QUALITY MANAGEMENT PLAN

For

REGION 7

May 1, 2011

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

REGION 7 QUALITY ASSURANCE MANAGEMENT PLAN APPROVALS

_____

Rebecca Weber
Director, Air and Waste Management Division

_____

Ron Hammerschmidt
Director, Environmental Services Division

_____

Cecilia Tapia
Director, Superfund Division

_____

Karen Flournoy
Acting Director, Water, Wetlands, and Pesticides Division

_____

David Cozad
Office of Regional Counsel

_____

Rich Hood
Associate Regional Administrator for Media and Intergovernmental Relations
Office of Public Affairs

_____

Mark Hague
Director, Enforcement Coordination Office

_____

Luetta Flournoy
Acting Assistant Regional Administrator
Office of Policy and Management

REGION 7 QUALITY ASSURANCE MANAGEMENT PLAN APPROVALS

_____

Diane Harris
Regional Quality Assurance Manager

_____

Karl Brooks
Regional Administrator

_____

Monica Jones
Acting Director, Quality Staff

TABLE OF CONTENTS

LIST OF ATTACHMENTS

Attachment A:	Region 7 Organization Chart with QA Lines of Authority and Communication
Attachment B:	Quality Assurance Review for Extramural Projects Form
Attachment C:	Standard Form 424
Attachment D:	Programmatic Certification Authorization to Award Assistance Agreement
Attachment E:	Quality Assurance Requirement Form
Attachment F:	Glossary

LIST OF ACRONYMS

AWMD – Air and Waste Management Division

CAA - Clean Air Act

CNSL - Office of Regional Counsel

DQA – data quality assessment

ECO - Enforcement Coordination Office

EMMC - Environmental Monitoring Methods Council

ENSV - Environmental Services Division

EPA - Environmental Protection Agency

MSR - management systems review

NARA - National Archives and Records Administration

OPA - Office of Public Affairs

OIRM - Office of Environmental Resources Information Management

PLMG - Office of Policy and Management

PPAs - Performance Partnership Agreements

QA - quality assurance

QAARWP - quality assurance annual report and work plan

QAPP - quality assurance project plan

QC - quality control

QMP - quality management plan

QSA - quality systems audit

RLAB - Regional Laboratory

RCRA - Resource Conservation and Recovery Act

RQAM - Regional Quality Assurance Manager

SOP - standard operating procedure

SPP - systematic planning process

SUPR - Superfund Division

TEP - Technical Evaluation Panel

TSA - technical systems audit

WWPD - Water, Wetlands, and Pesticides Division

1.   MANAGEMENT AND ORGANIZATION

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 use environmental data. This QMP was prepared according to EPA Requirements for Quality Management Plans, EPA QA/R-2, March 2001, reissued May 2006 and Chapter 3 of the EPA Quality Manual for Environmental Programs, 5360 A1, May 5, 2000 to document the quality assurance policies and management structure to be used in implementing the Region 7 quality system.

1.1. 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; or 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.

1.2. Data Collection Activities 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.

1.3. 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 as well as investigations or studies that involve acquired data.

1.4. Region 7 Mission

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 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.

1.5. Quality Assurance Policy

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 or used for its programs will be of known and documented quality and 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:

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

1.6. Organization

Region 7 is organized into four Divisions: Air and Waste Management (AWMD); Environmental Services (ENSV); Superfund (SUPR); and Water Wetlands, and Pesticides (WWPD); and four Offices: Office of Regional Counsel (CNSL); Office of Public Affairs (OPA); Enforcement Coordination Office (ECO); and Office of Policy and Management (PLMG). This QMP reflects the overall regional organization found at http://r7atwork.r07.epa.gov/intranet/pdf/orgchart_overview.pdf. See http://r7atwork.r07.epa.gov/intranet/pdf/orgchart_ensv.pdf for the ENSV organizational structure including the position of the RQAM and QA Team. See Attachment A for the QA lines of authority and communication for the RQAM and the QA Team.

1.6.1. Air and Waste Management Division (AWMD)

AWMD, under the supervision of its Director, is responsible for the Clean Air Act (CAA), Resource Conservation & Recovery (RCRA), Underground Storage Tank, Leaking Underground Storage Tank, Risk Management Plan (CAA 112(R)), Emergency Planning Community Right to Know Act, Spill Prevention Control Measures, TSCA PCB programs, regulatory (other than Water) and industrial sector programs. The Pollution Prevention program, also housed in AWMD, serves as an advocate for Pollution Prevention approaches for all Region 7 programs and manages the Region 7 Pollution Prevention grants.

1.6.2. Environmental Services Division (ENSV)

The Environmental Services, under the supervision of its Director, 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.

1.6.3. 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, Brownfields and Oil spills programs.

1.6.4. Water, Wetlands, and 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, Endangered Species Act, lead-based paint, asbestos AHERA, underground injection, and Sustainable Infrastructure.

1.6.5. Office of Regional Counsel (CNSL)

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

1.6.6. Office of Public Affairs (OPA)

The Office of Public Affairs, 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; Intergovernmental relations; small business assistance; community involvement/outreach; information sharing; Freedom of Information Act; product review; environmental

education; Web; and audio-visual. The Regional Community Based Environmental Protection Program is also managed within OPA.

1.6.7. Enforcement Coordination Office (ECO)

The Office of Enforcement Coordination Office, 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 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.

1.6.8. 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, and other administrative services (supplies, motor pool, mail, etc.).

1.7. Key Region 7 Personnel

1.7.1. 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.

1.7.2. 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.

