QUALITY MANAGEMENT PLAN

for

REGION 7

Region 7
United States Environmental Protection Agency
901 North 5th Street
Kansas City, KS 66101

REGION 7 QUALITY ASSURANCE MANAGEMENT PLAN APPROVALS

William A. Spratlin
Director, Air, RCRA, and Toxics Division

9/1/00
Date

Leo Alderman
Director, Environmental Services Division

8/28/00
Date

Michael J. Sanderson
Director, Superfund Division

8/28/00
Date

U. Gale Hutton
Director, Water, Wetlands, and Pesticides Division

8-28-00
Date

Martha Steincamp
Office of Regional Counsel

8/28/00
Date

Karen Flournoy
Director; Office of External Programs

8/28/00
Date

Diane Callier
Director, Enforcement Coordination Office

8/28/00
Date

Nat Scurry
Assistant Regional Administrator
Office of Policy and Management

8/28/00
Date

REGION 7 QUALITY ASSURANCE MANAGEMENT PLAN APPROVALS

for Ernest L. Arnold
Regional Quality Assurance Manager

6 Sep 2000
Date

Dennis Grams
Regional Administrator

9-12-00
Date

Nancy W. Wentworth
Director, Quality Staff

12/27/00
Date

Margaret Schneider
Deputy Assistant Administrator
Office of Environmental Information

12/27/00
Date

TABLE OF CONTENTS

LIST OF ATTACHMENTS

LIST OF ACRONYMS

ARTD - Air, RCRA, and Toxics Division

CNSL - Office of Regional Counsel

DQA - data quality assessment

ENSV - Environmental Services Division

EPA - Environmental Protection Agency

MSR - management systems review

OEP - Office of External Programs

PLMG - Office of Policy and Management

QA - quality assurance

QAARWP - quality assurance annual report and work plan

QAC - quality assurance coordinator

QAPP - quality assurance project plan

QC - quality control

QMP - quality management plan

RLAB - Regional Laboratory

RQAM - Regional Quality Assurance Manager

SOP - standard operating procedure

SPP - systematic planning process

SUPR - Superfund Division

TSA - technical systems audit

WWPD - Water, Wetlands, and Pesticides Division

1. INTRODUCTION

Agency policy initiated by the Administrator in memoranda of May 30, 1979 and June 14, 1979 requires participation in a centrally-managed quality system by all Environmental Protection Agency (EPA) organizations (laboratories, program offices, or regional offices) and by non-EPA organizations conducting environmental programs which are supported or mandated through contracts, regulations, or other formalized agreements. The Agency's policy and program requirements to implement the mandatory quality system are contained in EPA Order 5360.1 A2 which invokes the use of the American National Standard ANSI/ASQC E4-1994, Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs. ANSI/ASQC E4-1994 is a national consensus standard designed specifically for quality systems applied to environmental data collection and environmental technology programs.

The Office of Environmental Information is responsible for developing, coordinating, and directing implementation of the Agency quality system. The Office of Environmental Information has designated the Quality Staff to serve as the cental management authority for the Agency quality system.

To document the adherence to EPA Order 5360.1 A2, EPA requires each organizational unit to develop a quality management plan per the specifications in EPA Requirements for Quality Management Plans, EPA QA/R-2. The quality management plan (QMP) is a formal document describing the management policies, objectives, procedures, organizational authority, roles, and responsibilities of an agency, organization, or laboratory for ensuring environmental data are of the type and quality needed for their intended use.

To implement Agency policy, EPA Laboratories, Program Offices, and Regional Offices are required to prepare a QMP covering all intramural and extramural environmental programs which generate and process environmental data for Agency use. This QMP was prepared according to EPA Requirements for Quality Management Plans, EPA QA/R-2, November 1999 to document the quality assurance policies and management structure to be used in implementing the Region 7 quality system.

2. DEFINITION OF ENVIRONMENTAL DATA AND SCOPE OF REGION 7 QUALITY MANAGEMENT PLAN

2.1 Definition of Environmental Data

Environmental data are any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For Region 7, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as databases or the literature.

Acquired data are data or information used for project implementation or decision making which meet the following criteria:

1. are compiled from other sources
2. were originally collected for some other purpose
3. are obtained from non-measurement sources such as computer databases, programs, literature files, and historical databases

The quality of acquired data will directly impact the quality of the project results or environmental decision to which they are applied and are subject to the Region 7 quality system requirements .

2.2 Types of Data Collection Activities and Region 7 Programs Covered by the Quality Management Plan

The QMP encompasses data directly generated by Region 7 programs, their contractors, or grantees as well as data obtained for Region 7 programs from other sources. The QMP also covers environmental data that Region 7 programs require States, tribal governments, and grantees to collect.

2.3 Region 7 Programs Covered by the Quality Management Plan

The Region 7 QMP is applicable to all Region 7 environmental programs. This includes field and laboratory data-gathering activities or investigations that involve the determination of chemical, physical, or biological characteristics related to the environment.

3. MANAGEMENT AND ORGANIZATION

3.1 Region 7 Mission

Region 7's vision is achieving a healthier environment through a professional, dedicated, and diverse workforce. Region 7's mission is to protect and enhance the quality of our air, water, and terrestrial environment from pollution for the benefit of all. This will be accomplished by:

- Preventing or minimizing the release of pollutants into our environment by ensuring compliance with environmental laws, and enforcing against those who violate these laws;
- Working in partnership with those federal, tribal, state, and local agencies with whom we have shared responsibility for environmental protection;
- Working with stakeholders to implement flexible voluntary approaches to solve environmental problems;
- Conducting environmental education and outreach to the public and regulated community to enable them to prevent or reduce the generation of wastes, and to become better environmental stewards;
- Making environmental quality information easily accessible to the public to enable them to make choices about the level of environmental quality they expect, and
- Ensuring all our nation's communities have equal protection from pollution.

3.2 Quality Assurance Policy Statement

It is the policy of Region 7 that, within the constraints of available resources, quality assurance activities shall be conducted to assure environmental data generated, processed, or used for its programs' requirements will be of known quality and will be adequate for their intended use. The Region shall also support and implement a graded approach to the quality system which bases the level of managerial controls applied to an item or work commensurate with the intended use of the results and the degree of confidence needed for the results.

To ensure that this quality assurance policy is uniformly applied to Region 7 environmental programs, the Region 7 Quality Assurance Manager (RQAM) is authorized to conduct oversight of the Region 7 quality system. The authority covers environmental programs as a result of:

a. Region 7 in-house environmental activities;
b. Contracts;
c. Interagency Agreements;
d. Grants;
e. Cooperative Agreements;
f. Partnerships with industry, state and local offices, tribes, and other EPA Offices; and
g. Enforcement agreements.

3.3 Organization

Region 7 is organized into four Divisions: Air, RCRA, and Toxics (ARTD); Environmental Services (ENSV); Superfund (SUPR); and Water Wetlands, & Pesticides (WWPD); and four Offices: Office of Regional Counsel (CNSL); Office of External Programs (OEP); Enforcement Coordination (ECO); and Office of Policy and Management (PLMG). This QMP reflects the regional organization described in Appendix A. Region 7 has a Quality Assurance Manager and each Division and Office has a Quality Assurance Coordinator (QAC).

3.3.1 Air, RCRA, and Toxics Division (ARTD)

The Air, RCRA, and Toxics Division, under the supervision of its Director, is responsible for the Clean Air Act (CAA), Resource Conservation & Recovery (RCRA), Toxic Substance Control, Underground Storage Tank, Leaking Underground Storage Tank, regulatory (other than Water) and industrial sector programs. The Pollution Prevention program, also housed in ARTD, serves as an advocate for Pollution Prevention approaches for all Region 7 programs and manages the Region 7 Pollution Prevention grants.

3.3.2 Environmental Services Division (ENSV)

The Environmental Services is responsible for compliance inspections (air, RCRA, and water enforcement), environmental monitoring (ambient air and water), the State Safe Drinking Water Act Laboratory certification program, managing the Regional quality system, environmental evaluations, Geographical Information Systems (GIS) , providing laboratory services, developing an expanded cross-media data integration and analysis program, and the National Environmental Policy Act program.

3.3.3 Superfund Division (SUPR)

The Superfund Division, under the supervision of its Director, is responsible for Superfund Emergency Response/Preparedness, Site Assessment, Remedial, Removal, Federal Facilities, and Oil spills programs. The Brownfields program is also managed within SUPR. The Superfund Division has an approved divisional QMP which further outlines the technical activities and programs requiring quality management within the Division.

3.3.4 Water, Wetlands, & Pesticides Division (WWPD)

The Water, Wetlands, & Pesticides Division, under the supervision of its Director, is responsible for the Clean Water Act, Safe Drinking Water Act, Federal Insecticide, Fungicide and Rodenticide Act, and Endangered Species Act. The Regional Community Based Environmental Protection Program is also managed within WWPD.

3.3.5 Office of Regional Counsel (CNSL)

The Office of Regional Counsel, under the supervision of Regional Counsel, serves as a central legal office providing regional and national leadership in the environmental arena, particularly in the area of enforcement.

3.3.6 Office of External Programs (OEP)

The Office of External Programs, under the supervision of its Director, is responsible for environmental outreach and cultivating environmental values with Agency customers, the states and tribal partners. Other major responsibilities include: media relations; Congressional relations; small business assistance; small community outreach; information sharing; Freedom of Information Act; peer review of journal articles and public statements; and environmental education.

3.3.7 Enforcement Coordination Office (ECO)

The Office of Enforcement Coordination, under the supervision of its Director, provides cross-program enforcement coordination for the Region 7 divisions. The Office is a focal point for review and dissemination of national enforcement guidance and strategy, and coordination of enforcement agreements with headquarters and states. The Office manages Project XL and other re-invention initiatives, as well as compliance assistance and general coordination for federal facilities. The Office is responsible for environmental justice coordination and managing the Region 7 environmental justice grant program.

3.3.8 Office of Policy and Management (PLMG)

The Office of Policy and Management, under the supervision of its Assistant Regional Administrator, is responsible for policy, strategic planning, state relations including capacity building, tribal and multimedia program coordination, budget formulation, financial implementation, contracts, grants, cooperative agreements, facilities, human resources, health and safety, information management, computer services, library and other administrative services (supplies, motor pool, mail, etc.).

3.4 Key Region 7 Personnel

3.4.1 Management

Regional Administrator

The Regional Administrator is responsible to the Administrator, within the boundaries of Region 7, for the execution of the Regional environmental programs of the Agency and such other responsibilities

as may be assigned. The direct responsibility for assuring data quality rests with regional Division and Office Directors. Ultimately, the Regional Administrator is responsible for establishing quality assurance policy and for resolving quality assurance issues identified through the quality system. Major quality assurance related responsibilities of the Regional Administrator include the following:

- ensure that all Region 7 components and programs comply fully with the requirements of this QMP;
- ensure that quality assurance is an identified activity with associated resources adequate to accomplish program and Regional goals in planning, implementing, and evaluating all environmental programs;
- ensure that all applicable environmental programs delegated to state, local, and Tribal governments or performed by organizations outside EPA pursuant to EPA mandates comply fully with the requirements of this QMP;
- ensure that quality assurance (QA) and quality control (QC) training is provided to Regional management and staff, as defined by this QMP;
- ensure that state and local governments performing environmental data collection for EPA have current EPA-approved QMPs;
- ensure that QA and QC training are provided to state and local governments performing environmental data generation for EPA, as defined by this QMP; and
- ensure periodic evaluations are conducted of internal and external environmental programs to determine the effectiveness of their quality systems.

The Regional Administrator authorizes the Division and Office Directors to be responsible for quality assurance development and implementation in accordance with this QMP. The RQAM within ENSV has been authorized to conduct oversight and management of the Region 7 quality system.

Environmental Services Division Director

The Environmental Services Division Director serves a dual role as Director of a Regional division and as the Senior Staff member with oversight of the Regional quality system.
The Division Director, in conjunction with the RQAM, will resolve any QA issues as they pertain to operations performed by the Data Integration and Support Operations Branch.

Manager, Data Integration and Support Operations Branch

Major responsibilities include:

- supporting the RQAM and other QA staff (collectively, the QA Team) with required resources;
- meeting regularly with the RQAM to provide feedback and guidance on QA matters;
- approving recommendations relating to QA matters; and
- advocating the QA Team cause and working to overcome barriers.

The Manager of the Data Integration and Support Operations Branch serves as the first line supervisor of the RQAM.

3.4.2 Quality Assurance Personnel

The RQAM is responsible for ensuring Region 7 management and staff understand the requirements for the quality system as defined in the QMP. The RQAM and the permanently assigned QA staff form the QA Team. The RQAM is the Team Leader for the QA Team and receives additional QA support from the Quality Assurance Coordinators (QACs).

Quality Assurance Team - Regional Quality Assurance Manager

The RQAM is the authorized manager of the Region 7 quality system and has direct access to the Regional Administrator on all matters pertaining to quality assurance. The main responsibility of the RQAM is quality assurance oversight and ensuring that all personnel understand the QMP and their QA and QC responsibilities. The RQAM reviews and approves a variety of quality system documents and provides additional QA support as needed. Responsibilities include:

- interpreting Agency QA policy and developing the QA policy for Region 7 in accordance with Agency QA policies and direction from Regional management;
- maintaining the QMP in an up-to-date condition in regard to content and conformity with Agency requirements, as appropriate;
- preparing a Quality Assurance Annual Report and Work Plan (QAARWP) for the Regional Administrator and the Agency's Quality Staff;
- reviewing and approving QMPs from regional, state, tribal, local, or other governmental program offices, and contractors;
- developing quality assurance budgets;
- assisting project officers and project managers in developing QA documents and in providing answers to technical questions;
- ensuring that all personnel involved in environmental data generation and use have access to any training or QA information needed to be knowledgeable in QA requirements, protocols, and technology;
- reviewing and approving quality assurance project plans (QAPPs) and other project-level documents;
- reviewing and approving the QA review form submitted for contracts to determine the necessary quality assurance requirements and to certify that the review took place;
- reviewing and approving standard operating procedures (SOPs);
- overseeing the implementation of internal and external QA management evaluations;
- assisting in solving QA-related problems at the lowest possible organizational level;
- serving as the Regional liaison with the Agency's Quality Staff; and
- responding to evaluations performed on the Regional quality system and establishing corrective

actions

The RQAM has the authority to carry out these responsibilities and to bring to the attention of the Regional Administrator/Deputy Regional Administrator any issues associated with these responsibilities. If the issues are in dispute, however, Section 3.6 of this QMP addresses dispute resolution.

