QUALITY MANAGEMENT PLAN

For

REGION 7

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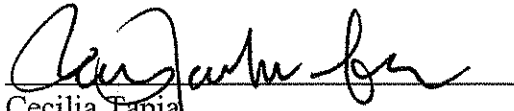**901 North 5th Street**
Kansas City, KS 66101

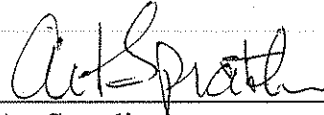# REGION 7 QUALITY ASSURANCE MANAGEMENT PLAN APPROVALS

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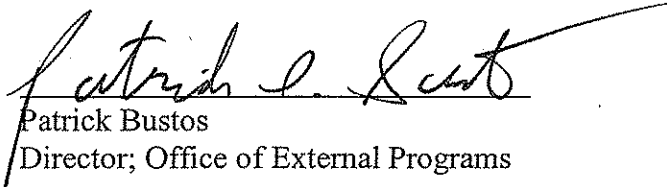Director, Environmental Services Division

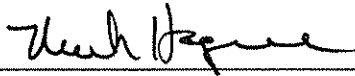Cecilia Tapia
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REGION 7 QUALITY ASSURANCE MANAGEMENT PLAN APPROVALS

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LIST OF ACRONYMS

AMM - Analytical Methods Manual

ARTD - Air, RCRA, and Toxics Division

CAA - Clean Air Act

CNSL - Office of Regional Counsel

DQA – data quality assessment

ECO - Enforcement Coordination

EMMC - Environmental Monitoring Methods Council

ENSV - Environmental Services Division

EPA - Environmental Protection Agency

MSR - management systems review

NARA - National Archives and Records Administration

OEP - Office of External Programs

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

QAC - quality assurance coordinator

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. INTRODUCTION

Agency policy initiated by the Administrator in memoranda of May 30, 1979 and June 14, 1979 requires participation in a centrally managed quality system by all Environmental Protection Agency (EPA) organizations (laboratories, program offices, or regional offices) and by non-EPA organizations conducting environmental programs which are supported or mandated through contracts, regulations, or other formalized agreements. The Agency's policy and program requirements to implement the mandatory quality system are contained in EPA Order 5360.1 A2 which invokes the use of an American National Standard for quality systems for environmental data collection and technology programs. Although the Order references the 1994 version, the standard was revised and replaced by ANSI/ASQ E4-2004 Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs. ANSI/ASQ E4-2004 is a national consensus standard designed specifically for quality systems applied to environmental data collection and environmental technology programs.

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

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

To implement Agency policy, EPA Laboratories, Program Offices, and Regional Offices are required to prepare a QMP covering all intramural and extramural environmental programs which generate and process environmental data for Agency use. This QMP was prepared according to EPA Requirements for Quality Management Plans, EPA QA/R-2, March 2001 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.

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

2.1   Definition of Environmental Data

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

Acquired data are data or information used for project implementation or decision making which meet the following criteria: 1) are compiled from other sources; 2) were originally collected for some other purpose; 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.

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

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

2.3   Region 7 Programs Covered by the Quality Management Plan

The Region 7 QMP is applicable to all Region 7 environmental programs. This includes field and laboratory data-gathering activities or investigations that involve the determination of chemical, physical, or biological characteristics related to the environment as well as investigations or studies that involve acquired data (as defined in Section 2.1).

3.   MANAGEMENT AND ORGANIZATION

3.1   Region 7 Mission

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

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

Three separate but related priorities have been identified by the Region to advance our mission of protecting human health and the environment. These priorities are agriculture, critical ecosystem protection, and sensitive populations. Each supports the five national goals while still addressing the regional characterization of those goals.

3.2   Quality Assurance Policy Statement

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

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

b.   Contracts;
c.   Interagency Agreements;
d.   Grants;
e.   Cooperative Agreements;
f.   Partnerships with industry, state and local offices, tribes, and other EPA Offices; and
g.   Enforcement agreements.

3.3   Organization

Region 7 is organized into four Divisions: Air, RCRA, and Toxics (ARTD); Environmental Services (ENSV); Superfund (SUPR); and Water Wetlands, & Pesticides (WWPD); and four Offices: Office of Regional Counsel (CNSL); Office of External Programs (OEP); Enforcement Coordination (ECO); and Office of Policy and Management (PLMG). This QMP reflects the overall regional organization described in Appendix A. Additional detail on the Region's organizational structure can be found at http://www.epa.gov/region07/orgchart.htm. Region 7 has a Quality Assurance Manager and each Division and Office has a Quality Assurance Coordinator (QAC). See Attachment A-1 for the proposed ENSV reorganization including the position of the RQAM and QA Team. See Attachment A-2 for the QA lines of authority and communication for the RQAM, the QA Team, and the QA Coordinators.