1.7.3. Deputy Division Director, Environmental Services Division

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 Deputy Division Director of the Environmental Services Division serves as the first line supervisor of the RQAM and the QA Team.

1.7.4. Quality Assurance Personnel

The RQAM is responsible for ensuring Region 7 management and staff understands the requirements for the quality system as defined in the QMP. The RQAM and the permanently assigned QA staff form the QA Team.

1.7.4.1. 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. Conditions which might require management intervention involve issues the QA Team does not have the authority to unilaterally decide upon and could include, but not be limited to:

- Significant or fundamental changes to Regional QA policy as set forth in this QMP

- New or changing QA training requirements different from what is documented in the QMP
- The need for additional QA resources such as FTEs, travel funds, training dollars; and
- Regional personnel or financial assistance recipient who knowingly and willfully refuses to comply with Agency and/or Regional QA requirements.

The process to obtain management intervention would begin by the RQAM working through the ENSV Deputy Division Director for their support and assistance in addressing the issues and for contacting other managers who may need to be involved. For those issues that cut across programs and divisions, the ENSV Division Director would send an email to the RA, ARA, and the Staff Coordinator asking to be placed on the agenda for the weekly Senior Staff meetings to brief them about the situation and to get their concurrence on changes to Regional QA policy; their agreement with new or changing QA training requirements; their support for additional QA resources; their help with addressing any Regional personnel or financial assistance recipient who refuses to comply with Agency and/or Regional QA requirements, or their assistance with any other situation that might require management intervention. If this process leads to disputes, the dispute resolution as described in section 1.9 would be followed.

See Attachment A for the QA lines of authority and communication for the RQAM and the QA Team. 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. The RQAM 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;
- Assisting project officers, project managers, states, tribes, local governments and other financial assistance recipients 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 1.9 of this QMP addresses dispute resolution.

1.7.4.2. Quality Assurance Team - Permanently Assigned QA Staff

The permanently assigned QA staff provides 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.

1.7.5. 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).

1.7.6. 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.

1.7.7. 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;
- team leaders;
- work assignment managers;
- compliance officers;
- remedial project managers;
- inspectors; and
- on-scene coordinators

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;
- identifying, resolving, and implementing project-specific QA and QC issues

    (which may include data quality assessment, information management, data integration, and data validation); and
- providing review and approval of QAPPs from a programmatic perspective

1.8 Delegated and Authorized Programs

The following programs have been delegated or authorized 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: Kansas, Missouri and Nebraska have partial delegation;
- Toxic Substances Control Act (TSCA);
- 402 of TSCA (Lead Training Certification program): All four states in the Region are currently running the program with Iowa having received final approval; and
- 406 (b) of TSCA (Pre-Renovation Notification program): Kansas and Iowa are running the program with Iowa having received final approval

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

The Region=s QA responsibilities in relation to these delegated programs include 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 this QMP.

1.9 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.

2. QUALITY SYSTEM COMPONENTS

To meet its stated mission using environmental data, Region 7 must implement a quality system that assures environmental data are of known and documented 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.

2.1. Quality System Documents

2.1.1. Internal Quality Management Plan

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. Management is implementing these quality assurance policies to ensure that all environmental data generated for or by Region 7 are of known and documented quality and are acceptable for their intended use.

The QMP is developed by the RQAM with assistance, as appropriate, from the permanently assigned QA staff and Division and Office Directors. The QMP is intended for use by all Regional staff. A hardcopy of the QMP will be maintained by the Regional QA Office.   The QMP will also be accessible to all Regional staff through the Regional Intranet 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 Director of the Quality Staff. The approval is effective for up to five years, pending changes to the organization or

results from management system reviews. On or before the five year anniversary, the QMP will be updated as necessary and resubmitted for approval by the RQAM, Division/Office Directors, Regional Administrator, and the Director of the Quality Staff.

2.1.2. 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 (found at http://www.epa.gov/quality/qs-docs/qmp-checklist.pdf). 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.

The approval of a QMP is effective for five years unless significant changes are needed. On or before the five year anniversary date, the organization must resubmit the QMP for the same approval as the original document; otherwise, the QMP will be considered out-of-date and no longer applicable. If the anniversary date cannot be met, the organization can request a one-time extension from the RQAM, not to exceed three months beyond the anniversary date.

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 4.2.1 of this QMP for further details) and will only apply to the QMP requirement.

2.1.3.   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 the direction received from the Quality Staff by the RQAM with cooperation from the permanently assigned QA staff and other Regional staff as applicable. The QAARWP will also be used to identify minor changes or updates to Region 7's QMP. The QAARWP will be submitted to the Quality Staff by the other date as specified and in the manner requested (e.g., electronically, hard copy, or both).

2.2. Management Evaluations

2.2.1.   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 9.2.1 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 9.2.1.2 of this QMP.

2.2.2.   Program Reviews

The QA Team will participate in annual program reviews as identified in Section 9.2.2 of this QMP.

2.2.3.   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 7.2.1 of this QMP provides additional detail regarding the use of systematic planning, including the Data Quality Objectives process.

2.2.4. 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 7.2.2 - 7.2.8 of this QMP for more information pertaining to the Region=s requirements for QAPPs.

2.2.5. Routine Procedures Documents

2.2.5.1. 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 8.3 of this QMP.

2.2.5.2. 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 8.4 of this QMP.

2.2.6. Project-Level Evaluations

2.2.6.1. 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 9.2.6 of this QMP.

2.2.6.2. 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 9.2.3 of this QMP.

2.2.6.3.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 9.2.4 of this QMP.

2.2.6.4.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 9.2.7 of this QMP.

2.2.7. 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 3 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.