Quality Assurance Team - Permanently assigned QA Staff

The permanently assigned QA staff provide assistance to the RQAM in the oversight and management of the quality system. The responsibilities of the permanently assigned QA staff, as authorized by the RQAM, include:

- assisting the RQAM with the development and maintenance of the QMP;
- providing input to the QAARWP as requested;
- reviewing QMPs from contractors, regional, state, tribal, local, or other government program offices and commenting to RQAM on content;
- assisting with the development of quality system documents;
- reviewing QAPPs and other project-level documents, commenting on content to RQAM, and recommending approval actions;
- reviewing SOPs and commenting on their content to the RQAM;
- developing and presenting QA training as required;
- assisting with the conduct of internal and external management evaluations and technical evaluations as assigned; and
- providing technical assistance on QA-related issues as requested.

Quality Assurance Coordinators (QACs)

Additional support is provided to the RQAM through the division and office QACs. The QACs are the main points of contact within each of the four Regional Divisions and the four Regional Offices. The responsibilities for the QACs include:

- acting as a conduit for QA information to Division and Office staff;
- assisting the RQAM in developing quality assurance policies and procedures;
- providing input to the QMP and the QAARWP as requested by the RQAM;
- promoting quality assurance within Region 7 and with cooperating organizations; and
- coordinating with the RQAM to provide QA support to other staff and external organizations as needed.

Each division and office QAC has the authority to carry out these responsibilities and to bring to the attention of his or her respective Division and Office Director any issues related to these responsibilities. For divisions and offices which have an approved divisional or office QMP, the QAC will have additional responsibilities which will be specified in their approved divisional or office QMP.

3.4.3 Division and Office Directors, Supervisors, and Project Managers

Division and Office Directors

The Division and Office Directors have overall responsibility for their respective quality system. The Director is responsible for ensuring that quality assurance is an identifiable activity within their program(s), for providing adequate resources to support quality system efforts, and for accomplishing the quality assurance objectives of all intramural and extramural environmental data activities within their program(s).

Supervisors

Supervisors are ultimately responsible for the quality of data and include all supervisory personnel at the branch, unit, and section levels. The responsibilities for Supervisors include:

- assessing staff members' QA training needs and arranging for such training with the RQAM;
- participating in a systematic planning process;
- assuring that QAPPs are in place before projects begin;
- ensuring that all sampling, analytical, and data-handling procedures performed within the organization are consistent with accepted scientific principles and EPA mandates, documented, and adequately reviewed; and
- ensuring that corrective actions are implemented.

Project Officers/Project Managers/Work Assignment Managers

Project managers are defined, in the context of this QMP, as those individuals assigned the responsibility of handling, directing, or managing a task or activity. Region 7 project managers can include, but not be limited to, the following:

- project officers;
- work assignment managers;
- remedial project managers;
- on-scene coordinators.
- team leaders;
- compliance officers;
- inspectors; and

For the purposes of this QMP, the term Project Manager will be used generically to indicate any of the above positions or any other individual acting in the capacity of a Project Manager. Project Managers are responsible for ensuring that the quality assurance requirements in this QMP are met as they relate to their responsibilities. It is recognized that the Project Manager may not have experience in quality assurance. Therefore, it is critical that they work closely with the RQAM to be sure QA issues are appropriately addressed including QA requirements related to grants, contracts, cooperative agreements, interagency agreements, enforcement-related documents, and special initiatives/projects.

Project Managers have primary responsibility for coordinating the following QA and QC activities for their assigned projects with the RQAM:

- ensuring that work assignments, work plans, and contract deliverables include appropriate QA documents;
- preparing and implementing approved QAPPs for intramural projects;
- ensuring that approved QAPPs are developed for and implemented in extramural projects;
- coordinating with the RQAM on the selection and design of audits and performance evaluation materials appropriate for the project; and
- identifying, resolving, and implementing project-specific QA and QC issues (which may include data quality assessment, information management, data integration, and data validation).

3.5 Delegated Programs

The following programs have been delegated to the states in Region 7:

- RCRA - Subtitle C (hazardous waste): Nebraska and Kansas have the base program, Missouri has the majority of the program, and Iowa has no delegation;
- RCRA Subtitle I (underground storage tanks);
- Air - Clean Air Act Title I permits, Title V permits, and most of Title III air toxics
- Public Water Supply;
- Underground Injection Control: Region 7 has direct implementation responsibilities for Iowa;
- Pesticides: all four states in Region 7 have primacy;
- National Pollutant Discharge Elimination System;
- Pretreatment: Missouri and Nebraska have partial delegation; and
- Toxic Substances Control Act (TSCA)
  - 402 of TSCA (Lead Training Certification program): Iowa, Missouri, and Kansas are currently running the program with final approval pending
  - 406 (b) of TSCA (Pre-Renovation Notification program): Iowa has applied

There are no delegations for the Sludge, Oil Pollution Act, Wetlands, Water Quality Standards, or Chlorofluorocarbons (CFCs) programs. The TMDL (Total Maximum Daily Load) program is not an officially delegated program; the states have first responsibility.

The Region's QA responsibilities in relation to these delegated programs is oversight through management systems reviews, program audits, and review and approval of QAPPs. The Region's QA responsibilities in relation to those programs not delegated includes the review and approval of QA documents as outlined in Chapters 4 and 9 of this QMP.

3.6 Dispute Resolution

For those situations in which issues regarding quality assurance are in dispute, resolution should be sought at the lowest management level practicable. Such disputes may occur in situations involving technical issues (e.g., audits, data quality assessments) and management issues (e.g., QMP reviews, QAPP reviews, management system reviews).

All parties should make every effort to resolve disputes through discussion and negotiation. Disagreements should be resolved at the lowest administrative level possible. Should agreement not be reached at this level, the issue will be resolved by the Region 7 senior management team (office and division directors). The Region 7 Deputy Regional Administrator has final dispute authority on all Region 7 quality assurance issues.

4. QUALITY SYSTEM COMPONENTS

To meet its stated mission using environmental data as identified in Section 3.1 of this QMP, Region 7 must implement a quality system that assures environmental data are of known quality and can be used for their intended purpose. The principal components of the Region 7 quality system are quality system documents, management evaluations, project-level planning, project-level documents, routine procedures documents, project-level evaluations, and quality system personnel standards. The following tools are used in implementing the principal components of the quality system:

- Quality Management Plans (quality system documents)
- Quality Assurance Annual Report and Work Plan (quality system documents)
- Quality System Audits and Management System Reviews (management evaluations)
- Annual Program Reviews (management evaluations)
- Systematic Planning Process (project-level planning)
- Quality Assurance Project Plans (project-level documents)
- Generic Quality Assurance Project Plans (project-level documents)
- Standard Operating Procedures (routine procedures documents)
- Analytical Methods Manual (routine procedures documents)
- Data Quality Assessments (project-level evaluations)
- Technical System Audits (project-level evaluations)
- Performance Evaluations (project-level evaluations)
- Quality Assurance Training (quality system personnel standards)

Details regarding how the identified components are implemented and the responsibilities for management and staff are included in the description for each quality system tool.

4.1 Quality System Documents

4.1.1 Internal Quality Management Plans

The Region 7 QMP contains the quality assurance policies, procedures, and management systems governing the Region 7 quality system. The document 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 evaluating activities conducted. Region 7 management is implementing these quality assurance policies to ensure that all environmental data generated for or by Region 7 are of known and acceptable quality.

The QMP is developed by the RQAM with assistance, as appropriate, from the permanently assigned QA staff, QACs, and Division and Office Directors. The QMP is intended for use by all Regional staff. A hardcopy of the QMP will be filed with each Regional Division/Office and the Regional Library. A hardcopy will also be filed with the Regional Directives Manager. The approved QMP will also be accessible to all Regional staff through the Regional InfoNet and to external

organizations through the Region 7 home page. Approval of the QMP will include the RQAM, Division/Office Directors, and the Regional Administrator. It will then be submitted for approval to the Acting Assistant Administrator for the Office of Environmental Information, based on an affirmative recommendation by the Director of the Quality Staff . The approval is valid for up to five years, pending changes to the organization or results from management system reviews.

A regional division or office may be authorized to administer Region 7 quality system policies and procedures. The authority will be documented in the form of a QMP prepared according to the most current version of EPA Requirements for Quality Management Plans, EPA QA/R-2. The QMP must describe the management policies, objectives, procedures, organizational authority, roles, and responsibilities to be implemented by the division or office to ensure environmental data are of the type and quality needed for their intended use. The QMP will be reviewed by the RQAM or designee for compliance with R-2 and the QMP Review Checklist (included as Attachment B to this QMP). The QMP must be approved by the RQAM and the Regional Administrator. The Superfund Division currently has an approved QMP in place.

4.1.2 External Quality Management Plans

All applicants for Region 7 financial assistance involving environmental data generation or use must prepare a QMP according to the most current version of EPA Requirements for Quality Management Plans, EPA QA/R-2. The QMP must describe the management policies, objectives, procedures, organizational authority, roles, and responsibilities to be implemented by the organization to ensure environmental data are of the type and quality needed for their intended use. The QMP will be reviewed by the RQAM or designee for compliance with R-2 and the QMP Review Checklist (included as Attachment B to this QMP). The QMP must be approved by the RQAM and the Regional Administrator for organizations receiving assistance for a variety of environmental programs. The QMP must be approved by the RQAM, the regional program manager, and/or the Regional Administrator for organizations receiving assistance for an individual program.

Under the EPA quality system, QMPs are supported by project-specific QAPPs; however, there may be situations when a single document is applicable. Because of these situations and the fact that the Region supports the use of the graded approach, the RQAM may grant exceptions or modifications to the requirement for a QMP from an organization receiving financial assistance from Region 7. Each exception or modification will be determined on a case-by-case basis by the RQAM. A document in place of a QMP will still be required but the content of this document will be defined by the RQAM. In general, organizations receiving financial assistance may be granted an exception or modification to the QMP requirement if they meet criteria which may include, but not be limited to, the following:

- small grants as defined by the EPA Small Grants Policy;
- one-time, short-term, and special projects or projects of limited scope; and
- organizations using or generating environmental data for public education purposes.

If an organization is granted an exemption or modification, it will be documented on the Programmatic Certification-Authorization to Award an Assistance Agreement form (see Section 6.2.1 of this QMP for further details) and will only apply to the QMP requirement.

4.1.3 Quality Assurance Annual Report and Work Plan (QAARWP)

The QAARWP is a summary of specific activities within the quality system. The Region's implemented QA activities of the previous fiscal year and the planned QA activities for the upcoming fiscal year beginning in October are summarized in the QAARWP. It will be prepared according to Chapter 4 of the most current version of the EPA Quality Manual (5360 A1) by the RQAM with cooperation from the permanently assigned QA staff and the QACs. The QAARWP will also be used to identify minor changes or updates to Region 7's QMP. The QAARWP will be electronically submitted to the Director of the Quality Staff by November 15 of each year (or other date as specified by the Director of the Quality Staff). The electronic submittal will be followed by a hard copy of the QAARWP signature page signed by the RQAM and the Regional Administrator. Section 10.1 of this QMP provides additional information about the use and approval of the QAARWP.

4.2 Management Evaluations

4.2.1 Quality System Audits (QSAs) and Management System Reviews (MSRs)

A quality system audit (QSA) or management system review (MSR) is a qualitative evaluation 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. They are used to determine the effectiveness of, and adherence to, the quality system and the adequacy of resources and personnel provided to achieve and ensure quality in all activities. The Quality Staff plans to implement independent QSAs of the Region 7 quality system once every three years. See Section 11.2.1 of this QMP for more information regarding QSAs.

MSRs of internal programs and external organizations will be conducted by the QA Team as detailed in Section 11.2.1.2 of this QMP.

4.2.2 Program Reviews

The QA Team will participate in annual program reviews as identified in Section 11.2.2 of this QMP.

4.3 Project Level Planning - Systematic Planning Process

A systematic planning process is a common sense, graded approach to planning projects to ensure that the level of detail in planning is commensurate with the importance and intended use of the work and the available resources. Section 9.2.1 of this QMP provides additional detail regarding the use of systematic planning, including the Data Quality Objectives process.

4.4 Project-Level Documents - Quality Assurance Project Plans

A QAPP is a project-level document describing in comprehensive detail the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of work performed will satisfy the stated performance criteria. The QAPP is also used as a means for documenting the results of a systematic planning process. The EPA Order 5360.1 A2 requires all applicable projects and tasks involving environmental data to have a written and approved QAPP prior to the start of the data generation or use. See Sections 9.2.2 - 9.2.8 of this QMP for more information pertaining to the Region's requirements for QAPPs.

4.5 Routine Procedures Documents

4.5.1 Standard Operating Procedures

Regional routine technical and administrative activities will be documented in an SOP to ensure consistency in the quality of the product. The SOPs will include thoroughly described steps and techniques and will be sufficiently clear to be readily understood by a person knowledgeable in the general concept of the procedure. Details regarding the Regional SOP System, the preparation, and the review and approval process for SOPs are described in Section 10.3 of this QMP.