3.3.1   Air, RCRA, and Toxics Division (ARTD)

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

3.3.2   Environmental Services Division (ENSV)

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

3.3.3   Superfund Division (SUPR)

The Superfund Division, under the supervision of its Director, is responsible for Superfund Emergency Response/Preparedness, Site Assessment, Remedial, Removal, Federal Facilities, and Oil spills programs. The Brownfields program is also managed within SUPR.

3.3.4 Water, Wetlands, & Pesticides Division (WWPD)

The Water, Wetlands, & Pesticides Division, under the supervision of its Director, is responsible for the Clean Water Act, Safe Drinking Water Act, Federal Insecticide, Fungicide and Rodenticide Act, and Endangered Species Act.

3.3.5 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.

3.3.6 Office of External Programs (OEP)

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

3.3.7 Enforcement Coordination Office (ECO)

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

3.3.8 Office of Policy and Management (PLMG)

The Office of Policy and Management, under the supervision of its Assistant Regional Administrator, is responsible for policy, strategic planning, state relations including capacity building, tribal and multimedia program

coordination, budget formulation, financial implementation, contracts, grants, cooperative agreements, facilities, human resources, health and safety, information management, computer services, and other administrative services (supplies, motor pool, mail, etc.).

3.4   Key Region 7 Personnel

3.4.1   Management

Regional Administrator

The Regional Administrator is responsible to the Administrator, within the boundaries of Region 7, for the execution of the Regional environmental programs of the Agency and such other responsibilities as may be assigned. The direct responsibility for assuring data quality rests with regional Division and Office Directors. Ultimately, the Regional Administrator is responsible for establishing quality assurance policy and for resolving quality assurance issues identified through the quality system. Major quality assurance related responsibilities of the Regional Administrator include the following:

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

- ensure periodic evaluations are conducted of internal and external environmental programs to determine the effectiveness of their quality systems

The Regional Administrator authorizes the Division and Office Directors to be responsible for quality assurance development and implementation in

accordance with this QMP. The RQAM within ENSV has been authorized to conduct oversight and management of the Region 7 quality system.

Environmental Services Division Director

The Environmental Services Division Director serves a dual role as Director of a Regional division and as the Senior Staff member with oversight of the Regional quality system.

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.

3.4.2   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. The RQAM is the Team Leader for the QA Team and receives additional QA support from the Quality Assurance Coordinators (QACs).

Quality Assurance Team - Regional Quality Assurance Manager

The RQAM is the authorized manager of the Region 7 quality system and has direct access to the Regional Administrator on all matters pertaining to quality assurance. 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; any 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 her 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 RQAM would fill out the required request form 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 3.6 would be followed.

See Attachment A-2 for the QA lines of authority and communication for the RQAM, the QA Team, and the QA Coordinators. 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;
● developing quality assurance budgets;
● 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 3.6 of this QMP addresses dispute resolution.

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

Quality Assurance Coordinators (QACs)

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

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

● coordinating with the RQAM to provide QA support to other staff and external organizations as needed

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

3.4.3 Division and Office Directors, Supervisors, and Project Managers
Division and Office Directors

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

Supervisors

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

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

Project Officers/Project Managers/Work Assignment Managers

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

❖ project officers;
❖ 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

3.5   Delegated Programs

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

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

  - 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 TMDL (Total Maximum Daily Load) program is not an officially delegated program; the states have first responsibility.

The Region's QA responsibilities in relation to these delegated programs 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 Chapters 4 and 9 of this QMP.

3.6   Dispute Resolution

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

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

4. QUALITY SYSTEM COMPONENTS

To meet its stated mission using environmental data as identified in Section 3.1 of this QMP, Region 7 must implement a quality system that assures environmental data are of known 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.

4.1 Quality System Documents

4.1.1 Internal Quality Management Plans

The Region 7 QMP contains the quality assurance policies, procedures, and management systems governing the Region 7 quality system. The document describes the quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and evaluating activities conducted. 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, QACs, and Division and Office Directors. The QMP is intended for use by all Regional staff. A hardcopy of the QMP will be filed with each Regional Division/Office and the Regional Library.