2.2.8. Information Quality Guidelines

EPA's Information Quality Guidelines (IQGs) contain EPA's policy and procedural guidance for ensuring and maximizing the quality of information the Agency disseminates and complements EPA's Quality System for assuring the quality of EPA's products and information. "Information" generally includes any communication or representation of knowledge or position/policy such as facts or data, in any medium, or form. This includes "preliminary" information that EPA has endorsed or adopted, and also conclusions or facts drawn from or based upon other, existing information. This QMP incorporates by reference all definitions, principles, policies, and procedures found in EPA's IQGs (http://www.epa.gov/quality/informationguidelines).

2.2.8.1.Implementation Policy and Procedures

In accordance with EPA's IQGs, Region 7 has established policies and procedures for complying with these guidelines, as described below, with emphasis on using existing Regional processes or procedures wherever possible to comply with the requirements of the IQGs. The review process is intended to ensure the quality of the Region's disseminations and is described in the *Region 7 Product Development and Approval Plan* which can be found at http://r7atwork.r07.epa.gov/intranet/oldr7/proceduresforms/opa/r7_product_devlpmnt_and_apprvl_pln.html. The Region 7 Product Review form can be found at http://r7atwork.r07.epa.gov/intranet/oldr7/proceduresforms/opa/pdf/r7_product_rev_form.pdf . The Region 7 Information Quality Guidelines Officer is located within the

Office of Policy and Management which has taken the lead for IQGs.

2.2.8.2. Requests for Correction

The IQGs allow for affected persons to request correction of information if that information does not comply with EPA or Office of Management and Budget Information Quality Guidelines. The Office of Environmental Information (OEI) will receive these complaints and forward them to the Region 7 IQG Officer when the information in question belongs to or involves Region 7. Although a formal process for handling requests for correction is still under development, and to date the Region has not received any requests for correction, in general the process will be as follows:

Upon receipt of the request for correction from OEI, the IQG Officer will determine who in Region 7 has ownership of the information. The IQG Officer will forward the request to the appropriate Division coordinator. The Division coordinator will then manage the request for correction and ensure compliance with the 90-day turnaround time for responding to these requests as established by the EPA IQGs.

The Region will notify the requester and take corrective action if the request is approved. If the request for correction is not approved, the Region will notify the requester and explain the reason for not approving the request.

3. 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.

3.1. 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.

3.2. 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. The Region 7 LAN Bulletin Board will be used to internally announce scheduled training to Regional Office staff. An email list will be maintained by the QA Team and used to announce scheduled training to our external partners. In general, the core courses will be offered at least once a year, but will typically be offered 3-4 times throughout the year depending upon available time and resources. 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	4 hours	A detailed overview of the Agency's quality system requirements and how they are implemented in Region 7
Systematic Planning Process	4 hours	An introduction to systematic planning with a detailed focus on the DQO process
Quality Assurance Project Plans	4 hours	An in-depth review of QAPP format, content, review, and approval requirements
Data Quality Assessment	4 hours	A basic introduction to DQA; intended for non-statisticians
QA Refresher	2 hours	A briefing on updates/changes to the quality system; required for Region 7 staff every 3 years

Training courses covering SOPs and QMPs are also available and given upon request. The QA training courses are tailored to target a specific audience (e.g., Senior Staff, managers, Brownfields grantees, etc.) as requested and as resources allow.

3.2.1. 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 and program offices will be provided when needed. Modifications to the core courses may be made to address programmatic issues. However, each key topic must be described in order to maintain the basic integrity of the original course.

3.2.2. 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 in the Quality Assurance Training Tracking System (QATTS). This database will provide the record of all QA training, the necessary recertification information, and notes about any waivers. The Regions' training tracking system, Registrar, will be the secondary record for QA training of EPA personnel.

At the end of each fiscal year, a summary of the QA training will be provided in the QAARWP as requested.

3.2.3. 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.

3.2.3.1. 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 AOrientation to Quality Assurance for Managers@. The individual Divisions and Program Offices with the necessary assistance from the RQAM are responsible for identifying needed QA training within their organizations.

3.2.3.2. 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 should attend the "Orientation to Quality Assurance" course. Additional training, including an introductory course tailored to supervisors' needs, may be provided depending on the specific duties and responsibilities of the individual.

On an annual basis, a report listing the QA training completed by their staff will be sent to each supervisor. A request asking the supervisor to identify any changes to their staff and QA training needs for their staff for the upcoming year accompanies this report.

3.2.3.3. 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 AOrientation to Quality Assurance@, ASystematic Planning Process and Quality Assurance Project Plans@, and AData Quality Assessment@. Additional training may be identified by the project manager, their supervisor, or the RQAM.

3.2.3.4. Permanently assigned QA Staff

Permanently assigned QA Staff are responsible for assisting the RQAM with quality issues. As part of this responsibility, the permanently assigned QA Staff will assist in writing or reviewing quality documents, including QAPPs, SOPs, and QMPs. Therefore, it is critical that the RQAM and permanently assigned QA Staff receive the necessary training, including AOrientation to Quality Assurance,@ ASystematic Planning Process and Quality Assurance Project Plans,@ AData Quality Assessment,@ AStandard Operating Procedures,@ and AQuality Management Plans.@ Additional training may be identified by their supervisor or the RQAM.

3.2.3.5. 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:

- Coordination occurs with supervisors to provide QA training for them and their staff as requested and as resources allow, including ensuring project managers and EPA personnel have a minimum of 16 hours QA training;
- Quality Assurance personnel 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 QA training is made available to all grantees including State and Tribal personnel;
- QA Refreshers are routinely offered to ensure Regional Office staff get recertified in a timely manner; 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.