4.5.2 Analytical Methods Manual

Laboratory analytical methods will be documented using the Environmental Monitoring Methods Council format and will be compiled in the Region 7 Analytical Methods Manual. Details regarding the Analytical Methods Manual and the review and approval process are described in Section 10.4 of this QMP.

4.6 Project-Level Evaluations

4.6.1 Data Quality Assessments

A data quality assessment (DQA) is the scientific and statistical evaluation of data to determine if data obtained from environmental data operations are of the right type, quality, and quantity to support their intended use. The use of the DQA process in Region 7 is covered by Section 11.2.6 of this QMP.

4.6.2 Technical Systems Audits

Technical systems audits (TSAs) are a thorough, systematic, on-site, qualitative audit of facilities, equipment, personnel, training, procedures, recordkeeping, data validation, data management, and reporting aspects of field and laboratory activities. TSAs, as they apply to Region 7, are further described in Section 11.2.3 of this QMP.

4.6.3 Other Technical Audits

Other types of technical audits can include, but not be limited to: readiness reviews, surveillance, and audits of data quality. These types of audits, as they apply to Region 7, are further described in Section 11.2.4 of this QMP.

4.6.4 Performance Evaluations

A performance evaluation (also referred to as a performance testing sample) is a type of audit where samples of known concentration are analyzed by a laboratory to evaluate the proficiency of an analyst or laboratory. Additional detail regarding performance evaluations can be found in Section 11.3 of this QMP.

4.7 Quality System Personnel Standards - Quality Assurance Training

Region 7 focuses on QA training to assure that QA responsibilities are recognized, understood, and implemented by Regional staff. All Regional personnel involved with environmental data generation or use will be required to have this QA training. The specific QA training requirements for the different levels of Regional personnel are detailed in Chapter 5 of this QMP. QA responsibilities are not currently incorporated into performance standards, however, the emphasis on QA training should have a greater impact on implementing the Region's QA policy statement and achieving the Region's stated mission.

5. QUALIFICATIONS AND TRAINING

It is Region 7's policy to provide the quality assurance and quality control training necessary to ensure that all persons involved in handling environmental data understand Region 7's quality system. The following sections describe Region 7's QA training program and the requirements for regional personnel involved with environmental data use and generation.

5.1 Region 7's QA Training Program

To assist personnel with their responsibilities and requirements, Region 7 has developed a formal training program. Region 7's QA Training Program consists of a core curriculum of courses which are administered by the QA Team in conjunction with additional courses which are administered by other regional offices, program offices, and the Quality Staff. This section describes the courses, the program logistics, and the associated documentation.

5.1.1 Courses

Region 7 implemented a routine QA training program in 1999. The program includes several courses which are offered on a routine basis. The specific schedule will be described in the QAARWP and posted on the Region 7 Info-Net and internet sites. In general, the core courses will be offered at least once a year, but will typically be offered 4-8 times throughout the year. The core courses are summarized in Table 1.

Additional courses may be developed as the needs are identified. Additionally, courses offered by the Quality Staff, other regions, and professional organizations may be invited to the Region to provide support in non-routine areas as needed.

Table 1 Quality Assurance Core Courses

Course Title	Length	Comments
Orientation to Quality Assurance for Managers	may vary	A brief overview of the components of the quality system with a focus on the Region 7 QMP
Orientation to Quality Assurance	4 hours	A detailed overview of the components of the quality system.
Quality Assurance for Supervisors	6-8 hours	A shortened course blending the Orientation and Project Manager's courses

Systematic Planning Process and Quality Assurance Project Plans	8 hours	An example of a project planning meeting while learning about the components of SPP and QAPP. Can be taught as two half-day courses.
Data Quality Assessments	4 hours	Introduction to DQA with a focus on DataQUEST. Taught to non-statisticians.
Quality Management Plans	4-6 hours	Customized for each customer. Usually as a special request for a program. May include time for drafting individual outlines for QMP.
Standard Operating Procedures	2 hours	The first hour describes the possible components within an SOP, and the second hour focuses on the organization's requirements. EPA's requirements follow G-6.
QA Refresher Course	1-2 hours	Projected completion in FY2001. Staff will be required to take this course every 3 years to maintain their QA proficiency.

5.1.2 Logistics

The RQAM and permanently assigned QA staff will provide the core courses on a routine basis. The QA Team will maintain and archive the necessary documentation for training, including copies of the course slides, related handouts, announcements, attendee lists, attendee evaluations, a database of attendees, and copies of the QAARWP.

The minimum training requirements are described in the training requirements section below. The RQAM and the ENSV Division Director are responsible for granting any variances or waivers for training. In order to grant a waiver for QA training, the individual must initiate a request for a waiver. This request must be routed through the requestor's Division Director and addressed to the ENSV Division Director. The ENSV Division Director and the RQAM will grant a waiver based on a certificate of completion for a functional equivalent course and the course outline, or a memo of justification which assures the Division Director and the RQAM that the individual understands the EPA Quality System.

Additional QA training needs which have been identified by the divisions, program offices, and QACs will be provided when needed. Modifications to the core courses may be made to address

programmatic issues. However, all key topics must be described in order to maintain the basic integrity of the original course.

5.1.3 Documentation of Training

After completion of a course, attendees will receive a certificate of completion from the RQAM. For this reason, attendees at the courses will be recorded. The QA Team will maintain a record of all QA training taken by all personnel. The regional training database, Registrar, will be the official record for EPA staff members. QA Training will be listed as a technical training course with the specific course title. Additionally, the QA Team's database, Quality Assurance Training Tracking System (QATTS), will be the secondary record for QA training of EPA personnel and the primary record for non-EPA personnel. This database will provide the record of all QA training, the necessary recertification information, and notes to any waivers.

At the end of each fiscal year, a summary of the QA training will be provided in the QAARWP, including but not limited to the courses offered, the number of attendees (both EPA and non-EPA), and a listing of all non-EPA participating organizations.

5.2 Training Requirements

In order for the quality system to be effective and to be implemented in a consistent manner throughout the Regional programs and organizations, the staff needs to be properly equipped with the appropriate level of knowledge of quality assurance policies, principles and procedures. The QA training program is intended to fulfill this need. The staff members who are directly involved in the generation and/or use of environmental data are the primary focus of the training program. However, there are others (such as supervisors and projects managers) who should have at least a familiarity with QA.

Region 7's training program incorporates a tiered approach relative to the functions performed by the various groups of personnel. This section outlines the minimum QA training requirements for the various groups of personnel.

5.2.1 Management

Division and Office Directors are responsible for ensuring the Region 7 quality system is implemented as described and the resources are available in meeting the criteria of the system. Therefore, it is critical that management has a good understanding of the quality system and quality management issues described in the regional QA training course "Orientation to Quality Assurance for Managers". The individual Divisions and Program Offices, through their QACs, and with the necessary assistance from the RQAM are responsible for identifying needed QA training within their

organizations.

5.2.2 Supervisors

Supervisors are ultimately responsible for the quality of data. Therefore, it is critical that supervisors receive the necessary awareness training to ensure their understanding of the importance of quality assurance, their responsibilities as supervisors of environmental data activities, and specific Region 7 quality assurance policies and procedures. Toward that end, supervisors who oversee environmental programs which generate or use environmental data will attend the "Orientation to Quality Assurance for Managers" overview. The "QA for Supervisors" course will be routinely offered for supervisors to provide a more in-depth description of the Region 7 quality system and how it applies to them and their environmental programs. Additional training may be required depending on the specific duties and responsibilities of the individual.

Supervisors and their divisional QAC, with necessary assistance from the RQAM, are responsible for identifying and providing program-specific quality assurance training. Minimally, supervisors will assess and summarize their needs annually, and will provide the listing to the QACs in September for input to the QAARWP which is further addressed in Section 10.1 of this QMP.

5.2.3 Project Managers, Lab and Field Personnel

Project managers, lab personnel, and field personnel are responsible for ensuring that all projects are conducted with known quality, and are in compliance with the agency standards. In the performance of these functions, the project manager prepares or reviews QAPPs. Therefore, it is critical that project managers receive the necessary training, including "Orientation to Quality Assurance", "Systematic Planning Process and Quality Assurance Project Plans", and "Data Quality Assessment". Additional training may be identified by the project manager, their supervisor, or the RQAM.

5.2.4 Permanently assigned QA Staff and QACs

QACs and permanently assigned QA Staff are responsible for assisting the RQAM with quality issues. As part of this responsibility, the QACs and permanently assigned QA Staff will assist in writing or reviewing quality documents, including QAPPs, SOPs, and QMPs. Therefore, it is critical that the RQAM, QACs and permanently assigned QA Staff receive the necessary training, including "Orientation to Quality Assurance", "Systematic Planning Process and Quality Assurance Project Plans", "Data Quality Assessment", "Standard Operating Procedures", and "Quality Management Plans". Additional training may be identified by their supervisor or the RQAM. QACs assist within program areas and may focus additional training within the program area, while the RQAM and permanently assigned QA Staff assist at the regional level and may focus additional training in general

areas such as statistics, auditing, and trainer training.

5.2.5 RQAM

The RQAM is responsible for identifying training needs, disseminating information regarding available training opportunities for Region 7 staff and management, and arranging region-wide quality assurance training, with guidance and assistance from the Quality Staff. Specifically, the RQAM will ensure that

- Supervisors have the orientation training and the in-depth Supervisor training is routinely offered;
- Project managers and EPA personnel will have a minimum of 16 hours QA training;
- Quality Assurance personnel (permanently assigned QA Staff and QACs) will have a minimum of 24 hours training. Any additional QA training to perform specific duties such as auditing or trainer training, and any technical training which would facilitate the understanding of the agency's operations would be discussed in the individual's mid-year and annual performance appraisal;
- The necessary training is made available to all grantees including State and Tribal personnel;
- All trained staff members are recertified every three years; and
- Any special training requests by EPA, state, or tribal personnel are coordinated.

The RQAM is responsible for arranging or providing for the training needs identified by the Divisions and Program Offices. Specific organizational training needs will be addressed annually in the QAARWP.

5.2.6 Recertification

All personnel who are involved in environmental data generation and use will be required to attend "QA Refresher Course" every three years to maintain their quality assurance proficiency. The "QA Refresher Course" will be developed by FY 2001.

5.3 Assurance for Grants and Contracts

All Project Managers are responsible for ensuring that all grant recipients or contract personnel involved with environmental data generation and use have the necessary QA training to successfully complete their granted or contracted tasks and functions. Minimum QA training requirements should be described in the organization's approved QMP.

The RQAM will ensure that fundamental training courses for grants and contracts include segments addressing QA requirements and responsibilities for project managers. Specifically, a QA

overview will be provided as part of the managing your financial assistance training and the contract administration training. This overview is to simply inform the trainees of the required training and the required quality assurance documents.

6. PROCUREMENT AND FINANCIAL ASSISTANCE

It is Region 7 policy to state the designated quality assurance and quality control requirements when acquiring items and/or services that may result in or relate to environmental programs. Within Region 7, procurement functions are conducted in accordance with the Federal Acquisition Regulations, and generally accepted business practices for the acquisition process. The Region 7 Quality System does invoke the Agency's graded approach. This approach allows the RQAM a certain degree of latitude in the requirements set forth below. Any deviation from the requirements set forth below must be documented in the project/contract file.

6.1 Procurement - Contracts

All procurements originating at Region 7 must meet established administrative and quality assurance requirements in the latest editions of:

- the Federal Acquisition Regulations, Part 13
- the Acquisition Handbook (AH),
- the Contracts Management Manual (CMM).

Quality assurance requirements for contracts are set forth in the EPA Contracts Management Manual and the Federal Acquisition Regulation (FAR) 46.202-4. The Contracts Management Manual is currently undergoing revision and until such time as the revisions are complete, the Procurement Policy Notice 01-02, "Guidance for Use of Higher-level Contract Quality Requirements in Acquisitions,"dated March 20, 2001, is in effect and will be followed by the Region.

Requirements include the QA Review Form, or other program-specific QA review form, that includes, as a minimum, the information shown in Attachment D. In addition to the QA Review Form, the Procurement Policy Notice forms for Contracting Officer Representatives (e.g., project officers, work assignment managers, task order managers, etc.) and for Contracting Officers will be used as part of the contracting process (Attachments I and J, respectively) as an interim measure until the Contracts Management Manual can be revised. The QA review form shall be completed as required and signed by the Project Manager and the RQAM to assure that all environmentally-related measurements which are funded by EPA or which generate data mandated by EPA are scientifically valid, defensible, and of known precision and accuracy.

Region 7 contracts (as opposed to those originating at Headquarters) involving environmental programs shall submit a QMP prepared in accordance with the specifications provided in the most current version of EPA Requirements for Quality Management Plans (QA/R-2), which describes the quality system implemented by the applicant. The QMP shall be reviewed and approved by the EPA Contracting Officer, the EPA Project Manager, and the RQAM as described in Section 4.1.2 of this

QMP as a condition for award of any contract. The QMP must be submitted as part of the application.

If the QMP is not submitted as part of the application and EPA decides to award the contract, EPA will include a term and condition in the contract. This term and condition requires the recipient to submit the QMP within a specified time after award of the contract and notifies the recipient that they may not begin work involving environmental programs until the EPA Contracting Officer informs them that the QMP has been approved.

The contractor shall also be required to submit QAPPs to EPA for review and approval by the EPA Project Manager and the RQAM as described in Section 9.2.3 of this QMP before undertaking any work involving environmental programs. All QAPPs shall be prepared using the most current version of EPA Requirements for Quality Assurance Project Plans (QA/R-5), which describes the quality assurance and quality control activities to be implemented to satisfy the performance criteria for the work involving environmental programs.