A hardcopy will also be filed with the Regional Directives Manager. The approved QMP will also be accessible to all Regional staff through the Regional InfoNet and to external organizations through the Region 7 home page. Approval of the QMP will include the RQAM, Division/Office Directors, and the Regional Administrator. It will then be submitted for approval to the Director of the Quality Staff. The approval is valid for up to five years, pending changes to the organization or results from management system reviews.

A regional division or office may be authorized to administer Region 7 quality system policies and procedures. The authority will be documented in the form of a QMP prepared according to the most current version of EPA Requirements for Quality Management Plans, EPA QA/R-2. The QMP must describe the management policies, objectives, procedures, organizational authority, roles, and responsibilities to be implemented by the division or office to ensure environmental data are of the type and quality needed for their intended use. The QMP will be reviewed by the RQAM or designee for compliance with R-2 and the QMP Review Checklist (included as Attachment B to this QMP). The QMP review checklist developed by the Quality Staff and available online at http://www.epa.gov/quality/qs-docs/qmp-checklist.pdf is also used to support the review of QMPs by the RQAM or their designee. The QMP must be approved by the RQAM and the Regional Administrator.

4.1.2   External Quality Management Plans

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

Under the EPA quality system, QMPs are supported by project-specific QAPPs; however, there may be situations when a single document is applicable. Because of these situations and the fact that the Region supports the use of the graded approach, the RQAM may grant exceptions or modifications to the requirement for a QMP from an organization receiving financial assistance from Region 7. Each exception or modification will be determined on a case-by-case

basis by the RQAM. A document in place of a QMP will still be required but the content of this document will be defined by the RQAM. In general, organizations receiving financial assistance may be granted an exception or modification to the QMP requirement if they meet criteria which may include, but not be limited to, the following:

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

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

4.1.3   Quality Assurance Annual Report and Work Plan (QAARWP)

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

4.2   Management Evaluations

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

A quality system audit (QSA) or management system review (MSR) is a qualitative evaluation of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained. They are used to determine the effectiveness of, and adherence to, the quality system and the adequacy of resources and personnel provided to achieve and ensure quality in all activities. The Quality Staff plans to implement

independent QSAs of the Region 7 quality system once every three years. See Section 11.2.1 of this QMP for more information regarding QSAs.

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

4.2.2   Program Reviews

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

4.3   Project Level Planning - Systematic Planning Process

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

4.4   Project-Level Documents - Quality Assurance Project Plans

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

4.5   Routine Procedures Documents

4.5.1   Standard Operating Procedures

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

4.5.2   Analytical Methods Manual

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

4.6   Project-Level Evaluations

4.6.1   Data Quality Assessments

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

4.6.2   Technical Systems Audits

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

4.6.3   Other Technical Audits

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

4.6.4   Performance Evaluations

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

4.7   Quality System Personnel Standards - Quality Assurance Training

Region 7 focuses on QA training to assure that QA responsibilities are recognized, understood, and implemented by Regional staff. All Regional personnel involved with environmental data generation or use will be required to have this QA

training. The specific QA training requirements for the different levels of Regional personnel are detailed in Chapter 5 of this QMP. QA responsibilities are not currently incorporated into performance standards, however, the emphasis on QA training should have a greater impact on implementing the Region′s QA policy statement and achieving the Region′s stated mission.

4.8   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).

4.8.1   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 is included as Attachment I and contains the Region's IQG checklists for influential information, influential risk assessment information, and non-influential information. The Region 7 Information Quality Guidelines Officer is located within the Office of Policy and Management which has taken the lead for IQGs. The IQG Officer is supported by Communication and Web Coordinators in each division.

4.8.2   Requests for Correction

The IQGs allow for affected persons to request correction of information if that information does not comply with EPA or OMB Information Quality Guidelines. The Office of Environmental Information 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:

1)   Upon receipt of the request for correction from OEI, the IQG Officer

will determine who in Region 7 has ownership of the information.

2)   The IQG Officer will forward the request to the appropriate Division coordinator.

3)   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.

4)   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.

5.   QUALIFICATIONS AND TRAINING

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

5.1   Region 7's QA Training Program

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

5.1.1   Courses

Region 7 implemented a routine QA training program in 1999. The program includes several courses which are offered on a routine basis. The specific schedule will be described in the QAARWP. 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 to maintain their QA proficiency

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.

5.1.2   Logistics

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

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

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

topic must be described in order to maintain the basic integrity of the original course.