3.2.4. Recertification

All personnel who are involved in environmental data generation and use will be required to attend AQA Refresher Course@ every three years (± 6 months) to maintain their quality assurance proficiency. Prior to presenting the "QA Refresher Course," the RQAM will notify staff and their supervisor that they are due for a refresher.

3.2.5. Assurance for Grants and Contracts

Minimum QA training requirements for grant recipients or contract personnel involved with environmental data generation or use should be described in the organization=s approved QMP. Grantees with a current relationship with EPA are welcome to attend the Region 7 QA training courses. Contractors may attend the training at the written request of their contracting officer or their designee. Project Managers are responsible for providing information about the Region's QA training to their grant recipients or contract personnel involved with environmental data generation or use to help insure they have the necessary QA training to successfully complete their granted or contracted tasks and functions.

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.

4. PROCUREMENT AND FINANCIAL ASSISTANCE

It is Region 7's 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.

4.1. 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); and
- the Contracts Management Manual (CMM).

Quality assurance requirements for contracts are set forth in the EPA Contracts Management Manual (Section 7.3.5.3 and Chapter 46) and the Federal Acquisition Regulation (FAR) 46.202-4 and 52.246-01.

Requirements include the QA Review Form, or other program-specific QA review form, that includes, as a minimum, the information shown in Attachment B. 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 2.1.2 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 7.2.3 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.

4.2. Financial Assistance

4.2.1. Grants and Cooperative Agreements

The applicant shall complete a Quality Assurance Requirement form (see Attachment E) 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 C). 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 D).

All applicants for grants or cooperative agreements involving environmental data generation or use 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 2.1.2 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 2.1.2 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 7.2.3 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 7.2.4 of this QMP describes Region 7's policy and process for this authorization. Oversight of an organization's QAPP approval process will be part of the MSR process as described in section 9.2.1.2 of this QMP.

Oversight of QA requirements in the grants and cooperative agreements process is included in the MSRs and program reviews performed by the QA Team on specific environmental programs (see Section 9.2.1.2 of this QMP). MSRs of both internal programs and external organizations will include a random sampling of the projects for that program or organization (a list of the projects will be requested from the program or organization as part of the MSR) to determine if the projects were correctly identified as including environmental data generation and/or use and if the QA requirements, including approved QAPPs prior to environmental data generation and/or use, were applied and adequately addressed. Additional mechanisms will be developed as needed through the Regional Grants Customer Relations 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, grant management specialists and the Financial Management Officer.

4.2.2. Interagency Agreements

Interagency agreements that are funded by EPA should include QMP and QAPP requirements in the agreement. Because 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.

5. 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. Region 7 adheres to the most current version of the Agency records management procedures including the National Archives Records Administration and *Records Management Policy* (EPA 2155.1) June 2009.

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 7.2.2-7.2.8 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. 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 and SOP 1330.5, "Handling and Disposition of Regional Quality Assurance Files." 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.

6. 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.

6.1. 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 System Life Cycle Document which assists all EPA Regional offices in complying with EPA Information Resource Management (IRM) standards by establishing a set of guidelines for all new and enhancement/replacement systems under development. It can be found at http://r7atwork.r07.epa.gov/intranet/information_sources/pdf/irmb_sdlc.pdf.

This procedure will be administered by the Information Resource Management Branch (IRMB) within the Region. IRMB will oversee all stages of the systems life cycle management process to ensure conformance to EPA IRM standards, improve systems quality, and develop more efficient and cost-effective systems. The centralization of this function will establish a consistent methodology for use throughout the Region. This oversight will include review and approval of all system front ends (user interface) and back ends (databases, etc.), complete documentation of all system development efforts (analysis, design, code, variables, processes, etc.) using standard documentation formats and forms that are maintained by the IRMB.

This document defines the different stages of the EPA-standard "generic" system development life cycle, lists points of contact for each stage, explains the required documentation, and provides a "checklist" of activities that must occur during each stage.

Please note that this document does not replace EPA IRM policies and procedures. Instead, it seeks to simplify and enumerate these policies and procedures and to establish one standard approach for systems development documentation practices. Much of the information in this document has been taken directly from EPA directives. Where available, web links to more information have been provided.

Region 7 is moving to performance-based contracts, so for IT contracts that involve applications development, the performance work statement will include, but not be limited to, requirements for system specification reviews; system development plans; data validation and transfer; acceptance testing, and report generation.

6.2. 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.

6.3. 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 National Institute of Standards and Technology;
- The Federal Information Processing Standards; and
- The EPA Data Standards Program is established.

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.

7. QUALITY PLANNING

7.1. Annual Planning

The primary vehicles for annual planning in the Region are the Agency Operating Guidance, the budget process, a Regional Plan (that somewhat resembles a work plan), Performance Partnership Agreements (PPAs), and state annual program work plans.

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 QA needs for a state are identified through the PPA process and the lead project officers on these PPAs, many of whom are representatives on the GCRC with the RQAM, are responsible, in consultation with the RQAM, for identifying and specifying the QA needs for a PPA including QMPs. The RQAM maintains a status table for external QMPs on the intranet which all Region 7 staff, including PPA project officers, have access to. The QA needs are then identified through conditions placed in the PPA. The PPA project officers are responsible for tracking the status of all conditions, including QA conditions, and for verifying they have been met. The required QA documentation is submitted to the RQAM for review and approval through the Project Officer.

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.

7.2. Project-level Planning

7.2.1. 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.