When a contract originates at the Regional level and involves the generation or use of environmental data, the RQAM or an individual knowledgeable in QA may be included as part of the Technical Evaluation Panel (TEP) to evaluate the adequacy of the QA documents required. The TEP develops the evaluation criteria and the Statement of Work for the solicitation and performs the technical evaluation of offers.

6.2 Financial Assistance

6.2.1 Grants and Cooperative Agreements

The applicant shall complete a Quality Assurance Requirement form (see Attachment G), indicating whether the assistance involves an environmental data generation or use. A narrative description of the program or project associated with the assistance is provided with Standard Form 424 (SF-424, see Attachment E). The description contains 5 parts:

1) Objective;
2) Results or Benefits Expected;
3) Approach;
4) General Program/Project Information, and
5) Quality Assurance Requirement.

The decision on whether a grant or cooperative agreement involves environmental data generation or use is determined by the EPA Project Manager in consultation with the RQAM and a review of the narrative description provided with the SF-424. The Programmatic Certification-Authorization to Award an Assistance Agreement form is signed and dated by the EPA Project

Manager (see Attachment F).

All applicants for grants or cooperative agreements involving environmental programs shall submit a QMP prepared in accordance with the specifications provided in the most current version of EPA Requirements for Quality Management Plans (QA/R-2), which describes the quality system implemented by the applicant.

The applicant's QMP shall be reviewed and approved as described in Section 4.1.2 of this QMP as a condition for award of any assistance agreement. The QMP must be submitted as part of the application. If the QMP is not submitted as part of the application and EPA decides to fund the project, EPA will include a term and condition in the assistance agreement. This term and condition requires the recipient to submit the QMP within a specified time after award of the agreement and notifies the recipient that they may not begin work involving environmental programs until the EPA Project Manager informs them that the QMP has been approved. Modification or exceptions to the requirement for a QMP may be granted by the RQAM as identified in Section 4.1.2 of this QMP.

The recipient shall also be required to submit QAPPs to EPA for review and approval by the EPA Project Manager and the RQAM before undertaking any work involving environmental programs. All QAPPs shall be prepared using the most current version of EPA Requirements for Quality Assurance Project Plans (QA/R-5), which describes the quality assurance and quality control activities to be implemented to satisfy the performance criteria for the work involving environmental programs. Section 9.2.3 of this QMP provides additional detail regarding the review and approval of QAPPs in Region 7.

Approval of the recipient's QMP may authorize the recipient to review and approve QAPPs, in place of the RQAM, based on procedures documented in the QMP. Section 9.2.4 of this QMP describes Region 7's policy and process for this authorization.

Oversight of QA requirements in the grants and cooperative agreements process is included in the MSRs performed by the QA Team on specific environmental programs (see Section 11.2.1.2 of this QMP). Additional mechanisms will be developed as needed through the Regional Grants Council established to provide a region-wide forum for the discussion and resolution of matters relating to the management of EPA's assistance programs. The Council includes the Senior Resource Official, the Grants Management Officer, up to two representatives from each division/office with responsibilities for managing assistance activities, a grant management specialist and the Financial Management Officer.

6.2.2 Interagency Agreements.

Interagency agreements that are funded by EPA should include QMP and QAPP requirements in the agreement. Since EPA cannot unilaterally impose such requirements, these requirements must be

negotiated into each agreement.

The QMP shall be prepared in accordance with the specifications provided in the most current version of EPA Requirements for Quality Management Plans (QA/R-2), which describes the quality system implemented by the party involved in the environmental program. The prepared QMP shall define the approving officials of the QMP; minimally, this will be the EPA RQAM.

The QMP shall be supported by QAPPs which are submitted to EPA for review and approval before undertaking any work involving environmental programs. All QAPPs shall be prepared using EPA Requirements for Quality Assurance Project Plans (QA/R-5), which describes the quality assurance and quality control activities to be implemented to satisfy the performance criteria for the work involving environmental programs. The prepared QMP shall define the approving officials for QAPPs; minimally, this will be the RQAM.

7. DOCUMENT AND RECORDS MANAGEMENT

It is Region 7's plan to adopt and implement all Agency-approved records management policies and guidance developed by the Office of Administration and Resources Management, Office of Environmental Information (formerly the Office of Information Resources Management). Region 7 adheres to the most current version of the following guidance and policies:

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

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

The EPA Project Manager is responsible for preparing, issuing, using , and revising Quality Assurance Project Plans (QAPPs) in accordance with Sections 9.2.2-9.2.8 of this QMP, as applicable. The RQAM is responsible for reviewing and approving all QAPPs in accordance with the most current version of EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations, EPA QA/R-5. Designated individuals in Region 7 divisions or offices can be authorized by the RQAM to review and approve selected QAPPs if the division or office holds an approved QMP with provisions for such authorization. The RQAM is responsible for preparing, issuing, using and revising the Regional QMP in accordance with the most current version of EPA Requirements for Quality Management Plans, EPA QA/R-2. The Regional QMP requires review and approval by EPA personnel outside of Region 7, but this review is beyond the scope of this document.

When QAPPs are approved by the RQAM, they are returned to the Project Manager. The RQAM does not maintain archival copies of project level quality-related documents, though temporary copies may be kept as needed for the convenience of the QA Team. The Project Manager is responsible for managing all project level quality-related documents and records, including transmittal,

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

8. COMPUTER HARDWARE AND SOFTWARE

The Environmental Protection Agency's ability to fulfill its mission is dependent upon a strong information technology infrastructure. Mission objectives rely on an infrastructure that is capable of supporting environmental information and dynamic communication among EPA offices. One of the most critical components of the EPA infrastructure is information technology. The hardware, software, and communications components that are encompassed by information technology form the foundation for environmental information and EPA-wide communication. The management of information technology, therefore, is critical to the success of the EPA.

The Office of Environmental Information (formerly, the Office of Information Resources Management) and the National Technology Services Division (Office of Technology Operations and Planning, Office of Environmental Information) are responsible for managing the EPA's information technology infrastructure and components. In that role, the Office of Environmental Information and the National Technology Services Division have established information technology standards to manage and ensure that information technology components integrate properly into the infrastructure.

8.1 Region 7 Information Management System

All information management system development, improvements, and updates will comply with EPA Directive 2100, Information Resources Management Policy Manual to include a systematic and comprehensive dialogue among the data providers, data and system users, and system developers, prior to the design of the system.

It is Region 7 policy to work closely with the Office of Environmental Information on all phases of system development, improvements, and updates. During the operational phases of information management systems, Region 7 will comply with requirements within EPA Directive 2100 Information Resources Management Policy Manual and the most current version of the Region 7 System Life Cycle Document. Compliance with the applicable information resource management standards will ensure that all hardware and software configurations are tested prior to use, to guarantee they perform as expected and meet user requirements.

8.2 Hardware and Software Requirements

In addition to the System Design and Development Guidance and Operations and Maintenance Manual, Region 7 will comply with the Office of Administration and Resources Management's Delegation of Procurement Authority Guide. This will ensure that purchased software will meet user requirements and will comply with the Office of Environmental Information.

8.3 Data Standards

All Federal agencies are required to adhere to Federally mandated data standards and regulations. It is the policy of Region 7 to comply with all applicable regulations, guidance, executive orders, and internal policy documents concerning data standards. These include:

- The EPA's information data standards and regulations appear in the Catalog of Data Policies and Standards, 21M-1019, July 1991. It is the responsibility of each individual Region 7 office to be aware of the current standards and regulations.
- The National Institute of Standards and Technology develops standards and guidelines to achieve the most effective use of Federal information.
- The Federal Information Processing Standards are the Federal data standards for all data exchange among agencies. Applicable Federal Information Processing Standards are listed in the EPA document Catalog of Data Policies and Standards, 21M-1019, July 1991.
- The EPA Data Standards Program is established and documented in the EPA Directive 2100 Information Resources Management Policy Manual. Within EPA, adherence to data standards policy is accomplished through the direction of the Office of Environmental Information.

EPA's data-related policies apply to all EPA organizations and personnel, including contractors, Senior Environmental Employee (SEE) Program participants, and other personnel assigned to EPA who design, implement, and maintain information management systems for Region 7 and EPA.

9. QUALITY PLANNING

9.1 Annual Planning

The primary vehicles for annual planning in the Region are the Agency Operating Guidance, the budget process, Regional strategic planning, Performance Partnership Agreements (PPAs), and state annual program work plans. Based on the budget for the Region and guidance from the program managers in EPA Headquarters (contained in the Agency Operating Guidance), the Regional Administrator and the Division/Office Directors develop a Regional strategic plan for the fiscal year. This strategic plan establishes overall goals, priorities for resource utilization and distribution of the Regional budget.

The PPAs describe overall operating objectives and goals between EPA and the state agencies. The individual program managers negotiate with each appropriate state agency to obtain commitments from them on the work they will complete during the fiscal year. These negotiations with the state agencies result in the preparation of the annual program work plans by the state agencies.

The end result of the above efforts is the establishment of overall operating plans for the Region to meet the goals within each program based on state, Regional, and other available resources. The planning for QA is fully integrated into this annual planning process. Any specific QA requirements are included in the PPAs as a condition for grant approvals or in the annual program work plans. Based on the availability of resources and requirements of the Regional Administrator, specific QA activities performed by or for the RQAM are projected in the QAARWP.

9.2 Project-level Planning

9.2.1 Systematic Planning Process

A systematic planning process shall be used for all environmental programs conducted by or for Region 7. The Data Quality Objectives process as described in the most current version of Guidance for the Data Quality Objectives Process, EPA QA/G-4, is recommended and encouraged by the Region but is not mandatory. Any other systematic planning process that is used must include the elements defined in Chapter 3 of the EPA Quality Manual (5360 A1). The Project Manager is responsible for ensuring that a systematic planning process is used and documented. Guidance and technical support in using a systematic planning process will be provided by the QA Team as requested.

9.2.2 Quality Assurance Project Plans

All projects and tasks involving the generation or use of environmental data (as defined in Section 2.1 of this QMP) that are conducted by or for Region 7 shall have an approved QAPP in place prior to the start of data generation or use. It is the responsibility of the Project Manager to ensure an approved QAPP is in place prior to the start of data generation or use. This includes QAPPs prepared for projects or tasks involving environmental data to be performed by Regional staff or through grants and cooperative agreements (40 CFR Parts 30, 31, and 35), and contracts (48 CFR Chapter 15, Part 1546). Interagency agreements are addressed separately in Section 6.2.2 of this QMP.

9.2.3 Quality Assurance Project Plan Preparation, Review, and Approval

Quality Assurance Project Plans are prepared, reviewed and approved in accordance with the most current versions of EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations, EPA QA/R-5, and Guidance on Quality Assurance Project Plans, EPA QA/G-5. All QAPPs prepared by or for Region 7 will be approved by the RQAM or designee for QA requirements and by the Project Manager for technical and programmatic requirements. This includes QAPPs prepared for projects or tasks involving environmental data to be performed by Regional staff or through grants and cooperative agreements (40 CFR Parts 30, 31, and 35), and contracts (48 CFR Chapter 15, Part 1546). Interagency agreements are discussed separately in Section 6.2.2 of this QMP.

The Region 7 SOP 1330.2, Review of Project-level Quality Assurance Related Documents describes in detail the Region 7 process for the review and approval of QAPPs submitted to the RQAM. All QAPPs must be submitted to the RQAM through the Project Manager. Once a QAPP is received the RQAM or designee will review it for compliance with the requirements outlined in R-5 (as identified above). A QAPP review checklist will also be used to facilitate the review; an example of this checklist is included as Attachment C to this QMP. The QAPP review checklist is based upon the most current version of Guidance on Quality Assurance Project Plans, EPA QA/G-5, and will be updated as the guidance is revised. The completed checklist is for internal use by the QA Team and is not provided to the Project Manager or others outside the QA Team; however, a copy of a blank QAPP review checklist is available for use by others on the Region 7 home page. Comments are provided to the Project Manager through four types of review memoranda:

- Approved - the document complies with R-5 and addresses the key issues satisfactorily.
- Approved with comments - although the document satisfactorily addresses most of the key issues and complies with R-5, minor issues were noted. These issues should not have a direct impact on the quality of the resulting data, but are noteworthy of pointing out for the record.
- Approved with conditions - the document was found to be incomplete in addressing some key areas to the extent of potentially jeopardizing the quality of the data. These areas are fully

described in this review memorandum and can be adequately addressed by incorporation into the document but without resubmission. The document would not be approved without the inclusion of the recommendations.

! Resubmission Requested - the document was found to be insufficient in describing the key issues. Further clarification of specific issues is required prior to approval of the plan and initiation of the data collection activity.

Once all critical issues have been addressed, the RQAM will sign the QAPP and return it to the originator of the review. The QA Team will keep only a file copy of the final review memorandum and a copy of the completed QAPP signature page. See Chapter 7 of this QMP for additional details regarding the retention and maintenance of quality-related documents and records.

9.2.4 Quality Assurance Project Plan Review and Approval Authorization

States, tribes, local governments, Regional programs, and other organizations can be authorized to approve some QAPPs in place of the RQAM where federal regulations allow. In order to receive this authorization, an adequate and appropriate process for the development, review, approval, and revision of QAPPs within the organization or program must be documented in an approved QMP. The QMP must be prepared, reviewed, and approved as defined in Sections 4.1.1 and 4.1.2 of this QMP. Other organizations cannot be authorized to approve QAPPs, in place of the RQAM, for ambient air projects (40 CFR 58 Appendix A) and Superfund pre-remedial (40 CFR 35 Subpart O), remedial (40 CFR 35 Subpart O), and removal projects (40 CFR 300). QAPPs falling into these categories must be forwarded to the RQAM for review and approval as previously identified.