5.1.3   Documentation of Training

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

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

5.2   Training Requirements

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

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

5.2.1   Management

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

QACs, and with the necessary assistance from the RQAM are responsible for identifying needed QA training within their organizations.

5.2.2   Supervisors

Supervisors are ultimately responsible for the quality of data. Therefore, it is critical that supervisors receive the necessary awareness training to ensure their understanding of the importance of quality assurance, their responsibilities as supervisors of environmental data activities, and specific Region 7 quality assurance policies and procedures. Toward that end, supervisors who oversee environmental programs which generate or use environmental data 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.

Supervisors and their divisional QAC, with necessary assistance from the RQAM, are responsible for identifying and providing program-specific quality assurance training. 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.

5.2.3   Project Managers, Lab and Field Personnel

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

5.2.4   Permanently assigned QA Staff and QACs

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

program areas and may focus additional training within the program area, while the RQAM and permanently assigned QA Staff assist at the regional level and may focus additional training in general areas such as statistics, auditing, and trainer training.

5.2.5 RQAM

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

- 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 (permanently assigned QA Staff and QACs) will have a minimum of 24 hours training. Any additional QA training to perform specific duties such as auditing or trainer training, and any technical training which would facilitate the understanding of the agency's operations would be discussed in the individual's mid-year and annual performance appraisal;
- The 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.

5.2.6 Recertification

All personnel who are involved in environmental data generation and use will be required to attend "QA Refresher Course" every three years ($\pm$ 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.

5.3 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.

6.   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.

6.1   Procurement - Contracts

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

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

Quality assurance requirements for contracts are set forth in the EPA Contracts Management Manual (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 D. The QA review form shall be completed as required and signed by the Project Manager and the RQAM to assure that all environmentally related measurements which are funded by EPA or which generate data mandated by EPA are scientifically valid, defensible, and of known precision and accuracy.

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

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

has been approved.

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

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

6.2   Financial Assistance

6.2.1   Grants and Cooperative Agreements

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

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

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

All applicants for grants or cooperative agreements involving environmental programs shall submit a QMP prepared in accordance with the specifications provided in the most current version of <u>EPA Requirements for</u> including approved QAPPs prior to environmental data generation and/or use <u>Quality Management Plans</u> (QA/R-2), which describes the quality system

implemented by the applicant.

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

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

Approval of the recipient's QMP may authorize the recipient to review and approve QAPPs, in place of the RQAM, based on procedures documented in the QMP. Section 9.2.4 of this QMP describes Region 7's policy and process for this authorization. Oversight of an organization's QAPP approval process will be part of the MSR process as described in section 11.2.1.2 of this QMP.

Oversight of QA requirements in the grants and cooperative agreements process is included in the MSRs performed by the QA Team on specific environmental programs (see Section 11.2.1.2 of this QMP). 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.

6.2.2   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.

7.   DOCUMENT AND RECORDS MANAGEMENT

It is Region 7's plan to adopt and implement all Agency-approved records management policies and guidance developed by the Office of Administration and Resources Management,

Office of Environmental Information (formerly the Office of Information Resources Management). Region 7 adheres to the most current version of the following guidance and policies:

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

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

The EPA Project Manager is responsible for preparing, issuing, using, and revising Quality Assurance Project Plans (QAPPs) in accordance with Sections 9.2.2-9.2.8 of this QMP, as applicable. The RQAM is responsible for reviewing and approving all QAPPs in accordance with the most current version of EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations, EPA QA/R-5. 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.

8.   COMPUTER HARDWARE AND SOFTWARE

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

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

8.1   Region 7 Information Management System

All information management system development, improvements, and updates will comply with EPA Directive 2100, <u>Information Resources Management Policy Manual</u> 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 <u>Information Resources Management Policy Manual</u> and the most current version of the Region 7 <u>System Life Cycle Document</u> which can be found at http://r7atwork.r07.epa.gov/intranet/informationsources/sdlc.pdf. The life cycle includes an application review process that covers all software applications that are used in Region 7, specifically those applications that are purchased, created, developed, or modified to conduct the mission of the Agency. The goal of this process is to have a uniform approach and review of applications under consideration by Region 7. The process will determine if an application has management support, IRM support, is doable in the time frame needed, and is within the resources constraints identified. Compliance with the applicable information resource management standards will ensure that all hardware and software configurations are tested prior to use, to guarantee they perform as expected and meet user requirements.

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.