7.2.2. 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 4.2.2 of this QMP. Oversight to ensure Regional projects and projects funded by EPA through financial assistance agreements or contracts will be performed through internal and external MSRs and program reviews by the Region 7 QA Team. These reviews will include a random sampling of the projects for that program or organization (a list of the projects will be requested from the program or organization) to determine if the projects were correctly identified as including environmental data generation and/or use and if the QA requirements, including approved QAPPs prior to environmental data generation and/or use, were applied and adequately addressed.

7.2.3. 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 4.2.2 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 (found at http://www.epa.gov/region7/qa/pdf/r-5-cheklst.pdf). 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.
- 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 approval will be effective for the length of the project or for five years; whichever is less unless significant changes are needed (see Section 7.2.8 for how revisions are handled). If the QAPP will be used beyond the original length of the project or beyond five years, the QAPP must be submitted for the same approval as the original document.

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 5 of this QMP for additional details regarding the retention and maintenance of quality-related documents and records.

7.2.4. Quality Assurance Project Plan Review and Approval Authorization

Some 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 Section 2.1.2 of this QMP.   Other organizations cannot be authorized to approve QAPPs, in place of the RQAM, for 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. Oversight of an organization's QAPP approval process which has been authorized by an approved QMP will be part of the MSR process as described in section 9.2.1.2 of this QMP.

Due to changes in the Superfund regulations, Brownfields and State Response Program activities, although CERCLA, are no longer funded through the Superfund Trust (these are now STAG grants) and have been determined to not be subject to 40 CFR Part 35, Subpart O. Therefore, states, tribes, local governments, Regional programs, and other organizations can be authorized to review and approve QAPPs prepared in support of these Brownfields activities in place of the RQAM. In order to receive this authorization, the same criteria as described above for an adequate and appropriate process for the review, approval, and revision of these QAPPs apply, and this process must be documented in an organization=s approved QMP. Oversight of an organization's QAPP

approval process which has been authorized by an approved QMP will be part of the MSR process as described in section 9.2.1.2 of this QMP.

Because of resource constraints and to facilitate the Brownfields process, Region 7 may request assistance from a state program with the review and approval of QAPPs for non-state EPA grantees.   For this to occur, the state program must be authorized, as described in the first paragraph of this section through an approved QMP, to review and approve QAPPs in lieu of the RQAM. Review and approval of non-state EPA Brownfields grantee QAPPs by a state program will be limited to those instances where there is mutual agreement among the parties involved (the state, Region 7, and the grantee), and a relationship has been established between the state program and the non-state EPA grantee following the guidelines established by the state for their Brownfields program. The request for such assistance will be made through the EPA Project Officer in consultation with the RQAM as necessary. Oversight of an organization's QAPP approval process for Brownfields which has been authorized by an approved QMP will be part of the MSR process as described in section 9.2.1.2 of this QMP.

Per OSWER Directive 9272.0-17, the UFP-QAPP is designated for use in Federal facilities projects where environmental data are collected. The UFP-QAPP may be used, but is not currently required, for other non-Federal facilities projects in Region 7 as well.

7.2.5. 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 7.2.4 of this QMP. The appropriateness of a generic QAPP is determined on case-by-case basis by the Project Manager in cooperation with the RQAM.

7.2.6. 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. NPDES permit requirements and the SOP 2332.2, "NPDES Compliance Sampling Inspections" have been determined to adequately cover the environmental data generation activities performed by the Regional NPDES inspectors and are used in lieu of a traditional QAPP.

7.2.7. 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.

7.2.8. 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.

7.3. Acquired Data

As defined in Section 2 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; and
- 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; and
- 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 7.2.3 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.

8. 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

8.1. Program Implementation

The QMP will be reviewed annually by the RQAM, with assistance from the QA staff, to determine if the information remains relevant to the Region.   If changes are required, they will be made in time to be reported to the Quality Staff through 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 2.2.1 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 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.

8.2. Project Implementation

Section 7.2.7 of this QMP discusses the implementation of QAPPs. Due to unforeseen circumstances, changes in a QAPP and planned procedures may become necessary during the project. Refer to Section 7.2.8 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.

8.3. 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 are 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.

All SOPs will be approved, via signatures on the cover page, at a minimum by a peer reviewer, the author=s immediate supervisor, and the RQAM. All SOPs will be reviewed every two years at which time the SOPs will be revised, recertified or archived (i.e., no longer active). 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.

8.3.1. 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.

8.3.2. 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. 1330.4, <u>Preparation of Standard Operating Procedures</u>) 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

8.4. Analytical Methods

Laboratory analytical methods will be documented using the Environmental Monitoring Methods Council (EMMC) format and will be reviewed, approved, tracked, and maintained similarly to SOPs as outlined in SOP 1330.4

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 1330.4.

8.4.1. Use of Analytical Methods

Generally, the analytical methods are for use by all RLAB analytical personnel and in-house laboratory contractors. The analytical methods 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 method itself.

8.4.2. Implementation of Analytical Methods

The CARB Branch Manager and Section Chiefs are responsible for the implementation of laboratory procedures and for ensuring all analyses are documented with an approved CARB method. Implementation of procedures will be ensured through CARB internal reviews according to SOP 2430.6, *Periodic Internal Program Review of the Region 7 Laboratory*, and internal MSRs conducted by the QA Team as described in Section 2.2.1 of this QMP.

9. EVALUATION AND RESPONSE

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

9.1. 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 members participate in the review of the Region-wide quality system. The Division and Office Directors will review and approve significant 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.