The SUPR QAC has been authorized to review and approve some SUPR QAPPs, in place of the RQAM, through the approved SUPR QMP. However, Superfund generic, cross-program, and state-prepared QAPPs must still be forwarded to the RQAM for review and approval.

9.2.5 Generic Quality Assurance Project Plans

For multiple projects or sites with the same objectives and environmental decision(s), a generic QAPP may be prepared. The generic QAPP will still be prepared according to the most current version of EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations, EPA QA/R-5, and Guidance on Quality Assurance Project Plans, EPA QA/G-5, but will address the issues which remain constant among the different projects or sites. Most generic QAPPs will also be supported by site-specific or project-specific addenda which address the issues unique to each site or project. The generic QAPP will specify the preparation, review, and approval of the site-specific or project-specific addenda. Generic QAPPs require a QA review and approval by the RQAM and a technical and program review by the Project Manager. The QA approval of generic QAPPs for external organizations can be authorized in a similar manner as described in Section 9.2.4 of this QMP.

As previously stated, QACs cannot be authorized to review and approve generic QAPPs, in place of the RQAM, because of a generic QAPP's potential long-term and/or cross-program impact. The appropriateness of a generic QAPP is determined on case-by-case basis by the Project Manager in cooperation with the RQAM.

9.2.6 Regulated Facilities

Programs are encouraged to include QA and QAPP requirements in permits and other compliance documents to ensure data of known and documented quality are obtained and to ensure sound environmental decision making.

9.2.7 Quality Assurance Project Plan Implementation

The Project Manager is responsible for ensuring that QAPPs are implemented. This can be done on an informal basis using routine on-site surveillance or project status reports (or other project reports as required and identified in the project-specific QAPP). The Project Manager can also use a more formal process like a TSA to ensure implementation of a QAPP. The TSA can be done with the assistance of the QA Team upon request. The use of a TSA (or some other evaluation) will be identified and described in each QAPP.

9.2.8 Quality Assurance Project Plan Revision

Any revisions required to the approved QAPP can be documented in a second or subsequent revision or an addendum. However, sometimes the scope of a project can change which may have the potential to affect the quality of the data. If these changes are significant (as determined by the Project Manager in consultation with the RQAM as needed) and affect the scope and objectives of the project, data use, or data quality, the revised QAPP or addendum must be reviewed and approved in the same manner as the original QAPP. The Project Manager is responsible for ensuring all appropriate personnel receive a copy of the revised QAPP or addendum once it is approved.

9.3 Acquired Data

As defined in Section 4 of this QMP, acquired data are data or information used for project implementation or decision making which meet some or all of the following criteria:

- are compiled from other sources
- were originally collected for some other purpose
- are obtained from non-measurement sources such as computer databases, programs, literature files, and historical databases

The use of acquired data must be addressed in each project-specific QAPP to include the following information:

- the type of data needed from non-measurement sources
- the acceptance criteria for their use
- a description of any limitations of such data
- the individual(s) responsible for evaluating and qualifying the acquired data

The Project Manager is responsible for ensuring acquired data is addressed in a project-specific QAPP. For those projects which involve the compiling and use of acquired data exclusively (i.e., there will be no direct environmental data generation performed to accomplish the project), a project-specific QAPP will still need to be prepared, reviewed, and approved as described in Section 9.2.3 of this QMP. The Project Manager is responsible for ensuring a QAPP is prepared for these types of environmental data projects. Because the Region supports the use of the graded approach, the content of QAPPs for these types of projects will vary and the standard QAPP format (as identified in the R-5 document) may need to be modified to better meet the needs of these projects. Assistance for developing a modified QAPP regarding acquired data projects will be provided by the QA Team as requested.

10. IMPLEMENTATION OF WORK PROCESS

The procedures described in this section on the implementation of work process must be followed within all Divisions/Offices of Region 7. Within this Section, the implementation of programs will be discussed through the use of the QMP and the QAARWP with the proper levels of management participation and approval identified. Project implementation will also be considered by focusing on the implementation of QAPPs, SOPs, and the Analytical Methods Manual.

10.1 Program Implementation

The QMP will be reviewed annually by the RQAM, with assistance from the QA staff and the QACs, to determine if the information remains relevant to the Region. A briefing of the findings will be provided to senior management. If changes are required, they will be made by November 1 of each year. A description of the changes will be sent out via E-mail to all Region 7 staff and will be submitted to the Quality Staff as an attachment to the QAARWP. The on-line version of the QMP will also be updated to include the changes. Every five years, based upon the original approval date, the QMP will undergo a thorough review, in its entirety, and go through the complete approval cycle. The QMP will also go through the complete approval cycle anytime changes are made to the QMP that include major reorganization, significant changes to the Region's mission, or other major changes to the Region's quality system.

Region 7 developed the QMP as a means of documenting how a Region 7 organization will plan, implement, and evaluate the effectiveness of quality assurance and quality control operations applied to environmental programs. All Divisions and Offices within Region 7 are responsible for their implementation of the QMP. Quality System Audits, internal and external MSRs (as defined in Section 4.2.1 of this QMP) will ensure that the Region 7 quality system is being implemented as documented in this QMP.

The implementation of the Region 7's quality system will also be monitored through the QAARWP. All EPA organizations conducting environmental programs that have a QMP must submit an approved QAARWP to the Director of the Quality Staff as required by the annual call letter and the EPA Quality Manual (5360 A1). The QAARWP will be approved by the RQAM and the Regional Administrator. The purpose of the QAARWP is to inform Agency senior management and Region 7 senior management about the status and effectiveness of Region 7's quality system. The QAARWP documents the findings of management's evaluation of Region 7's quality system, documents performance during the immediate past fiscal year, and provides the work plan for the upcoming fiscal year's priorities for Region 7's quality system.

10.2 Project Implementation

It is Region 7's policy that QAPPs are written for the process that acquires and/or qualifies the data that support decisions. Section 9.2.7 of this QMP discusses the implementation of QAPPs.

Due to unforseen circumstances, changes in a QAPP and planned procedures may become necessary during the project. Refer to Section 9.2.8 of this QMP for further details on how revisions to QAPPs are handled. The Project Manager is responsible for verifying the changes were made as described. This verification can be accomplished on an informal basis using routine on-site surveillance or project status reports (or other project reports as required and identified in the project-specific QAPP). The Project Manager can also use a more formal process like a TSA.

10.3 Standard Operating Procedures

Routine technical (except laboratory analytical methods) and administrative activities will be documented in SOPs to ensure consistency in the quality of the products and/or processes. The SOPs will thoroughly describe steps and techniques, and will be sufficiently clear to be readily understood by a person with knowledge in the general concept of the procedure or process. The need for an SOP for a specific activity or operation can be identified by any staff member in the Region, and can be written by any Regional staff member who is knowledgeable of the activity, equipment, procedure or process to be addressed.

The primary guidance document for the preparation of SOPs is Region 7's SOP No. 1330.4, Preparation of Standard Operating Procedures. The basis of the contents of the SOP is the Quality Staff's document entitled Guidance for the Preparation of Standard Operating Procedures, EPA QA/G-6. The SOP outlines responsibilities, development, approval and filing of SOPs. Also, the specific elements to be addressed in both technical and administrative type SOPs is included in the SOP. All Regional SOPs will be tracked and maintained by the SOP Coordinator as outlined in SOP No, 1340.3, Standard Operating Procedures Tracking and Reporting System. Copies of these documents are readily available from the Regional Quality Assurance Office.

All SOPs will be approved, via signatures on the cover page, by a peer reviewer, the author's immediate supervisor, and an independent QA reviewer (can be a QAC or the RQAM as determined by the immediate supervisor and appropriate QAC or as defined in a Divisional or Office QMP). All SOPs will be reviewed at least every two years from the time of implementation or the last review at which time the SOPs will be revised, recertified or archived (i.e., no longer active). A central set of SOPs will be maintained by the QA Team and the SOPs will be accessible online by all Regional personnel via the Region 7@work intranet site. The SOP Coordinator will maintain signed versions of all Regional SOPs and will maintained the archived SOP file.

10.3.1 Uses of SOPs

The use of SOPs is encouraged as a means of documenting routine or repetitious activities, operations and processes; of formally documenting routine actions; of providing a reference that can be cited in QA documents; and for facilitating the consistency of procedures and processes which will result in reliable data and results. The SOPs developed in Region 7 are accessible by all Region 7 personnel. The Region's SOPs can be referenced in QAPPs and other documents, as appropriate, in order to alleviate having to include descriptions of entire processes or procedures that are routinely performed. Any limitations on the use or applicability of an SOP will be included in the SOP itself.

10.3.2 Implementation of SOPs

The implementation of SOPs is a responsibility that may cross organizational and functional lines depending on the type of SOP (i.e., technical or administrative as defined in SOP No. 2120.1, Preparation of Standard Operating Procedures) and the situation involved. Generally, SOPs are implemented by personnel who perform the activity or function to which the SOP pertains. It is normally the responsibility of the applicable organization's manager to ensure that specific SOPs that pertain to the organization's operations are implemented. It is normally the responsibility of the project manager to ensure SOPs referenced in specific QAPPs are implemented. It is the responsibility of the individual users of an SOP to follow the procedures contained in the SOP, or to document any deviations. The implementation of SOPs will be assessed through internal MSRs, TSAs or other oversight activities.

10.4 Analytical Methods Manual

Laboratory analytical methods will be documented using the Environmental Monitoring Methods Council (EMMC) format and will be compiled in the Region 7 Analytical Methods Manual. The Analytical Methods Manual will be maintained and updated by the Analytical Methods Manual (AMM) Coordinator according to the SOP 2410.13, Maintenance of Region 7 Laboratory Analytical Methods Manual and will be made available on the Region 7 InfoNet. SOP 2410.13 describes the preparation, review, approval, revision, and withdrawal procedures for the analytical methods to be included in the Analytical Methods Manual. The QA Team will maintain a hard copy of the Analytical Methods Manual for use and reference by Regional personnel. The AMM Coordinator will maintain the master copy at the Laboratory. Each method in the manual must be reviewed and approved by the Analytical Operations Program Manager, the RLAB QA/QC Coordinator, and by the RLAB Manager.

Each method in the Analytical Methods Manual will be reviewed at least once every two years and then recertified, updated, or removed from use and archived. If a method needs to be changed or updated, the revised method must undergo the same review and approval process as the original

document. The AMM Coordinator will be responsible for ensuring the Analytical Methods Manual available on the InfoNet and the master copy of each method are updated as necessary. If at any time a decision is made that an analytical method should be available for use by individuals outside of the Region, the analytical method will be become subject to the requirements for an SOP (although the EMMC format will be retained).

Laboratory procedures that do not directly result in the generation of environmental data, but which may or may not be related to a specific analytical method (e.g., glassware cleaning) are called Standard Laboratory Operating Methods (SLOMS) and are reviewed, approved, maintained, and tracked per Regional SOP 2410.13, Maintenance of Region 7 Laboratory Analytical Methods Manual.

10.4.1 Use of the Analytical Methods Manual

Generally, the Analytical Methods Manual is for use by all RLAB analytical personnel and in-house laboratory contractors. The analytical methods within the Analytical Methods Manual can be referenced in QAPPs and other SOPs as appropriate. Any additional limitations on the use or applicability of a method will be documented in the Analytical Methods Manual.

10.4.2 Implementation of the Analytical Methods Manual

The RLAB team leaders and Analytical Operations Branch Manager are responsible for the implementation of the Analytical Methods Manual and for ensuring all analyses are documented with an approved RLAB method. Implementation of the Analytical Methods Manual (as well as verification of implementation of changes in methods) will be ensured through RLAB QA checks including spot checks and yearly evaluations (conducted by RLAB team leaders and the Analytical Operations Program Manager) and internal MSRs conducted by the QA Team as described in Section 4.2.1 of this QMP.

11. EVALUATION AND RESPONSE

It is Region 7's policy to evaluate formally the Region 7 quality system on a regular basis. The mechanisms to be used for this evaluation are summarized below.

11.1 Annual Review of the Quality System and Quality Management Plan

The Region-wide quality assurance procedures described in the QMP will be assessed annually and the QMP updated as necessary. The RQAM will be responsible for coordinating this effort and ensuring that appropriate changes are incorporated into the QMP. Each Division and Office Director will be responsible for ensuring that appropriate staff in their offices participate in the review of the Region-wide quality system. The Division and Office Directors will review and approve changes to the QMP prior to their submittal to the Quality Staff. The annual review of the QMP and the quality system will be undertaken at the same time as the development of the Region 7 QAARWP.

11.2 Audits

Internal and external audits will be the principal means for determining compliance with and effectiveness of the quality system defined in the Region 7 QMP. Internal audits are conducted by the Region 7 QA Team and technical staff. External audits are conducted by the Quality Staff, Office of Inspector General auditors, or Headquarters' program office personnel. The internal and external audits should be conducted at a frequency sufficient to ensure that appropriate quality assurance measures are being implemented. If auditing resources are limited, environmental data collection programs or activities that are highly visible will be given priority.

Section 10 of the SUPR Divisional QMP describes the evaluation program implemented in the SUPR Division. The evaluation program will include MSRs, TSAs, and DQAs. The SUPR QMP describes the process, who is responsible, the training and qualification of assessors, and response to findings. Project-level evaluations in the SUPR Division will be conducted per the site-specific QAPP. Reviews of state SUPR programs are conducted biennially and the review agenda is prepared to address specific issues with each state program.

11.2.1 Quality System Audits (QSAs) and Management System Reviews (MSRs)

Quality system audits and MSRs evaluate a specific quality system to determine its effectiveness and to identify areas where additional attention would bring significant benefits. Quality system audits of Region 7 will be conducted by the Quality Staff and MSRs of internal programs and external organizations will be conducted by the QA Team.

