35	N/A	Contained in the individual Federal Regulation
Tribal Government	48 CFR 46	40 CFR 30, 31, 35	40 CFR 30, 31, 35	N/A	Contained in the individual Federal Regulation

*Grants include Performance Partnership Grants and Performance Partnership Agreements.

Quality requirements are negotiated into interagency agreements and consent agreements, and may be included in consent orders. This is done on a case-by-case basis by the EPA organization sponsoring or overseeing the work. Additional quality requirements may be included in Federal regulations. For example, 40 CFR 160.35, "Federal Insecticide, Fungicide, Rodenticide Act," contains additional quality management requirements specific to this Act.

3.4.2.3 *Organizational-specific or Program-specific Policies for both EPA and non-EPA Organizations*

Each EPA organization or program integrates the Agency-wide quality policies into its individual quality policies, procedures, and practices. These organizations or programs also:

(1)   tailor internal policies in their Quality Management Plan (see Appendix A, Section A.1.1) to better meet their organization-specific needs; and

(2)   define additional quality-related requirements for non-EPA organizations to ensure that program-specific goals and objectives are satisfied. These requirements are written into program-specific Federal Regulations or individual extramural agreements.

All program or organization-specific policies must be consistent with the Agency-wide policies.

3.4.3   *Organization/Program Components*

The organization/program components include management policies and processes that have broad application across an organization or program. There are four key components: Quality System Documentation; System Assessments; Annual Reviews and Planning; and Training. Successful implementation of each component is essential to an effective Quality System. For each of these components, EPA has developed tools to assist in the implementation. These tools are italicized in the discussion below and described in Section A.1 of Appendix A.

The use of a component or tool should reflect the needs of the organization relative to its environmental programs and the organization's policy. The Organization/Program components should address the policies and responsibilities that apply to activities that are common to all projects performed by (or for) the organization or program. For example, an organization's policy requiring QA Project Plans along with the process for reviewing and approving those plans should be included in the quality system documentation (an Organization/Program component) since the process would apply to all QA Project Plans. The Organization/Program components include:

Quality System Documentation – Documentation that describes the authorities, policies, and procedures specific to an organization. EPA organizations are required to document their quality system in a *Quality Management Plan*.

System Assessments – Systematic assessments of a program and/or organization's quality system. EPA uses *Quality Systems Audits*, Management System Reviews, and other assessment techniques to evaluate EPA and supporting organizations. EPA organizations are required to assess their organization at least annually.

Annual Reviews and Planning – A review of the activities within, and changes to, an organization's quality system; work accomplished; and the planning of future quality-related activities. Each EPA organization is required to submit a *QA Annual Report and Work Plan* to document their review and planning.

Training – Education to ensure that all personnel with responsibility for management, data collection activities, or the use of environmental technology have the necessary skills, knowledge, and proficiency in accordance with their organization's quality system. EPA organizations are required to document their *Training Program* in their Quality Management Plan.

3.4.4 Project Components

These components apply to projects within an organization or program that involve environmental data generation, acquisition, and use. Note that projects are not limited to those involving the collection of environmental measurements; the project components of the EPA quality system also apply to projects involving the use of measurements collected for a different project or purpose, produced from models, and compiled from other sources such as data bases or the literature.

There are three project components – planning, implementation, and assessment – that correspond to the Project Life Cycle (see Figure 3) and lead to a specific product or decision. The project life cycle is iterative in nature; each component feeds back into the others for improvements. Use of each component is critical for ensuring that the quality of environmental information can be determined and whether the information can be used for a specific decision.

Figure 3. The Project Life Cycle

For each project component, EPA has developed quality management tools to assist in the implementation. These tools are italicized in the discussion below and described in Section A.2 of Appendix A. Individuals who typically use these tools are identified in Section 5.

Planning: Prospective data users use *systematic planning*, such as the *Data Quality Objectives Process*, to develop performance criteria for the data (i.e., the type, quantity, and quality of data needed for a specific purpose), to develop a sampling plan that satisfies the criteria, and to determine the level of oversight and quality control activities needed to ensure the criteria are satisfied. The systematic planning results are documented in the *QA Project Plan* or other planning documents.