9.2. 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 of Region 7 environmental programs are conducted by the Region 7 QA Team and technical staff (usually on a division by division basis). External audits of the Region 7 quality system are conducted by the Quality Staff, Office of Inspector General auditors, or Headquarters' program office personnel. External audits of the Regional Laboratory quality system are performed by the Region's NELAC Accrediting Authority per the current NELAC standards. Audits of Region 7 states, tribes and other external organizations participating in the Region 7 quality system are performed by the Region 7 QA Team. 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.

9.2.1.   Quality System Audits (QSAs) and Management System Reviews (MSRs)

9.2.1.1.QSAs by the Quality Staff

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 Quality Staff and MSRs of R7 internal programs and external organizations will be conducted by the QA Team. 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.

9.2.1.2.MSRs by the Region 7 QA Team

    The RQAM will be responsible for MSRs of internal programs and external organizations. All internal and external MSRs conducted by the Region 7 QA Team will be performed as described in this section. 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. MSRs of both internal programs and external organizations will include a random sampling of the projects for that program or organization (a list of the projects will be requested from the program or organization as part of the MSR) to determine if the projects were correctly identified as including environmental data generation and/or use and if the QA requirements, including approved QAPPs prior to environmental data generation and/or use, were applied and adequately addressed. MSRs will also evaluate an organization's QAPP approval process which has been authorized by an approved QMP will be part of the MSR process as described in section 9.2.1.2 of this QMP. Currently, this only applies to external MSRs because there is no QAPP approval authority in place beyond the RQAM for internal organizations and programs.

    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. Because external MSRs are conducted by Region 7 QA Team personnel on organizations external to Region 7, independence of the MSR team is ensured. If technical assistance is needed for an external MSR, that assistance will be obtained through Region 7 or from a different organization than the one being reviewed. Before a QA Team member 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 3.2.4). 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 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.

9.2.2. 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.

9.2.3. 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. Although a project manager will be responsible for ensuring any planned TSA is

accomplished, under no circumstances will a project manager ever be responsible for auditing his/her own work. For most projects in Region 7, the work for a project is actually being performed by a contractor, a facility, the facility's consultant, a grantee, or some other party and the Project Manager provides oversight. For example, many RCRA Project Managers will contract with USGS to perform oversight and split sampling activities as part of technical oversight of a facility and/or their consultant.

The QA Team will perform a TSA or otherwise provide assistance for a TSA in a situation where the Project Manager is responsible for actually performing the work. A 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. During QAPP reviews, the QA Team will ensure that the process described in a QAPP for a TSA covers the completion of assessment reports in a timely manner including appropriate levels of review and approval as well as how and when corrective actions are to be taken in response to the findings.

9.2.4. 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. During QAPP reviews, the QA Team will ensure that the process described in a QAPP for technical audits covers the completion of assessment reports in a timely manner including appropriate levels of review and approval as well as how and when corrective actions are to be taken in response to the findings. 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.

9.2.5. 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.

9.2.6. 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 EPA's DQA guidance (QA/G-9R and G-9S), 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.

9.2.7. 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.

It is the practice of Region 7 ENSV to periodically incorporate performance evaluation samples into analytical activities managed by ENSV regardless of where the analyses are performed. A Region 7 Project Manager may also request performance evaluation samples. Performance evaluation samples are addressed and requested per Region 7 SOP 2430.7, "Performance Evaluation Sample Program Guidance" and are prepared per SOP 2430.9, "Preparation and Performance Evaluation Samples in Water, Wipe, and Soil Matrices". The performance evaluation samples are then submitted "blind" to the laboratory being evaluated.

Performance evaluation of the Regional Laboratory is addressed in Region 7 SOP 2430.11, "Region 7 Laboratory Participation in Proficiency Testing."

9.2.8.   Dispute Resolution

If disputes are encountered as a result of evaluations, the dispute resolution process as defined in Section 1.9 of this QMP shall apply.

10. QUALITY IMPROVEMENT

It is Region 7 policy that quality assurance be 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.

10.1.   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 as needed.

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 8.1 of this QMP for more details regarding the review and revision of the QMP and the preparation of the QAARWP.

10.2.   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 8.3 and 8.4 of this QMP for more details regarding the maintenance of the Regional SOP system and analytical methods, respectively.

10.3.   Program Reviews

Program reviews, as described in Section 9.2.2 of this QMP, and internal MSRs, as described in Section 9.2.1.2 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.

10.4.   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; and
- 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.

10.5.   Quality Improvement Responsibilities

Region 7 staff, at all levels, is 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 8 and 9 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. 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 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 QA Refresher also offers staff an opportunity to provide their input and suggestions about the quality system.