11.2.1.1 QSAs by the Quality Staff

The Quality Staff plans to implement independent QSAs of the Region 7 quality system once every three years. Usually a review team of four members (two from the Quality Staff and two from other Regions) will spend a week in Region 7 meeting with management, conducting personnel interviews, and performing file reviews. Results are reported to the Region through a Draft Findings Report. The Region must respond to the results of the audit and develop a Corrective Action Plan to address any issues which require corrective action. The roles and responsibilities of auditors, experience and training for audit personnel, independence of audit personnel, and headquarters' management review of and response to findings for QSAs conducted by the Quality Staff are established by the Quality Staff and are beyond the scope of this QMP. The QAARWP will summarize the results of and response to any QSA conducted by the Quality Staff during the previous fiscal year.

11.2.1.2 MSRs by the Region 7 QA Team

The RQAM will be responsible for MSRs of internal programs and external organizations. The MSRs will be conducted by a Region 7 review team with a minimum of two members according to the most current version of Guidance for Preparing, Conducting, and Reporting the Results of Management Systems Reviews, EPA QA/G-3 as modified by regional policy. Modifications to the MSR process as described in the guidance are defined in the MSR work plan templates and checklists developed by the QA Team and approved by the RQAM. The team members will usually consist of permanently assigned staff from the QA Team in order to ensure independence of the reviewers. For MSRs of internal programs, a QAC from another Division may also be invited to participate on the review team if there is a potential conflict of interest issue with any QA Team member. Before a QA Team member or QAC can be assigned to an MSR review team, they must have completed the QA training required by this QMP for permanently assigned QA Staff (Section 5.2.4) as well as the training course "Management Systems Reviews" developed by the Quality Staff or its equivalent. The RQAM will assign the MSR review team members based upon the internal program to be reviewed to ensure QA Staff with the appropriate experience, competence, and technical knowledge are included on the MSR review team. The RQAM may request assistance from the QACs, other Regions, or the Quality Staff to supplement the experience, competence, and technical knowledge of the MSR review team, if needed to accomplish a particular MSR. The review team will be expected to develop an MSR work plan, to prepare notification and verification letters or memoranda regarding the MSR, coordinate dates and times for the MSR meetings and interviews, conduct the MSR, and prepare the MSR report. Typically a review team leader will be designated by the RQAM to coordinate the MSR effort with the other review team members and the reviewed organization or program.

The MSRs will consist of meetings with the management of the reviewed organization or program, interviews with personnel, and file reviews. The verification letter or memorandum is a

follow-up to the initial notification letter to verify the dates, times, and location for the MSR. The verification letter will also inform the reviewed organization or program of the programs, personnel, documents, and records to be addressed by the MSR to ensure the review team will have the required access to complete the evaluation. Because the Regional Administrator has directed the RQAM to conduct internal MSRs and the QA Team is centrally located within ENSV, the review team will have sufficient authority and organizational freedom to identify quality problems and noteworthy practices, propose recommendations, and independently confirm implementation and effectiveness of solutions. Results of the MSR will be reported to management through a Draft Findings Report. The reviewed organization or program will be given the opportunity to respond to the Draft Findings Report and to develop a Corrective Action Plan to address any issues identified as requiring corrective action. The Corrective Action Plan must identify the corrective action, responsible official(s), and the projected completion date for each finding requiring corrective action. The RQAM will review the Corrective Action Plan and prepare any necessary responses for discussion with the management of the reviewed organization or program. Once any outstanding issues have been addressed and the corrective actions agreed upon by the RQAM and the reviewed organization's or program's management, a Final Report will be issued. The confirmation and implementation of the corrective actions will be done through the submittal of associated documents (e.g., a revised QMP) to the RQAM for review or through a follow-up evaluation. The QAARWP will identify the MSRs of internal programs or external organizations planned for the upcoming fiscal year.

11.2.2 Annual Program Reviews

The QA Team will participate in annual program reviews as requested by the applicable Region 7 Program Coordinator for each state or tribe (State Coordinator). These reviews will follow the same process as an MSR conducted by the QA Team (as described in Section 11.2.1.2 of this QMP) with modifications made as necessary to meet the particular needs of the program being reviewed and the State Coordinator. The QAARWP will identify participation by the QA Team in annual program reviews for the upcoming fiscal year if the information is available at the time the QAARWP is prepared.

11.2.3 Technical Systems Audits

Technical systems audits are a thorough, systematic, on-site, qualitative audit of facilities, equipment, personnel, training, procedures, recordkeeping, data validation, data management, and reporting aspects of field and laboratory activities. Project-level documents, such as a QAPP, will specify the need for a TSA for a particular project. The Project Manager is responsible for ensuring the specified TSA is accomplished. The TSA can be conducted with the assistance from the QA Team as requested. The QAARWP will identify any other TSAs planned for the upcoming fiscal year. The most current version of the document Guidance on Technical Audits and Related Assessments for Environmental Data Operations, EPA QA/G-7, can be used to assist with the conduct of a TSA. The

individual(s) conducting the TSA should, at a minimum, have completed the QA training courses as required in this QMP (or their functional equivalent). The roles, responsibilities, and independence of the evaluation personnel, the process for reviewing, reporting and responding to corrective actions, and the process for ensuring the implementation and effectiveness of corrective actions can vary among projects; therefore, these details will be defined in a QAPP.

11.2.4 Other Technical Audits

Other types of technical audits can include, but not be limited to: readiness reviews, surveillance, and audits of data quality. Project-level documents, such as a QAPP, will specify the need for these types of technical audits for a particular project. The Project Manager is responsible for ensuring the specified technical audit is accomplished. These technical audits can be conducted with the assistance from the QA Team as requested. The QAARWP will identify any other technical audits planned for the upcoming fiscal year. The most current version of the document Guidance on Technical Audits and Related Assessments for Environmental Data Operations, EPA QA/G-7, can be used to assist with the conduct of these other technical audits.

11.2.5 Response Actions

Senior management is responsible for determining necessary actions and developing a plan to address weaknesses disclosed in any audit. Milestones will be developed so that progress on corrective actions can be measured. This information will be included in the audit file, which is to be maintained by the RQAM. Regional managers are responsible for ensuring compliance with the approved corrective actions. Progress is to be reported to the Regional Administrator, Division and Office Directors, and the Regional Federal Managers' Financial Integrity Act Coordinator. This will include identifying any problems in audits discussing corrective actions and summarizing follow-ups on the previous year's agenda. If major deficiencies are found, follow-up audits may be required and should be discussed with senior management.

11.2.6 Data Quality Assessments

A data quality assessment (DQA) is the scientific and statistical evaluation of data to determine if data obtained from environmental data operations are of the right type, quality, and quantity to support their intended use. The use of the DQA process will be specified in project-level documents such as a QAPP. The most current version of Guidance for Data Quality Assessment Practical Methods for Data Analysis, EPA QA/G-9, can be used to assist in the DQA process. Data quality assessments are the responsibility of the Project Managers and the level of effort for the DQA will be commensurate with the project objectives and intended use of the data. An individual(s) conducting DQAs should, at a minimum, have completed the DQA training course and associated prerequisites required by this QMP (or their functional equivalent). The QA Team will provide technical assistance

as requested. If assistance is requested from the QA Team, the Project Manager will ensure the QA Team has access to all project documents and records needed to complete a DQA. The results of the DQA will be documented and provided to the Project Manager. The Project Manager will then be responsible for reviewing the results, determining if and what corrective actions are needed, and for confirming implementation and effectiveness of corrective actions.

11.3 Performance Evaluations

A performance evaluation, also known as a performance test sample, is a type of audit where samples of known concentration are analyzed by a laboratory to evaluate the proficiency of an analyst or laboratory. Performance evaluations programs are developed as a tool to help ensure the quality of the Agency's and Region 7's environmental data collection activities. Performance evaluation programs are important because environmental data are used as a basis for regulatory and guidance development and for compliance evaluation across the Agency. Performance evaluations are strongly supported and should be used by the Region, States, and local agencies.

Because performance evaluations are project-level evaluations, their use will be specified in a project's QAPP. It is the responsibility of the Project Manager to determine the applicability of performance evaluations for a project and to ensure they are accomplished as defined in QAPPs. The Project Manager will also be responsible for reviewing the results of performance evaluations, determining corrective actions, and confirming the implementation and effectiveness of corrective actions.

11.4 Dispute Resolution

If disputes are encountered as a result of evaluations, the dispute resolution process as defined in Section 3.6 of this QMP shall apply.

12. QUALITY IMPROVEMENT

It is Region 7 policy that quality assurance is a critical component of all the work functions within our programs. The intent of this QMP is to provide the basis for integrating appropriate quality assurance activities into the full cycle of Region 7 programs from the planning phases through the evaluation phases. If the principles outlined in the QMP are followed, problems can be detected in a timely manner, before programmatic and financial issues become critical and hinder program implementation and decision making.

Within Region 7, there are several levels of review that will help uncover problems with the quality system.

12.1 Internal Region 7-Wide Reviews

Each year the quality system and QMP will be reviewed by Region 7 staff and management as part of the QAARWP development process to ensure that the QMP is still relevant to the Region 7 mission. It will be the responsibility of the RQAM to coordinate the review. The QMP will be modified to reflect changing needs or additional guidance.

The RQAM meets with each program office staff as necessary. A key purpose of these meetings is to identify quality assurance issues of concern. Based on consultations with senior management, the RQAM will initiate MSRs or special projects to address and correct quality assurance problems identified by staff input. The RQAM will also respond to requests from management to address specific quality assurance problems of significance to the entire office. Actions developed to correct any major quality assurance deficiencies will be documented in the QAARWP and reviewed and approved by the appropriate Division/Office Director and the Regional Administrator. See Section 10.1 of this QMP for more details regarding the review and revision of the QMP and the preparation of the QAARWP.

12.2 SOP Reviews

At least every two years each Region 7 SOP will be reviewed to determine if they remain relevant to the mission of the program and properly describe the procedures used to obtain data of known and sufficient quality to support programmatic decisions. Ensuring that this review occurs is the responsibility of Supervisors and/or Division/Office Directors responsible for implementing the program. Actions will be developed by Supervisors or their designee to correct any major quality assurance deficiencies. The QAARWP should also describe any progress in quality assurance implementation. See Sections 10.3 and 10.4 of this QMP for more details regarding the maintenance of the Regional SOP system and Analytical Methods Manual, respectively.

12.3 Program Reviews

Program reviews, as described in Section 11.2.2 of this QMP, and internal MSRs, as described in Section 11.2.1.2 of this QMP, are conducted with the intent to look for opportunities for improving the quality system at either the state and tribal or Regional Office level, respectively. The program reviews and internal MSRs will be utilized as a means of evaluating implementation and effectiveness of quality systems.

12.4 Project Reviews

It is Region 7's policy that the Project Manager, with assistance from the RQAM and project participants, will review project implementation at regular intervals to identify where improvements in data quality can occur. Project reviews can consist of:

- Technical System Audits
- Data Quality Assessments
- Peer reviews
- Conference calls
- Meetings

Generally there should be a meeting at the end of the data collection phase of a project. If results from preliminary DQAs are available for this meeting, participants can use the information to determine whether a QAPP was followed and that quality was controlled to an acceptable level. The SOPs should be revised to reflect changes and improvements in procedures that were developed during the program. Weaknesses, problems, and recommended corrective actions for future programs should be documented in the quality assurance section of the final project report.

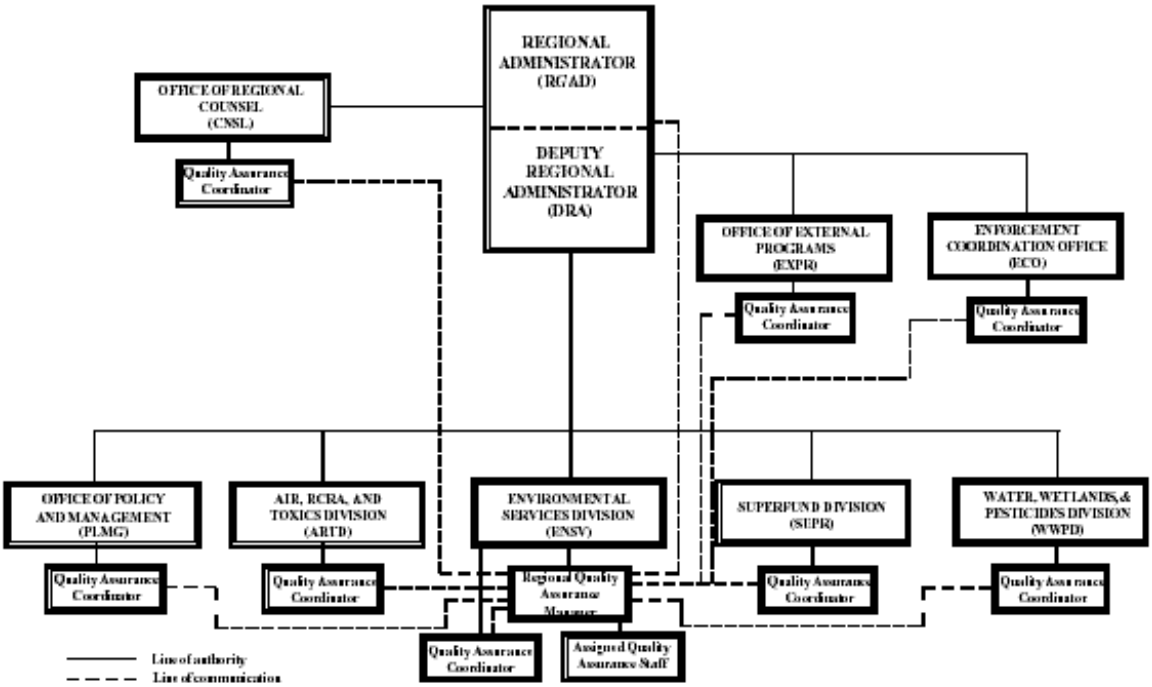
12.5 Quality Improvement Responsibilities

Region 7 staff, at all levels, are accountable for continuous quality improvement. The process of continuous quality improvement leads to a better and more responsive quality system. In order to minimize, prevent, detect, and promptly correct problems related to the quality system, the Region has implemented the evaluation approach as described in Chapters 10 and 11 of this QMP. Because the supervisors, Project Managers, and other technical staff are responsible for the day-to-day operations, they typically have the most direct experience with the quality system process and are encouraged to identify opportunities for improving the quality system by contacting the RQAM directly or through discussion with their management or QAC. During interviews conducted by the Region 7 QA Team during the MSR process, the review team includes questions regarding the support received by personnel from the QA Team and from the QACs in an effort to encourage open dialogue on how the quality system can be improved to help Regional staff perform their job functions. Another process by

which the QA Team actively encourages input on the quality system from Regional personnel is through the evaluation forms provided during each QA training course. After completion of the course, attendees complete an evaluation form which is used to evaluate the training program and to identify future training needs. The entire QA Team is given the opportunity to review the evaluation forms and QA training meetings are held regularly to discuss and address critical issues identified through these evaluation forms. The RQAM will also periodically meet with the QACs to discuss and address QA issues which have been identified by or to the QACs.