Implementation and Oversight: Data are acquired according to the approved methods and procedures documented in the QA Project Plan and *Standard Operating Procedures*. Oversight is performed using *technical audits* and assessments (such as product/service or process quality audits) to determine if the data are being acquired as required by the QA Project Plan and other planning documents. Actions are taken to correct problems identified through the audits or assessments.

Assessment: Project personnel use technical knowledge and statistical methods to determine whether or not the data meet the user's needs. The data are formally *verified and validated* to ensure that the measured values are free of gross errors due to procedural or technical problems and then are analyzed to determine if they meet the performance criteria documented in the QA Project Plan (*data quality assessment*). The results of a project may also be peer reviewed.

Also, an assessment of the overall project may be performed as part of a system assessment described in Section 3.4.4 at any time during the project life-cycle,

4.   REQUIREMENTS

4.1   Requirements for EPA Organizations

There are 11 basic quality management requirements defined in EPA Order 5360.1 for all EPA organizations covered by the EPA Quality System. These requirements are to:

✓   Conform to the minimum specifications of ANSI/ASQC E4-1994 - see Section 3.2 for information about ANSI/ASQC E4-1994;

✓   Identify a QA Manager and ensure that this individual quality function is independent from environmental data collection and use - see Section 5.6.1 for responsibilities of a QA Manager;

✓   Develop a Quality Management Plan and implement this plan following Agency approval - see Section A.1.1 of Appendix A for more information on quality management plans;

✓   Provide sufficient resources to implement the quality system;

✓ Perform an assessment of the effectiveness of the quality system at least annually and implement corrective actions based on assessment results in a timely manner - see Section A.1.2 of Appendix A for more information on assessments of quality systems;

✓ Submit an QA Annual Report and Work Plan that summarizes the previous year's activities and outlines the work proposed for the current year - see Section A.1.3 of Appendix A for more information on the QA Annual Report and Work Plan;

✓ Implement Agency-wide Quality System requirements in all applicable EPA-funded extramural agreements - see Section 3.4.2.2 for specific requirements;

✓ Provide appropriate training for all levels of management and staff to assure that quality-related responsibilities and requirements are understood - see Section A.1.4 of Appendix A for more information on training;

✓ Use a systematic planning approach to develop acceptance or performance criteria for all work covered by the EPA Quality System - see Section A.2.1 of Appendix A for more information on systematic planning;

✓ Have approved QA Project Plans, or equivalent documents, for all applicable projects and tasks involving environmental data - see Section A.2.2 of Appendix A for more information on QA Project Plans; and

✓ Assess existing data, when used to support Agency decisions or other secondary purposes, to verify that they are of sufficient quantity and adequate quality for their intended use - see Section A.2.3-A.2.5 of Appendix A for more information on data assessment.

EPA Order 5360.1 also contains program-specific requirements and responsibilities for EPA managers and staff.

4.2 Requirements for Non-EPA Organizations

In general, EPA requires that recipients of funds for work involving environmental data collection comply with the American National Standard ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*. In addition, each EPA organization's Quality Management Plan describes how the organization will interact with, and any additional requirements for, the organizations they fund.

To demonstrate conformance to E4-1994, EPA requires two forms of documentation:

1.   Documentation of the organization quality system (usually called a Quality Management Plan), and

2.   Documentation of the application of quality-related activities to an activity-specific effort (usually called a QA Project Plan)[2].

Use of existing quality system documentation, such as that required by the ISO 9000 family of quality standards, may be an acceptable alternative.

For grants, contracts, and other extramural agreements that consist of a single project or task, these two documents may be combined into a single document that describes the organization's quality system and the application of this system to the work performed under the grant or contract. This can only be done with permission of the EPA QA Manager who will identify the elements that should be addressed in a combined document.