8.2 Hardware and Software Requirements

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

8.3 Data Standards

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

- The National Institute of Standards and Technology develops standards and guidelines to achieve the most effective use of Federal information.
- The Federal Information Processing Standards are the Federal data standards for all data exchange among agencies.
- The EPA Data Standards Program is established and documented in the EPA Directive 2100 <u>Information Resources Management Policy Manual</u>. Within EPA, adherence to data standards policy is accomplished through the direction of the Office of Environmental Information.

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

9.   QUALITY PLANNING

9.1   Annual Planning

The primary vehicles for annual planning in the Region are the Agency Operating Guidance, the budget process, 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.

9.2   Project-level Planning

9.2.1   Systematic Planning Process

A systematic planning process shall be used for all environmental programs conducted by or for Region 7. The Data Quality Objectives process as described in the most current version of <u>Guidance for the Data Quality Objectives Process</u>, 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 <u>Quality Manual</u> (5360 A1). The Project Manager is responsible for ensuring that a systematic planning process is used and documented. Guidance and technical support in using a systematic planning process will be provided by the QA Team as requested.

9.2.2   Quality Assurance Project Plans

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

9.2.3   Quality Assurance Project Plan Preparation, Review, and Approval

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

The Region 7 SOP 1330.2, Review of Project-level Quality Assurance Related Documents describes in detail the Region 7 process for the review and approval of QAPPs submitted to the RQAM. All QAPPs must be submitted to the RQAM through the Project Manager. Once a QAPP is received the RQAM or designee will review it for compliance with the requirements outlined in R-5 (as identified above). A QAPP review checklist will also be used to facilitate the review; an example of this checklist is included as Attachment C to this QMP. The QAPP review checklist is based upon the most current version of Guidance on Quality Assurance Project Plans, EPA QA/G-5, and will be updated as the

guidance is revised. The completed checklist is for internal use by the QA Team and is not provided to the Project Manager or others outside the QA Team; however, a copy of a blank QAPP review checklist is available for use by others on the Region 7 home page. Comments are provided to the Project Manager through four types of review memoranda:

- Approved - the document complies with R-5 and addresses the key issues satisfactorily.
- Approved with comments - although the document satisfactorily addresses most of the key issues and complies with R-5, minor issues were noted. These issues should not have a direct impact on the quality of the resulting data, but are noteworthy of pointing out for the record.
- Approved with conditions - the document was found to be incomplete in addressing some key areas to the extent of potentially jeopardizing the quality of the data. These areas are fully described in this review memorandum and can be adequately addressed by incorporation into the document but without resubmission.
- Resubmission Requested - the document was found to be insufficient in describing the key issues. Further clarification of specific issues is required prior to approval of the plan and initiation of the data collection activity.

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

9.2.4   Quality Assurance Project Plan Review and Approval Authorization

States, tribes, local governments, Regional programs, and other organizations can be authorized to approve some QAPPs in place of the RQAM where federal regulations allow. In order to receive this authorization, an adequate and appropriate process for the development, review, approval, and revision of QAPPs within the organization or program must be documented in an approved QMP. The QMP must be prepared, reviewed, and approved as defined in Sections 4.1.1 and 4.1.2 of this QMP.   Other organizations cannot be authorized to approve QAPPs, in place of the RQAM, for ambient air projects (40 CFR 58 Appendix A) and Superfund pre-remedial (40 CFR 35 Subpart O), remedial (40 CFR 35 Subpart O), and removal projects (40 CFR 300). QAPPs falling into these categories must be forwarded to the RQAM for review and approval as previously identified. 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 11.2.1.2 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 11.2.1.2 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 11.2.1.2 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.

9.2.5   Generic Quality Assurance Project Plans

For multiple projects or sites with the same objectives and environmental decision(s), a generic QAPP may be prepared. The generic QAPP will still be prepared according to the most current version of <u>EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations</u>, EPA QA/R-5, and <u>Guidance on Quality Assurance Project Plans</u>, EPA QA/G-5, but will address the issues which remain constant among the different projects or sites. Most generic QAPPs will also be supported by site-specific or project-specific addenda which

address the issues unique to each site or project. The generic QAPP will specify the preparation, review, and approval of the site-specific or project-specific addenda. Generic QAPPs require a QA review and approval by the RQAM and a technical and program review by the Project Manager. The QA approval of generic QAPPs for external organizations can be authorized in a similar manner as described in Section 9.2.4 of this QMP. As previously stated, QACs cannot be authorized to review and approve generic QAPPs, in place of the RQAM, because of a generic QAPP's potential long-term and/or cross-program impact. The appropriateness of a generic QAPP is determined on case-by-case basis by the Project Manager in cooperation with the RQAM.