ATTACHMENT A
REGION 7 ORGANIZATIONAL STRUCTURE

Title: Region 7 QMP
Revision No.: 1
Revision Date: 08/28/2000



Page 54 of 73

ATTACHMENT B
QMP REVIEW CHECKLIST

Organization:_____

	Question	YES	NO
	General		
1.	Is the QMP signed by the accountable manager who prepared the plan?		
2.	Is the QMP signed by the senior QA official?		
3.	Is the QMP signed by the senior management official(s)?		
4.	Does the QMP include a section for the signatures of the EPA official and RQAM?		
5.	Does the QMP format comply with EPA QA/R-2?		
	Management and Organization		
1.	Does the QMP include a statement of the organization's policy on quality assurance?		
2.	Does the QMP contain organizational charts and functional statements?		
3.	Is the current organizational structure of the quality system documented in the QMP reasonable?		
4.	Is the QA Manager shown on the organization chart?		
5.	Is an acceptable line of reporting from the QA Manager to the senior manager identified?		
6.	Is the organizational independence of the QA Manager indicated?		
7.	Does the QMP adequately describe the scope of the organization's environmental data collection programs?		
8.	Does the QMP discuss how management will assure that applicable elements of the quality system are understood and implemented in all environmental programs?		
	Quality System and Description		
1.	Does the QMP describe the organization's quality system?		

	Question	YES	NO
2.	Are the principal components of the quality system (e.g., quality system documentation, annual reviews and planning, project-specific documentation, etc.) described including the roles and implementation responsibilities of management and staff?		
3.	Does the QMP list the tools (e.g., QMPs, QAPPs, training plan, etc.) for implementing each component of the quality system?		
4.	Is the review and approval process for QMPs submitted by external organizations acceptable?		
5.	Does the QMP list any components of the organization that develop QMPs (or equivalent document) in support of the organization's quality system and the review and approval procedures for such documentation?		
	Personnel Qualifications and Training		
1.	Does the QMP state the organization's policy regarding training for management and staff?		
2.	Does the QMP identify an acceptable process for assuring that personnel are qualified to perform the environmental data collection activities needed?		
3.	Does the QMP describe an acceptable process for determining QA-related training needs and identifying the need for retraining based on changing requirements?		
4.	Does the QMP identify an acceptable individual for item (3) above as well as the roles, responsibilities, and authorities of management and staff?		
	Procurement of Items and Services		
1.	Does the QMP describe or reference the process for reviewing and approving procurement documents or extramural agreements (grants, cooperative agreements, contracted and subcontracted activities) involving or affecting environmental programs?		
2.	Does the QMP include the roles, responsibilities, and authorities of management and staff in the process in item (1) above?		
3.	Does the review process include ensuring procurement documents are accurate and complete?		
4.	Does the review process ensure procurement documents clearly describe the item or service needed, the technical and quality requirements, the quality system elements for which the supplier is responsible, and how the supplier's conformance to customer requirements will be verified?		
5.	Does the QMP explain the review and approval of all applicable responses to solicitations to ensure these documents satisfy all technical and quality requirements?		

	Question	YES	NO
6.	Does the process described ensure procured items and services are of acceptable quality?		
	Documents and Records		
1.	Does the QMP describe the process for identifying quality-related records (including electronic) requiring control?		
2.	Does the QMP include the process for preparing, reviewing, approving, issuing, using, and revising documents and records?		
3.	Is the process described for ensuring that records and documents accurately reflect completed work?		
4.	Does the QMP explain the process for maintaining documents and records including transmittal, distribution, retention, access, preservation, traceability, retrieval, removal of obsolete documentation, and disposition?		
5.	Does the process ensure compliance with statutory, regulatory, and EPA requirements?		
6.	Is the process explained for establishing and implementing appropriate chain of custody and confidentiality procedures for evidentiary records?		
7.	Are roles, responsibilities and authorities described in the above processes?		
	Computer Hardware and Software		
1.	Does the QMP describe the processes for developing, installing, testing, using, maintaining, controlling, and documenting computer hardware and software used in environmental programs?		
2.	Is the process described for assessing and documenting the impact of changes to user requirements and/or the hardware and software on performance?		
3.	Does the QMP address the process for evaluating purchased hardware and software to ensure it meets user requirements and complies with applicable contractual requirements and standards?		
4.	Is the process explained for ensuring data and information produced from or collected by computers meet applicable requirements and standards?		
5.	Are roles, responsibilities, and authorities included in the above processes?		

	Question	YES	NO
	Planning		
1.	Does the QMP contain a systematic planning process for planning environmental data operations (the DQO process is not mandatory but is the recommended planning approach for many EPA data collection activities)?		
2.	Does the QMP describe the process for developing, reviewing, approving, implementing, and revising QAPPs or equivalent planning document (see R-5)?		
3.	Is the process for evaluating and qualifying data collected for other purposes or from other sources included in the QMP?		
4.	Are the roles, responsibilities, and authorities for the above processes defined in the QMP?		
	Implementation of Work Process		
1.	Does the QMP contain an adequate process for ensuring that work is performed according to planning and technical documents?		
2.	Does the QMP describe how operations needing procedures are identified and the process for preparation, review, approval, revision, and withdrawal of these procedures?		
3.	Is the policy for use of these procedures defined?		
4.	Does the QMP include the process for controlling and documenting the release, change, and use of planned procedures including approval, specific times and points for implementing changes, removal of obsolete documentation from work areas, and verification that the changes are made as described?		
5.	Are roles, responsibilities, and authorities of management and staff identified?		
	Assessment and Response		
1.	Does the QMP describe the process for assessing the adequacy of the quality system at least annually?		
2.	Is the process for planning, implementing, and documenting assessments and reporting results to management included?		
3.	Does the process identified in item (2) above include how to select an assessment tool, the expected frequency, and the roles and responsibilities of the assessors?		
4.	Does the QMP address determining the level of competence, experience, and training necessary to ensure that assessment personnel are technically knowledgeable, have no real or perceived conflict of interest, and have no direct involvement or responsibility for the work being assessed?		

	Question	YES	NO
5.	Does the QMP describe the process for ensuring assessment personnel have sufficient authority, access to programs, managers, documents, and records and the organizational freedom to identify quality problems and noteworthy practices, propose recommendations, and independently confirm implementation and effectiveness of solutions?		
6.	Is the process for management's review of, and response to, findings defined?		
7.	Does the QMP include the process for identifying how and when corrective actions are to be taken in response to assessment findings?		
8.	Does the process identified in item (7) above include ensuring corrective actions are made promptly, confirming the implementation and effectiveness of any corrective action, and documenting such actions?		
9.	Does the QMP describe how any disputes encountered as a result of assessments are addressed?		
10.	Are roles, responsibilities, and authorities described in the above processes?		
	Quality Improvements		
1.	Does the QMP address the process for ensuring that conditions adverse to quality are prevented, identified promptly, corrected promptly, and actions are taken toward prevention?		
2.	Does the process identified in item(1) above include documenting all corrective actions and tracking such actions to closure?		
3.	Does the QMP describe the approach for encouraging staff to establish communications between customers and suppliers, identify process improvement opportunities, and identify and propose solutions for problems?		
4.	Are roles, responsibilities, and authorities included in the above processes?		

ATTACHMENT C
QAPP REVIEW CHECKLIST

06/99

Site Name: _____ Document No. _____

Site Manager: _____ Date of QAPP: _____

QAPP Author: _____ QAPP Reviewer: _____

	COMMENTS
A1. Title & Approval Sheet	
Title	
Organization's Name	
Dated signature of project manager	
Dated signature of quality assurance officer	
Other signatures, as needed	
A2. Table of Contents and Document Control Format	
A3. Distribution List	
A4. Project/Task Organization	
Identifies key individuals, with their responsibilities (data users, decision makers, project QA manager, subcontractors, etc.)	
A5. Problem Definition/Background	
Clearly states problem or decision to be resolved	
Provides historical & scientific background information	
A6. Project/Task Description	
Lists measurements to be made	
Cites applicable technical, regulatory, or program-specific quality standards, criteria, or objectives	
Notes special personnel or equipment requirements	
Identifies the assessment tools needed	
Provides work schedule	
Notes required project & QA records/reports	

	COMMENTS
A7. Quality Objectives & Criteria for Measurement Data	
States project objectives and limits, both qualitatively & quantitatively	
States & characterizes measurement quality objectives as to applicable action levels or criteria	
A8. Special Training Requirements/Certification Listed	
A9. Documentation & Records	
Lists information & records to be included in data report (e.g., raw data, field logs, results of QC checks, problems encountered)	
Describes process and responsibilities for ensuring that the most current approved version of the QAPP is available	
Specifies the level of detail of the field sampling and/or lab analysis narrative needed to completely describe difficulties encountered	
Gives retention time and location for records & reports	
B1. Sampling Process Design (Experimental Design)	
Lists samples required as to type & number	
States sampling network design & rationale	
Gives sampling locations & sampling frequency	
Identifies sample matrices	
Lists classification of each measurement parameter as either critical or needed for information only	
Gives appropriate validation study information for non-standard situations	
B2. Sampling Methods Requirements	
Identifies sample collection procedures & methods	
Lists equipment needed	
Identifies support facilities	
Identifies individuals responsible for corrective action	
Describes process for preparation and decontamination of sampling equipment	
Describes selection and preparation of sample containers and sample volumes	
Describes preservation methods and maximum holding times	

	COMMENTS
B3. Sample Handling & Custody Requirements	
Notes sample handling requirements	
Notes chain of custody procedures, if required	
B4. Analytical Methods Requirements	
Identifies analytical methods to be followed (with all options) & required equipment	
Provides validation information for non-standard methods	
Identifies individuals responsible for corrective action	
Specifies needed laboratory turnaround time if important to project schedule	
B5. Quality Control Requirements	
Identifies QC procedures & frequency for each sampling, analysis, or measurement technique, as well as associated acceptance criteria & corrective action	
Referenced procedures used to calculate QC statistics (precision & bias or accuracy)	
B6. Instrument/Equipment Testing, Inspection & Maintenance Requirements	
Identifies acceptance testing of sampling & measurement systems	
Describes equipment preventive & corrective maintenance	
Notes availability & location of spare parts	
B7. Instrument Calibration & Frequency	
Identifies equipment needing calibration & frequency for such calibration	
Notes required calibration standard and/or equipment	
Cites calibration records & manner traceable to equipment	
B8. Inspection/Acceptance Requirements for Supplies & Consumables	
States acceptance criteria for supplies & consumables	
Notes responsible individuals	

	COMMENTS
B9. Data Acquisition Requirements for Non-direct Measurements	
Identifies type of data needed from non-measurement sources (e.g., computer data bases and literature files) along with acceptance criteria for their use	
Describes any limitations of such data	
Documents rationale for original collection of data and its relevance to this project	
B10. Data Management	
Describes standard record keeping, data storage, & retrieval requirements	
Checklists or standard forms attached to QAPP	
Describes data handling equipment & procedures used to process, compile, and analyze data (e.g., required computer hardware and software)	
Describes process for assuring that applicable information resource management requirements are satisfied	
C1. Assessments & Response Actions	
Lists required number, frequency, & type of assessments with approximate dates & names of responsible personnel (assessments include but are not limited to peer review, management systems review, technical systems audits, performance evaluations, and audits of data quality)	
Identifies individuals responsible for corrective actions	
C2. Reports to Management Identifies frequency & distribution of reports for:	
Project status	
Results of performance evaluations & audits	
Results of periodic data quality assessments	
Any significant QA problems	
Preparers & recipients of reports	
D1. Data Review, Validation, & Verification	
States criteria for accepting, rejecting, or qualifying data	
Includes project-specific calculations or algorithms	

	COMMENTS
D2. Validation & Verification Methods	
Describes process for data validation & verification	
Identifies issue resolution procedure & responsible individuals	
Identifies method for conveying these results to data users	
D3. Reconciliation with User Requirements	
Describes process for reconciling project results with DQOs & reporting limitations on use of data	

ATTACHMENT D

CONTRACTS MANAGEMENT MANUAL 1900 CHG 14 06/16/97

QUALITY ASSURANCE REVIEW FOR EXTRAMURAL PROJECTS (CONTRACTS)

I. GENERAL INFORMATION

Descriptive Title: _____

Sponsoring Program Office: _____

Approximate Dollar Amount: _____

Duration: _____

II This contract requires environmental measurements.