5.   RESPONSIBILITIES

Responsibility for the EPA Quality System is spread across the Agency. Each EPA organization described below has a specific role and set of responsibilities. These responsibilities are summarized in Box 5 and the relationship between these organizations and individuals is shown in Figure 4.

5.1   Agency Senior Management Official for Quality

The Assistant Administrator for Environmental Information is the Agency's Senior Management Official for Quality and is responsible for developing and coordinating the Agency-wide Quality System and directing its implementation within EPA. In addition to the Agency-wide Quality responsibilities, the Assistant Administrator for Environmental Information has responsibilities specific to this office that are described in Section 5.4.

5.2   Quality and Information Council/Quality Subcommittee

The Quality and Information Council is an advisory group of Agency senior managers that assists the Assistant Administrator for Environmental Information in the role of Senior Management Official for Quality. This Council is supported by the Quality Subcommittee which

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[2]Note: EPA may provide the QA Project Plan (or equivalent documentation). In this case, the fund recipient would simply implement the Plan provided and not create a new one.

Box 5. Quality Management Responsibilities for EPA Organizations[1]

|	Asst. Administrator Env. Information[2]	Quality Staff	National Program Offices	Regional Offices
Quality Management Policies	Issue policies recommended by Quality Staff and/or Quality and Information Council and Quality Subcommittee	Develop for Agency-wide use	Develop for program – may apply to Regions Apply Agency-wide policies	Develop for Region, and State, local, and Tribal governments Apply Agency-wide policies
Quality Management Plan	Approve EPA plans	Review EPA organization's plans Recommend approval to the Sr. Official for Quality	Develop and implement for each program laboratory and organization Review/approve the plans of non-EPA organizations funded by EPA	Develop and implement for Region Review/approve the plans of State, local, and Tribal governments, and non-EPA organizations funded by EPA
Quality Management Procedures and Guidance	Issue procedures and guidance developed by Quality Staff	Develop for EPA, non-EPA organizations funded by EPA, and for internal use	Develop for program and activities delegated to Regions; coordinate implementation with Regions	Develop for Regions – may apply to State, local, and Tribal governments
Resources for Quality Management Activities	Recommend improvements and balance resource allocation	Monitor resource allocation across Agency and highlight differences and inconsistencies	Provide sufficient resources to implement organization's Quality Management Plan for their Office and related Regional programs	Provide sufficient resources to implement the organization's Quality Management Plan
System Assessments and Evaluation	Mandate Agency-wide corrective actions	Periodically review each EPA organization Identify Agency-wide problems and corrective actions	Perform internal assessments Assess supporting organizations (EPA or otherwise)	Perform internal assessments Assess supporting organizations (EPA or otherwise), including State agencies

Box 5. Quality Management Responsibilities for EPA Organizations[1]

	Asst. Administrator Env. Information[2]	Quality Staff	National Program Offices	Regional Offices
QA Annual Report and Work Plan	Report to EPA Administrator	Compile information in report to AA/OEI and EPA Administrator	Report yearly	Report yearly
Communication and Outreach	Represents EPA on quality practices and issues.	Perform outreach and consulting Host monthly conference calls, annual National QA Conference	Liaison with Quality Staff, EPA QA Managers, and holders of assistance agreements	Liaison with Quality Staff, other EPA QA Managers and State, local, and Tribal governments
Training	Issue generic training materials	Develop generic training materials Provide generic training on limited basis	Develop program-specific training Provide training to program management and staff	Develop Region-specific training Provide training to Regional management and staff Ensure training is available for State, local, and Tribal governments
Employee Evaluation (Performance) Standards	Issue general standards policy	Develop general standards policy	Ensure quality-related activities reflected in performance standards	Ensure Quality-related activities reflected in performance standards