ATTACHMENT A
Region 7 Organization Chart with QA Lines of Authority and Communication

```
                              ┌─────────────────────┐
                              │      REGIONAL       │
                              │   ADMINISTRATOR     │
                              │       (RGAD)        │
                              └─────────────────────┘

   ┌───────────────────┐        ┌───────────────────┐        ┌───────────────────┐
   │    OFFICE OF      │        │    OFFICE OF      │        │   ENFORCEMENT     │
   │    REGIONAL       │        │  PUBLIC AFFAIRS   │        │   COORDINATION    │
   │  COUNSEL (CNSL)   │        │      (OPA)        │        │   OFFICE (ECO)    │
   └───────────────────┘        └───────────────────┘        └───────────────────┘

 ┌──────────────┐  ┌──────────────┐  ┌──────────────┐  ┌──────────────┐  ┌──────────────┐
 │ENVIRONMENTAL │  │ AIR AND WASTE│  │  SUPERFUND   │  │    WATER,    │  │  OFFICE OF   │
 │  SERVICES    │  │  MANAGEMENT  │  │ DIVISION     │  │ WETLANDS AND │  │  POLICY AND  │
 │DIVISION(ENSV)│  │DIVISION(AWMD)│  │   (SUPR)     │  │  PESTICIDES  │  │ MANAGEMENT   │
 ├──────────────┤  └──────────────┘  └──────────────┘  │DIVISION(WWPD)│  │   (PLMG)     │
 │  Regional QA │                                      └──────────────┘  └──────────────┘
 │ Manager and QA│
 │     Team      │
 └──────────────┘
```
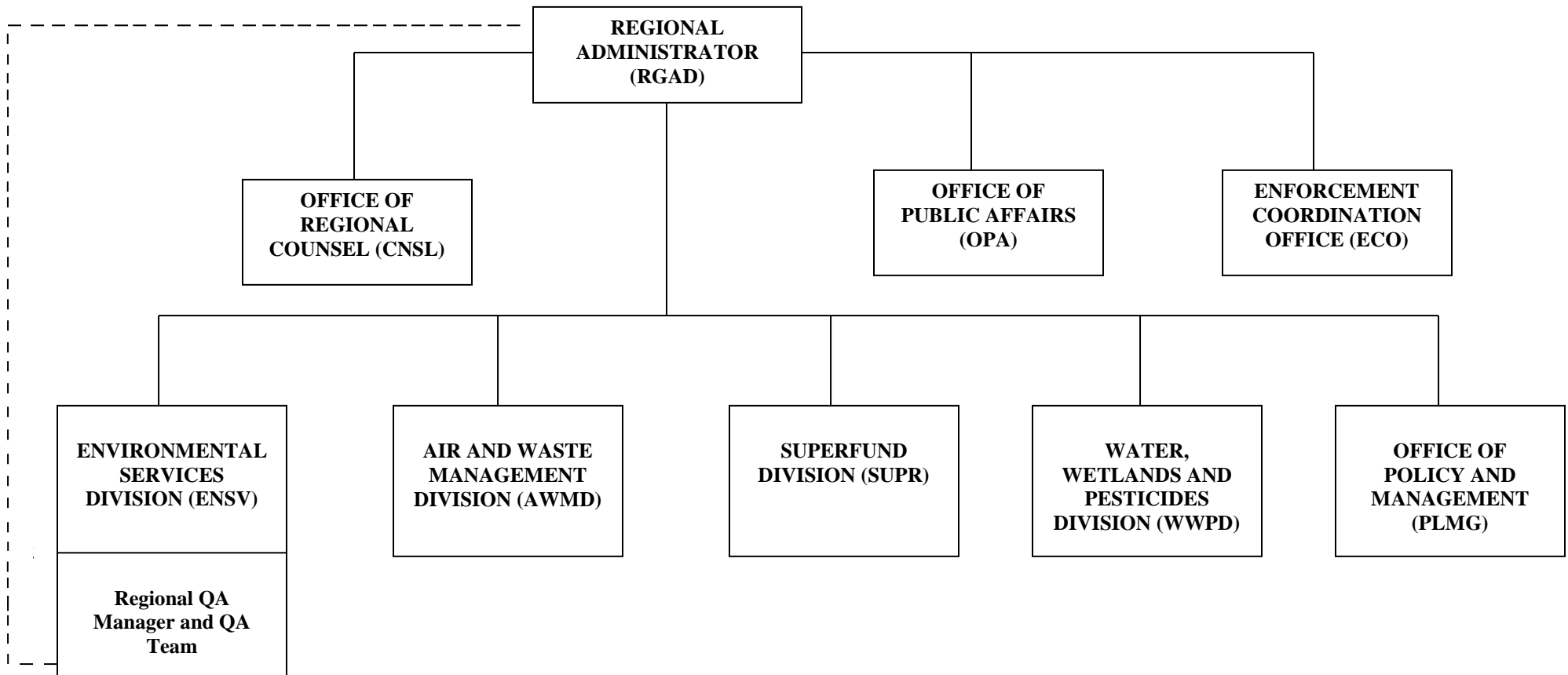
ATTACHMENT B
Quality Assurance Review Form

Contracts Management Manual   April 7, 2004

APPENDIX 46.1D U.S. EPA QUALITY ASSURANCE REVIEW FORM
FOR CONTRACT ACTIONS

I. **General Information**

    a. **Vehicle Type:**

        [ ] Solicitation/Sole Source (RFP #: _____)

        [ ] Delivery Order/Work Assignment /Task Order
            (SOW #: _____ and Contract #: _____)

    b. **Descriptive Title:**   _____
                             _____

    c. **Sponsoring Organization** *(e.g., Branch. Division, Office, etc.)*: _____

    d. **Project Duration:** _____

    e. **Is this a new [ ] or continuation of an existing [ ] project?**

II. **Scope of Work**

    [For example activities, see www.epa.gov/quality/examples.html.]

		Yes	No
a.	Does the work involve:		
	• the collection, generation, use and/or reporting of environmental data? (Environmental data are defined as any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.)		[ ]	[ ]
	• design, construction, and/or operation of environmental technologies?		[ ]	[ ]
	• development and/or use of models?		[ ]	[ ]
	• other activities that need quality assurance or quality control requirements as identified in your organization's Quality Management Plan? If yes, list: _____		[ ]	[ ]

        If all answers are No, skip Section III and complete Section IV.

    b.   Estimate of percentage of costs or level-of-effort allocated to the activities identified above:
        _____%.