_____ (YES) Complete form;

_____ (NO) sign form and submit with the procurement request or procurement initiation notice.

III. Quality Assurance Requirements (Projects involving environmental measurements):

YES NO
___ ____ a. Submission of a written quality assurance (QA) program plan (commitment of the offeror's management to meet the QA requirements of the scope of work) is to be included in the contract proposal.

YES NO
___ ____ b. Submission of a written QA project plan is to be included in the contract proposal.

YES NO
___ ____ c. A written QA project plan is required as a part of the contract.

YES NO
___ ____ d. Performance on available audit samples or devices shall be required as part of the evaluation criteria (see list on the next page).

CONTRACTS MANAGEMENT MANUAL 1900 CHG 14 06/16/97 2-F6-2

YES NO

___ ____ e. An on-site evaluation of the offeror's facilities will be made to ensure that a QA system is operational and exhibits the capability for successful completion of this project (see schedule on the next page).

YES NO

___ ____ f. QA reports will be required (see schedule on the next page).

IV. Determination (Projects involving environmental measurements)

Percentage of technical evaluation points assigned to QA _____.

PO estimate of percentage of cost allocated to environmental measures _____.

For each parameter measured attach a summary which provides the following information:

a. Is quality control reference sampling or device available?

b. Are there split samples for cross-comparison?

c. Is it required for pre-award?

d. Specify frequency during the contract.

QA System Audits are required: Pre-award _____;
during the contract _____.

QA Reports are required: with Progress Reports _____;
with the Final Report _____.

The signatures below verify that the QA requirements have been established.

_____ _____
Project Officer Signature Date

_____ _____
Quality Assurance Officer Signature Date

ATTACHMENT E
STANDARD FORM 424

APPLICATION FOR FEDERAL ASSISTANCE

1. TYPE OF SUBMISSION Application ☐ Construction ☐ Non Construction Preapplication ☐ Construction ☐ Non Construction		2. DATE SUBMITTED	Applicant Identifier
		3. DATE RECEIVED BY STATE	State Application Identifier
		4. DATE RECEIVED BY FEDERAL AGENCY	Federal Identifier

5. APPLICANT INFORMATION

Legal Name:	Organizational Unit:
Address (give city, county, state, and zip code):	Name and telephone number of the person to be contacted on matters involving this application (give area code)

6. EMPLOYER IDENTIFICATION (EIN): ☐☐ - ☐☐☐☐☐☐☐	7. TYPE OF APPLICANT: (enter appropriate letter here) _____ A. State H. Independent School District B. County I. State Controlled Institution of Higher Learning C. Municipal J. Private University D. Township K. Indian Tribe E. Interstate L. Individual F. Intermunicipal M. Profit Organization G. Special District N. Other (Specify): _____
8. TYPE OF APPLICATION: ☐ New ☐ Continuation ☐ Revision If Revision, enter appropriate letter(s) in box(es): ☐☐ A. Increase Award B. Decrease Award C. Increase Duration D. Decrease Duration Other Specify: _____	9. NAME OF FEDERAL AGENCY:
10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: ☐☐ — ☐☐☐ TITLE:	11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:
12. AREAS AFFECTED BY PROJECT (cities, counties, states, etc.):	

13. PROPOSED PROJECT:		14. CONGRESSIONAL DISTRICT OF:	
Start Date	End Date	a. Applicant	b. Project

15. Estimated Funding:	
a. Federal	$
b. Applicant	$
c. State	$
d. Local	$
e. Other	$
f. Program Income	$
g. TOTAL	$

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES. THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESSES FOR REVIEW ON:
DATE _____

b. NO. ☐ PROGRAM IS NOT COVERED BY E.O. 12372
☐ OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?
☐ YES If "Yes" attach an explanation. ☐ NO

18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT, THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED.

a. Typed Name of Authorized Representative	b. Title	c. Telephone Number
d. Signature of Authorized Representative		e. Date Signed

Previous Editions Not Usable — AUTHORIZED FOR LOCAL REPRODUCTION — Standard Form 424 (REV 7-97) Prescribed by OMB Circular A-102

ATTACHMENT F
PROGRAMMATIC CERTIFICATION

PROGRAMMATIC CERTIFICATION
Authorization to Award an Assistance Agreement
(Instructions for Completing this form are on the Reverse Side)

ASSISTANCE NUMBER	ASSISTANCE RECIPIENT NAME

DELEGATION NUMBER	PROGRAM CODE	STATUTORY AUTHORITY	APPROVED PROJECT PERIOD	
		ACT:	START	END
		SECTION:		

PROGRAM/PROJECT TITLE AND DESCRIPTION:

RECOMMENDED FUNDING: The proposed budget included in the Application for Federal Assistance, (which includes the Recipient and *Federal share of funds) has been reviewed for eligibility and reasonableness of costs related to program activities contained in the workplan.* I recommend funding as indicated below and have attached a Commitment Notice (EPA Form 2550-9) to obligate these funds:

TOTAL APPROVED>> PROGRAM/ PROJECT COSTS $ ______ FEDERAL FUNDS $ ______

OTHER REQUIREMENTS

	YES	NO
QUALITY ASSURANCE This grant/cooperative agreement includes activities that require the preparation and approval of Quality Assurance documents. *If YES, please indicate the following:*	☐	☐
The workplan adequately addresses QA requirements including preparation, review and approval of QA documents. If NO, please attach the required QA condition to the award.	☐	☐
COMPETITION This application was competed. If no, please attach the rationale for the decision to award this application non-competitively.	☐	☐
PEER REVIEW IS REQUIRED FOR THIS AWARD.	☐	☐
PROGRAMMATIC TERMS AND CONDITIONS OF AWARD ARE REQUIRED (attach conditions)	☐	☐
THIS IS A COOPERATIVE AGREEMENT.	☐	☐

CERTIFICATION: The approved workplan has been reviewed in conjunction with program-specific policies, statutory and regulatory authorities, and EPA Order 5700-1, Policy for Distinguishing Between Assistance and Acquisition. Signature and submittal of this Certification to the Grants Management Office is the programmatic approval, based on the review, that the proposed Application for Federal Assistance meets the programmatic requirements for award. A determination has been made that funding of this project does not duplicate other EPA funded efforts.

EPA PROJECT OFFICER

PRINTED NAME	TITLE	DIV/BRANCH/SECTION	EXTENSION

RECOMMENDING OFFICIAL

SIGNATURE & PRINTED NAME	TITLE	DATE

DECISION OFFICIAL (or their designee)

SIGNATURE & PRINTED NAME	TITLE	DATE

Grants Management Specialist: Sherill x 7461

R7 GMO 04/99

QUALITY ASSURANCE REQUIREMENT FORM

40 CFR 30.54 and 31.45

If your program/project involves environmentally related measurements or data generation, you are required to develop and implement quality assurance practices. Please complete this form in its entirety and return it with the Application for Federal Assistance, SF-424.

YES	NO	
☐	☐	The workplan, which is submitted with the Application for Federal Assistance, includes environmental sampling or data generation.
☐	☐	A Quality Management Plan was previously reviewed and approved by the U.S. EPA and is still current and applicable.

Please note that prior to environmental sampling or data generation, a site specific Quality Assurance Project Plan must be prepared and approved. For additional information concerning quality assurance, please contact the R7 Quality Assurance Manager at (913) 551-5000.

Date

Applicant Signature

Applicant Title

Applicant Organization

ENSV Revised 03/97

ATTACHMENT H
GLOSSARY

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

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

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

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

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

Environmental data - any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and/or compiled from other sources such as databases, the literature, or any other sources.

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

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

Environmental technology - an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply to

hardware-based systems; however, it will also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

Exportable standard operating procedures - technical SOPs which address techniques or processes which can be used by and distributed to other agencies, organizations, or individuals outside of Region 7 or the Agency. These SOPs will typically focus on environmental data generation, use or data quality.

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

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

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

Intramural standard operating procedures - administrative SOPs (desk top procedures) which are Region-specific and can be either common across the Region or can be division-specific. These SOPs are not available for use to others outside the Region 7.

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 systems review (MSR) - the qualitative evaluation 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.

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

Peer review - a documented critical review of work by qualified individuals (or organizations)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Technical 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.

ATTACHMENT I
Contracting Officer's Representatives Form
for Defining Contract Quality Requirements

Use this form to provide direction to the Contracting Officer on the quality assurance activities that are required in the solicitation and contract.

1. a. Select all documentation required **before award of the contract:**

	Documentation	Specifications
☐	Quality Management Plan	EPA Requirements for Quality Management Plans (QA/R-2) [dated 03/20/01]
☐	Joint Quality Management Plan/Quality Assurance Project Plan	EPA Requirements for Quality Management Plans (QA/R-2) [dated 03/20/01] and EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]
☐	Programmatic Quality Assurance Project Plan for the entire program (contract)	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]
☐	Other Equivalent: _____	*[Insert specification]* _____

b. If the standard specifications do not apply, identify equivalent specifications: _____.

2. a. Select all documentation required **after award of the contract** or upon issuance of the specific work to be performed under the contract:

	Documentation	Specifications	Due After
☐	Quality Management Plan	EPA Requirements for Quality Management Plans (QA/R-2) [dated 03/20/01]	Award of contract

☐	Joint Quality Management Plan/Quality Assurance Project Plan	EPA Requirements for Quality Management Plans (QA/R-2) [dated 03/20/01] and EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]	Award of contract
☐	Contract Quality Assurance Project Plan	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]	Award of contract
☐	Programmatic Quality Assurance Project Plan for the entire program (contract)	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]	Award of contract
☐	Quality Assurance Project Plan for each applicable project	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]	Issuance of statement of work
☐	Project-specific supplement to Programmatic Quality Assurance Project Plan	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]	Issuance of statement of work
☐	Other Equivalent: _____	*[Insert specification]* _____	*[Select one]* ☐ award of contract ☐ issuance of statement of work

b. If the standard specifications do not apply, identify equivalent specifications: _____.

3. List any additional quality standards besides *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (ANSI/ASQC E-4)* that apply:

Title: _____
Numbering: _____
Date: _____
Documentation required to determine conformance: _____
_____

ATTACHMENT J
Contracts Clause and Tailoring Language

Do not incorporate the instructions in brackets [ ] into the solicitation and contract.

Higher-Level Contract Quality Requirement (FAR 52.246-11) (Feb 1999).

[Contracting Officer (CO) to incorporate the following language into all solicitations and contracts that require higher-level quality standards. Include any additional quality standards identified by the Contracting Officer's Representative (COR).]

The Contractor shall comply with the higher-level quality standard selected below.

	Title	Numbering	Date	Tailoring
☒	*Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*	ANSI/ASQC E4	1994	See below.
☐				
☐				

As authorized by FAR 52.246-11, the higher-level quality standard ANSI/ASQC E4 is tailored as follows:

The solicitation and contract require the offeror/contractor to demonstrate conformance to ANSI/ASQC E4 by submitting the quality documentation described below.

In addition, after award of the contract, the Contractor shall revise, when applicable, quality documentation submitted before award to address specific comments provided by EPA and submit the revised documentation to the Contracting Officer's Representative.

After award of the contract, the Contractor shall also implement all quality documentation approved by the Government.

A. *[PRE-AWARD TAILORING LANGUAGE: CO, insert the following paragraph into the solicitation and contract using information provided by the COR.]*

Pre-award Documentation: The offeror must submit the following quality system documentation as a separate and identifiable part of its technical proposal: *(CO, select one or more)*

	Documentation	Specifications
☐	Quality Management Plan	EPA Requirements for Quality Management Plans (QA/R-2) [dated 03/20/01]
☐	Joint Quality Management Plan/Quality Assurance Project Plan for the contract	EPA Requirements for Quality Management Plans (QA/R-2) [dated 03/20/01] and EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]
☐	Programmatic Quality Assurance Project Plan for the entire program (contract)	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]
☐	Other Equivalent: *[CO, insert the QA Manager-specified documentation]* _____	*[CO, insert specification]* _____

This documentation will be prepared in accordance with the specifications identified above, or equivalent specifications defined by EPA, _____ *(CO, insert specifications)*. Work involving environmental data generation or use shall not commence until the Government has approved this documentation and incorporated it into the contract.

B. *[POST-AWARD TAILORING LANGUAGE: CO, insert the following three paragraphs into the solicitation and contract using information provided by the COR.]*

Post-award Documentation: The Contractor shall submit the following quality system documentation to the Contracting Officer's Representative at the time frames identified below: *(CO, select one or more)*

	Documentation	Specifications	Due After
☐	Quality Management Plan	EPA Requirements for Quality Management Plans (QA/R-2) [dated 03/20/01]	Award of contract

☐	Joint Quality Management Plan/Quality Assurance Project Plan for the contract	EPA Requirements for Quality Management Plans (QA/R-2) [dated 03/20/01] and EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]	Award of contract
☐	Quality Assurance Project Plan for the contract	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]	Award of contract
☐	Programmatic Quality Assurance Project Plan for the entire program (contract)	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]	Award of contract
☐	Quality Assurance Project Plan for each applicable project	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]	Issuance of statement of work for the project
☐	Project-specific supplement to Programmatic Quality Assurance Project Plan for each applicable project	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]	Issuance of statement of work for the project
☐	Other Equivalent: *[CO, insert QA Manager-specified documentation]* _____	*[CO, insert specification]* _____	*[CO, select one]* ☐ award of contract ☐ issuance of statement of work for the project

This documentation will be prepared in accordance with the specifications identified above or equivalent specifications defined by EPA, _____ *(CO, insert equivalent specifications)*.

The Government will review and return the quality documentation, with comments, and indicating approval or disapproval. If necessary, the contractor shall revise the documentation to address all comments and shall submit the revised documentation to the government for approval.

The Contractor shall not commence work involving environmental data generation or use until the Government has approved the quality documentation.

(Note: Statement of work includes statements of work to perform projects under work assignments, task orders, delivery orders, etc.)