[1]Non-EPA organizations are responsible for developing an EPA-approved Quality Management Plan. This plan should address the other elements listed on this table with the exception of performance standards.
[2]In conjunction with the Quality and Information Council and Quality Subcommittee.
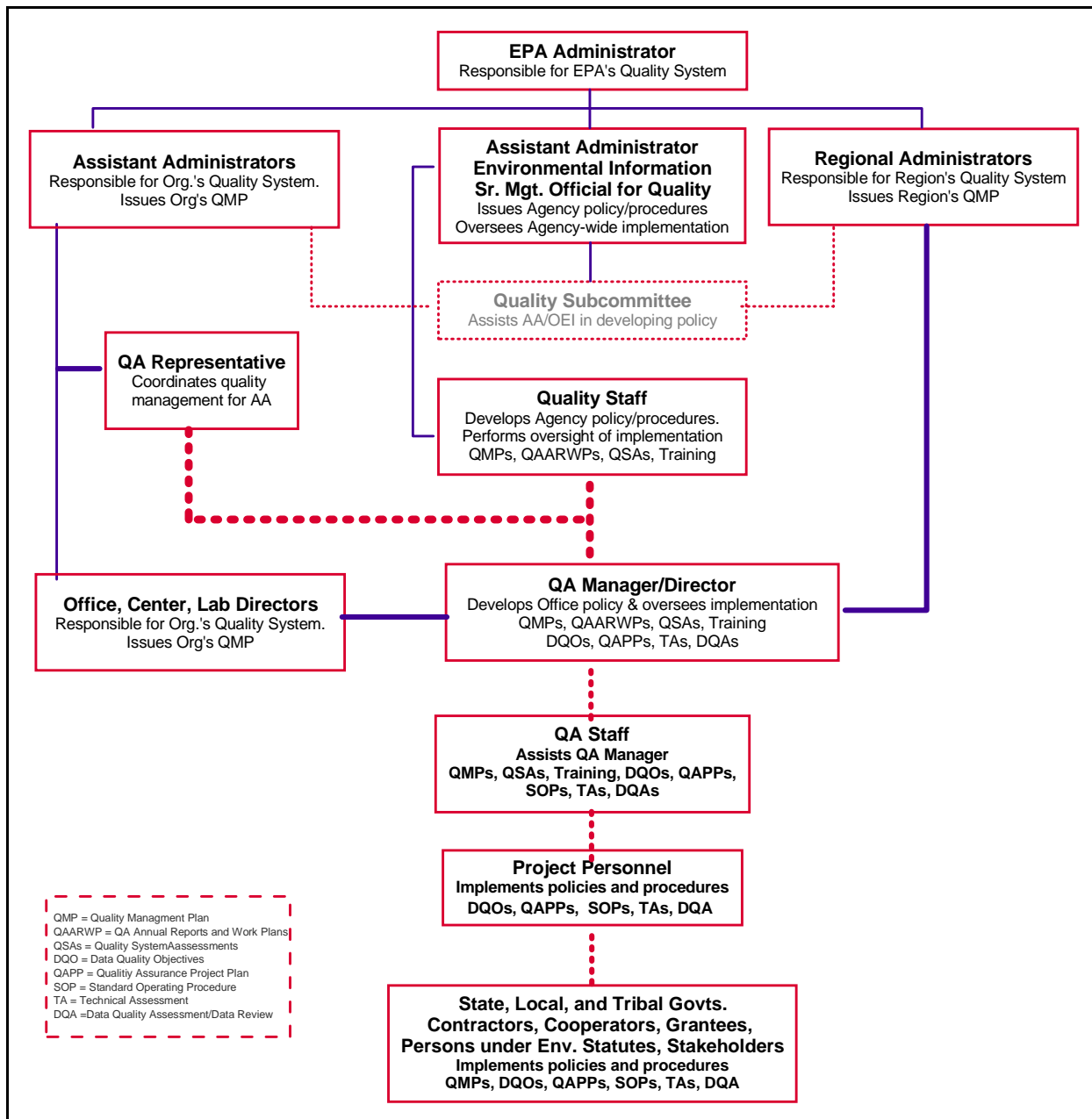
Figure 4. Quality Management Responsibilities by Individual

addresses Agency-wide policy issues in the implementation of the quality program. Both groups function as a forum in which Agency-wide Quality System issues are resolved.