Contracts Management Manual   **April 7, 2004**

III.   **Quality-Related Requirements**

[Where applicable, reference a specific section of the Statement of Work.]

a.   **For Solicitations Only** *[complete (b) - (f) below, as well]*

    1.   Insert the percentage of technical evaluation points assigned to offeror's quality system documentation, or P/F if the evaluation is pass/fail: _____

    2.   List any quality standards (from your organization's Quality Management Plan) that you will use in lieu of, or in addition to, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (ANSI/ASQC E4)*. These standards are

        Title: _____
        Numbering: _____
        Date: _____
        Requirements (Tailoring):   _____
        _____

b.   **QA Documentation Options:** *[For solicitations, complete items 1-4; for all actions other than solicitations, complete items 3-4. All documentation specified under "Other" must be defined in your organization's Quality Management Plan and be consistent with requirements defined in EPA Manual 5360 A1. For items checked under #2, there must be adequate information in the SOW for the offeror to develop this documentation.]*

Before Award Documentation[1]

    1.   ____   Documentation of an organization's Quality System: Either ☐ QMP developed in accordance with R-2 or ☐ Other: _____
          ____   Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by contract: Either developed in accordance with ☐ R-2 and R-5 or ☐ Other:

          _____

    2.   ____   Programmatic QA Project Plan: Either developed in accordance with R5 or ☐ Other:

          _____

---

[1]QMP refers to a Quality Management Plan. Programmatic QA Project Plan refers to a QA Project Plan that would cover multiple projects with similar activities. R-2 refers to EPA Requirements for Quality Management Plans (QA/R-2) (EPA/240/B-01/002, 03/20/01) and R-5 refers to EPA Requirements for Quality Assurance Project Plans (QA/R-5) (EPA/240/B-01/003, 03/20/01) – copies of these documents are available at www.epa.gov/quality.

Contracts Management Manual   **April 7, 2004**

___ Application of QA and QC activities to the single project covered by contract: Either ☐ QA Project Plan developed in accordance with R-5 or ☐ Other: _____

___ Not applicable.

After Award Documentation[1]

3. ___ Documentation of an organization's Quality System: Either ☐ QMP developed in accordance with R-2 or ☐ Other: _____

   ___ Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by the contract: Either developed in accordance with ☐ R-2 and R-5 or ☐ Other:

   _____

   ___ Not applicable.

4. ___ Documentation of the application of QA and QC activities to applicable project(s): Either developed in accordance with ☐ R-5; ☐ A supplement to the following Programmatic QA Project Plan _____; or ☐ Other: _____

   ___ Programmatic QA Project Plan with supplements for each specific project: Developed in accordance with: _____

   ___ Existing documentation of the application of QA and QC activities will be used: Either ☐ Documentation developed pre-award; ☐ Documentation will be identified in individual Statements of Work or ☐ Documentation identified in Section ____ of the Statement of Work.

c. **Reports:** Are quality reports or reports containing quality assurance information (for example, status of quality system implementation, review of a quality system, quality control data, etc.) required? [ ] **Yes** [ ] **No**

   If yes, identify the required reports and the time frame for submission: _____

   _____

d. **Assessments:** Select all quality assessments that will be performed either pre-award or post-award:

	Pre-Award	Post-Award
On-site evaluation of offeror's/contractor's facility		
Assessments of the offeror's/contractor's Quality System (e.g., quality system audits, management system reviews, etc.)		

Contracts Management Manual   **April 7, 2004**

Project-specific assessments (e.g., technical systems audits, surveillance, performance evaluations, data quality assessments. peer reviews, readiness reviews)		

For each assessment, specify type, date to perform, and who will perform it (if known):

_____

e. **Procedures to Update Documentation:** Identify any procedures/requirements for updating EPA-approved quality-related documentation: _____

_____

f. **Other Requirements:** Identify any other pertinent quality-related requirements (as identified in your organization's Quality Management Plan): _____

_____

IV. **The signatures below verify that the Statement of Work has been reviewed to ascertain if quality assurance or quality control activities are needed and that the appropriate quality requirements have been established.**

_____   _____
Contracting Officer's Representative   Date   Quality Assurance Manager   Date

ATTACHMENT C
STANDARD FORM 424

APPLICATION FOR FEDERAL ASSISTANCE		2. DATE SUBMITTED	Applicant Identifier

1. TYPE OF SUBMISSION

		3. DATE RECEIVED BY STATE	State Application Identifier

Application
- ☐ Construction
- ☐ Non-Construction

Preapplication
- ☐ Construction
- ☐ Non-Construction

	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
- B. County
- C. Municipal
- D. Township
- E. Interstate
- F. Intermunicipal
- G. Special District
- H. Independent School District
- I. State Controlled Institution of Higher Learning
- J. Private University
- K. Indian Tribe
- L. Individual
- M. Profit Organization
- 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:		16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?
a. Federal	$	a. YES. THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESSES FOR REVIEW ON:
b. Applicant	$	DATE _____
c. State	$	b. NO. ☐ PROGRAM IS NOT COVERED BY E.O. 12372
d. Local	$	☐ OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW
e. Other	$	
f. Program Income	$	**17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?**
g. TOTAL	$	☐ 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 D
PROGRAMMATIC CERTIFICATION
AUTHORIZATION TO AWARD AN ASSISTANCE AGREEMENT

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 programmatic 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 this 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 actions.

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

Grant Management Specialist: _Sherrill_ x 7461   R7 GMO 04/98

ATTACHMENT E
QUALITY ASSURANCE REQUIREMENT FORM

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. <u>For additional information concerning quality assurance, please contact the R7 Quality Assurance Manager at (913) 551-5000.</u>

_____   _____
Date   **Applicant Signature**

                        _____
                        Applicant Title

                        _____
                        Applicant Organization

ENSV   Revised   03/97

I-1

ATTACHMENT F
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.