5.3 Office of Environmental Information's Quality Staff

The Quality Staff of the Office of Environmental Information supports the Assistant Administrator for Environmental Information in his/her role as Senior Management Official for Quality. The Staff is the Agency organization assigned the responsibility for developing Agency-wide policy and procedures, coordinating with EPA's Program Offices, Laboratories, Regional Offices, and overseeing the implementation of the EPA Quality System. This role includes both supporting Agency organizations in developing and implementing their individual Quality Systems and performing assessments on these organizations. Specific responsibilities for the Quality Staff are described in Box 5.

5.4 National Program Offices

The Assistant or Associate Administrator of each National Program Office (including the Office of Research and Development) is responsible for its quality system (see Section 3.3 for example EPA Program Offices). Specific responsibilities of the National Program Offices are described in Box 5.[3] Each National Program Office has a QA Representative that reports to the Assistant Administrator; advises on quality-related activities; and assists in the planning, implementation, documentation, and assessment of the organization's quality system. Each line office within a National Program Office typically has a QA Manager or QA Director, QA Officers, QA Coordinators, and other QA personnel to provide support to the ongoing operations of the organization.

5.5 Regional Offices

Each Regional Administrator is responsible for the quality system in the Region. Specific responsibilities for the EPA Regional Offices are shown in Box 5. Each Regional Office has a QA Manager, who advises the Region's senior management on quality-related activities, and assists in the planning, implementation, documentation, and assessment of the Region's quality system. Each QA Manager is supported by QA personnel that provide support to the ongoing operations of the organization.

5.6 Individual Responsibilities

5.6.1 *EPA Quality Personnel Responsibilities*

EPA organizations are required by EPA Order 5360.1 to identify a QA Manager (or QA Director) who reports on quality issues to the senior management of the organization. This

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[3] Note, organizations within a National Program Office may have programs that are delegated to the EPA Regions, States, and Tribal governments, or are supported by Regional, State, or EPA National Research Centers and Laboratories. In this case, the National Program Office must define the quality management responsibilities for these programs (in their Quality Management Plan) and ensure these responsibilities are addressed.

individual must have sufficient technical and management expertise and authority to conduct independent oversight of and assure the implementation of the organization's quality system in the environmental programs of the organization. This individual must function independently of direct environmental data generation, model development, or technology development. See Gee (1996) and Pyzdek (1996) for a discussion on roles and activities of a QA Manager for a general organization. The responsibilities of a QA Manager and other quality management personnel include:

- facilitating the development and maintaining the organization's Quality Management Plan;
- representing the organization on matters pertaining to quality management;
- providing expert assistance on quality-related issues;
- developing and implementing a QA Training Program;
- reviewing and/or approving quality management documentation;
- providing quality management support; and
- overseeing and assessing the organization's quality system.

In addition to these general responsibilities, each EPA organization's Quality Management Plan defines specific responsibilities for its QA Manager and other quality management personnel.

5.6.2   EPA Managers and Staff

Quality-related responsibilities for EPA managers and staff are defined in their organization's Quality Management Plan. However, EPA managers are also responsible for ensuring that adequate resources are available for quality management activities and that environmental programs comply with EPA Order 5360.1. In addition, both EPA managers and staff are responsible for ensuring their applicable intramural and extramural programs and activities comply fully with EPA Order 5360.1 and for assuring that the results of environmental programs are of sufficient quantity and adequate quality for their intended use.

5.6.3   EPA Extramural Personnel

Responsibilities for EPA's Contracting Officers and Contracting Officer's Representatives are contained in the EPA Manual 1900 (EPA 1998), Contracts Management Manual (epawww.epa.gov/oamintra/policy/cmm.pdf). Quality-related requirements specific to the EPA Quality System, such as the use of a QA Review Form and criteria for the Technical Evaluation Panel, are contained in Chapter 2 of EPA Manual 1900.

EPA's Assistant Agreement Project Officers and other representatives are responsible for ensuring that all quality-related requirements for both proposals and assistance agreements are satisfied. More information is available on EPA's Internet (www.epa.gov/ogd) and Intranet (intranet.epa.gov/oinijhhk/ogd.htm).

5.7 Non-EPA Organizations

EPA can not define responsibilities for non-EPA organizations beyond what is contained in the Federal Regulations or in individual agreements (contracts, grants, etc.). General requirements are for non-EPA organizations are described in Section 3.4.2.2; specific requirements are contained in each individual agreement with EPA.

6. OTHER SOURCES OF INFORMATION

EPA uses several approaches to disseminate quality-related information to quality professionals and to collaborate with other organizations on new initiatives to improve quality management practices and procedures. These approaches include conference calls, guidance, conferences, Internet sites, and participation in professional societies.

Conference Calls: The EPA QA Managers participate in three monthly conference calls (one for the Regions, one for the Program Offices, and one for the Office of Research and Development) to exchange information and to discuss current issues and activities. These calls are restricted to EPA personnel only and are sponsored by the Quality Staff. EPA Program Offices may also sponsor conference calls for their quality management personnel.

Quality System Series Documents: EPA publishes a series of documents that describe the Agency-wide policies and procedures for planning, implementing, and assessing the effectiveness of the EPA Quality System and provide criteria and guidance on satisfying EPA quality requirements. These documents are called the Quality System Series and are available at www.epa.gov/quality/qa_docs.html.

Annual Quality Management Conference: EPA sponsors an annual conference so that EPA and other quality professionals can share experiences in managing and implementing their quality systems and quality-related practices. These conferences may be general in scope or have a specific focus, depending on the needs expressed by the quality management community. The conferences include presentations on national issues and feature presentations by EPA and other organizations on technical issues. The Quality Staff generally offers training in conjunction with these conferences to provide an optional opportunity for education and professional development in quality concepts and practices. Information on past and upcoming conferences is available at www.epa.gov/quality/meeting.html.

Annual Training Conference: EPA sponsors an annual training conference to equip quality management professionals with the knowledge and skills they need to promote effective management and implementation of environmental quality systems. These conferences offer practical educational opportunities and workshops of varying lengths that allow conference attendees to participate in Quality-related training events that are

specific to their organizational needs. The training curriculum includes classes in basic quality-related concepts and principles as well as specialized and advanced courses. Information on upcoming training conferences is available at www.epa.gov/quality/train.html.

Web Sites: The Agency-wide Quality System web site (www.epa.gov/quality) contains information on the EPA Quality System, quality requirements for organizations funded by EPA, training, the Annual Conference, the Quality System Series, and contact persons for each individual EPA organization. Most Regional Offices and a few program offices also maintain web sites with quality-related information. Link to these sites are maintained on the EPA Quality System web site.

Professional Societies and Standards Development: EPA participates in the quality management activities of several professional societies and standards developing organizations including the American Society for Quality, the American Society for Testing and Materials, the American National Standards Institute, and the International Organization for Standardization.

7.   REFERENCES

40 CFR 30, Code of Federal Regulations, "Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations."

40 CFR 31, Code of Federal Regulations, "Uniform Administrative Requirements for Grants and Cooperative Agreement to State and Local Governments."

40 CFR 35, Code of Federal Regulations, "State and Local Assistance."

48 CFR 46, Code of Federal Regulations, "Federal Acquisition Regulations."

ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, American National Standard, January 1995.

EPA Order 1900, *Contracts Management Manual*, February 1998.

EPA Order 5360.1 A2 (May 2000). *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, U.S. Environmental Protection Agency, Washington, DC.

EPA Manual 5360 A1 (May 2000). *EPA Quality Manual for Environmental Programs*, U.S. Environmental Protection Agency, Washington, DC.

Gee, G., Richardson, W., and Wortman, B. (1996). *CQM Primer*, Quality Council of Indiana, West Terra Haute, IN.

Pyzdek, T. (1996). *The Complete Guide to CQM*, Quality Publishing, Tuscon, AZ.

APPENDIX A

QUALITY SYSTEM TOOLS

For each components used to develop and implement a Quality System (discussed in Section 3.4), EPA has developed quality management tools to assist in implementation (see Box A-1 for a summary). The sections below describe these tools and provide references to the Quality System Series documents and other references that discuss the subjects in greater detail. The most recent copies of the Quality System Series are available at www.epa.gov/quality/qa_docs.html. In addition, web pages containing these documents, along with examples, training, and other resources, is identified below for each tool.

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│                  Box A-1.  Quality Management Tools                       │
│                                                                          │
│  Program/Organization Tools              Project Tools                    │
│                                                                          │
│  •  Quality Management Plans             •  The Data Quality Objectives   │
│  •  Quality System Audits                   Process                       │
│  •  QA Annual Report and Work Plan       •  QA Project Plans              │
│  •  QA Training Program                   •  Standard Operating Procedures │
│                                          •  Technical Assessments         │
│                                          •  Data Validation and Verification │
│                                          •  Data Quality Assessment       │
└─────────────────────────────────────────────────────────────────────────┘
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A.1   Program/Organizational Tools

A.1.1 *Quality Management Plan* – www.epa.gov/quality/qmps.html

Purpose: To document an organization's quality system for planning, implementing, and assessing the effectiveness of activities supporting environmental programs. It also documents how, when, and by whom an organization's quality system will be implemented and assessed.

Requirement: Both EPA and non-EPA organizations are required to document their quality systems in a Quality Management Plan (or equivalent).

References: EPA Manual 5360 A1 (May 2000). *EPA Quality Manual for Environmental Programs*, U.S. Environmental Protection Agency, Washington, DC. Chapter 3 (EPA Only)

EPA Requirements for Quality Management Plans (QA/R-2) (2000). EPA/240/B-01/002, U.S. Environmental Protection Agency, Office of Environmental Information.

MacLean, G. E. (1993). *Documenting Quality for ISO 9000 and Other Industry Standards*, ASQ Quality Press, Milwaukee, WI.

A.1.2   *Quality System Audit*s – www.epa.gov/quality/qsas.html

Purpose: To verify, by examination and evaluations of objective evidence, that applicable elements of the quality system are appropriate and have been developed, documented, and effectively implemented in accordance and in conjunction with specified requirements (Smith and Russell, 1997).

Requirement: EPA organizations are required to assess their quality systems on at least an annual basis using quality system audits or other assessment processes. The Quality Staff also performs periodic audits of EPA organizations to determine the effectiveness of their quality systems.

References: *Guidance on Assessing Quality Systems (G-3)* (2002). Peer Review Draft, U.S. Environmental Protection Agency, Office of Environmental Information.

Smith, J. L. and Russell, J. P. (1997). *The Quality Audit Handbook*, ASQ Quality Press, Milwaukee, WI..

A.1.3   *QA Annual Report and Work Plans* – www.epa.gov/quality/qaarwps.html

Purpose: To document an EPA organization's previous year's quality-related activities and those planned for the current year, including current and planned resources for the management and implementation of quality-related activities, training, accomplishments, and assessments.

Requirement: EPA organizations are required to submit a QA Annual Report and Work Plan to the Assistant Administrator of the Office of Environmental Information every year.

References: EPA Manual 5360 A1 (May 2000). *EPA Quality Manual for Environmental Programs*, U.S. Environmental Protection Agency, Washington, DC. Chapter 4.

A.1.4   *Training Program* – www.epa.gov/quality/training.html

Purpose: To assure that all personnel have the necessary skills in order to effectively accomplish their work and that quality management responsibilities and requirements are understood at every stage of project implementation throughout the Agency.

Requirement: EPA organizations are required to provide training, for all levels of management and staff, to assure that quality-related responsibilities and requirements are understood at every stage of project implementation;

References: *Guidance for Developing a Training Program for Quality Systems (QA/G-10)* (2000). EPA/600/B-00/004, U.S. Environmental Protection Agency, Office of Environmental Information.

A.2 Project Components

A.2.1 *Systematic Planning and the Data Quality Objectives Process* –
www.epa.gov/quality/dqos.html

Purpose: To identify the expected outcome of the project, the technical goals, the cost and schedule, and the acceptance criteria for the final result before a project begins. EPA recommends using the Data Quality Objectives Process when data are being used to select between two opposing conditions, such as determining compliance with a standard.

Requirement: EPA organizations must use a systematic planning process to develop acceptance or performance criteria for the collection, evaluation, or use of environmental data.

References: *Guidance for the Data Quality Objectives Process (QA/G-4)* (2000) EPA/600/R-96/055, U.S. Environmental Protection Agency, Office of Environmental Information.

The Data Quality Objectives Process for Hazardous Waste Sites (QA/G-4HW) (2000). EPA/600/R-00/007, U.S. Environmental Protection Agency, Office of Environmental Information.

A.2.2 *Quality Assurance Project Plans* – www.epa.gov/quality/qapps.html

Purpose: To document performance criteria and the project-specific plan for obtaining the type, quality, and quantity of data needed for a specific use.

Requirement: An EPA-approved QA Project Plan (or equivalent) is required for all projects and tasks involving environmental data.

References: EPA Manual 5360 A1 (May 2000). *EPA Quality Manual for Environmental Programs*, U.S. Environmental Protection Agency, Washington, DC. Chapter 5 (EPA Only)

EPA Requirements for Quality Assurance Project Plans (QA/R-5) (2001). EPA/240/B-01/003, U.S. Environmental Protection Agency, Office of Environmental Information.

Guidance for Quality Assurance Project Plans (QA/G-5) (1998). EPA/600/R-98/018, U.S. Environmental Protection Agency, Office of Environmental Information. Office of Research and Development.

A.2.3 *Standard Operating Procedures* – www.epa.gov/quality/sops.html

Purpose: To document the procedures necessary to carry out routine or repetitive administrative and technical activities.

Requirement: As Applicable.

References: *Guidance for the Preparation of Standard Operating Procedures for Quality-Related Documents (QA/G-6)* (2001). EPA/240/B-01/004, U.S. Environmental Protection Agency, Office of Environmental Information.

A.2.4 *Technical Audits* – www.epa.gov/quality/dqa.html

Purpose: To provide a systematic independent technical examination of a project to determine if a data collection activity is being conducted as planned and producing data and information of the type and quality specified in the QA Project Plan. Examples of technical audits include technical system audits, readiness reviews, surveillance, etc.

Requirement: As Applicable.

References: *Guidance on Technical Audits and Related Assessments for Environmental Data Operations (QA/G-7)* (2000). EPA/600/R-99/080, U.S. Environmental Protection Agency, Office of Environmental Information.

A.2.5 *Data Verification and Validation* – www.epa.gov/quality/vandv.html

Purpose: To determine if data has been collected in accordance to the QA Project Plan with respect to compliance, correctness, consistency, and completeness and to evaluate the technical usability of the data with respect to the planned objectives or intention of the project.

Requirement: As Applicable.

References: *Guidance on Environmental Data Verification and Validation (G-8)*
(2001). Peer Review Draft, U.S. Environmental Protection Agency,
Office of Environmental Information.

*Data Validation Functional Guidelines for Evaluating Environmental
Analyses* (1996). U.S. Environmental Protection Agency, Region I, EPA-
New England.

A.2.6 *Data Quality Assessment* – www.epa.gov/quality/dqa.html

Purpose: To provide a scientific and statistical assessment to determine whether
data are of the right type, quality, and quantity to achieve the objectives of
a project.

Requirement: As Applicable.

References: *Guidance for Data Quality Assessment: Practical Methods for Data
Analysis (QA/G-9)* (2000). EPA/600/R-96/084, U.S. Environmental
Protection Agency, Office of Environmental Information.

Bibliography of References for Assessing Secondary Data (2000). Draft,
U.S. Environmental Protection Agency.