9.2.6   Regulated Facilities

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

9.2.7   Quality Assurance Project Plan Implementation

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

9.2.8   Quality Assurance Project Plan Revision

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

9.3   Acquired Data

As defined in Section 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
- are obtained from non-measurement sources such as computer databases, programs, literature files, and historical databases

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

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

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

10.   IMPLEMENTATION OF WORK PROCESS

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

10.1   Program Implementation

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

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

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

10.2   Project Implementation

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

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

10.3   Standard Operating Procedures

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

The primary guidance document for the preparation of SOPs is Region 7's SOP No. 1330.4, <u>Preparation of Standard Operating Procedures</u>. The basis of the contents of the SOP is the Quality Staff's document entitled <u>Guidance for the Preparation of Standard Operating Procedures</u>, 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, <u>Standard Operating Procedures Tracking and Reporting System</u>. Copies of these documents are readily available from the Regional Quality Assurance Office.

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

10.3.1 Uses of SOPs

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

10.3.2 Implementation of SOPs

The implementation of SOPs is a responsibility that may cross organizational and functional lines depending on the type of SOP (i.e., technical or administrative as defined in SOP No. 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.

10.4   Analytical Methods Manual

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

Each method in the AMM will be reviewed at least once every two years (or as otherwise required for maintaining NELAP certification) and then recertified, updated, or removed from use and archived.   If a method needs to be changed or updated, the revised method must undergo the same review and approval process as the original document.

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

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

10.4.1 Use of the Analytical Methods Manual

Generally, the AMM is for use by all RLAB analytical personnel and in-house laboratory contractors. The analytical methods within the AMM 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 AMM.

10.4.2 Implementation of the Analytical Methods Manual

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

11. EVALUATION AND RESPONSE

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

11.1   Annual Review of the Quality System and Quality Management Plan

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

11.2   Audits

Internal and external audits will be the principal means for determining compliance with and effectiveness of the quality system defined in the Region 7 QMP. Internal audits 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. 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.

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

Quality system audits and MSRs evaluate a specific quality system to determine its effectiveness and to identify areas where additional attention would bring significant benefits. Quality system audits of Region 7 will be conducted by
Quality Staff and MSRs of R7 internal programs and external organizations will be conducted by the QA Team.

11.2.1.1   QSAs by the Quality Staff

The Quality Staff plans to implement independent QSAs of

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

11.2.1.2   MSRs by the Region 7 QA Team

The RQAM will be responsible for MSRs of internal programs and external organizations. 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 11.2.1.2 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. For MSRs of internal programs, a QAC from another Division may also be invited to participate on the review team if there is a potential conflict of interest issue with any QA Team member. 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 or QAC can be assigned to an MSR review team, they must have completed the QA training required by this QMP for permanently assigned QA Staff (Section 5.2.4) as well as the training course "Management Systems Reviews" developed by the Quality Staff or its equivalent. The RQAM will assign the MSR review team members based upon the internal program to be reviewed to ensure QA Staff with the appropriate experience, competence, and technical knowledge are included on the MSR review team. The RQAM may request assistance from the QACs, other Regions, or the Quality Staff to supplement the experience, competence, and technical knowledge of the MSR review team, if needed to accomplish a particular MSR. The review team will be expected to develop an MSR work plan, to prepare notification and verification letters or memoranda regarding the MSR, coordinate dates and times for the MSR meetings and interviews, conduct the MSR, and prepare the MSR report. Typically a review team leader will be designated by the RQAM to coordinate the MSR effort with the other review team members and the reviewed organization or program.

The MSRs will consist of meetings with the management of the reviewed organization or program, interviews with personnel, and file reviews. The verification letter or memorandum is a follow up to the initial notification letter to verify the dates, times, and location for the MSR. The verification letter will also inform the reviewed organization or program of the programs, personnel, documents, and records to be addressed by the MSR to ensure the review team will have the required access to complete the evaluation. Because the Regional Administrator has directed the RQAM to conduct internal MSRs and the QA Team is centrally located within ENSV, the review team will have sufficient authority and organizational freedom to identify quality problems and noteworthy practices, propose recommendations, and independently confirm implementation and effectiveness of solutions. Results of the MSR will be reported to management through a Draft Findings Report. The reviewed organization or program will be given the opportunity to respond to the Draft Findings Report and to develop a Corrective Action Plan to address any issues identified as requiring corrective action. The Corrective Action Plan must identify the corrective action, responsible official(s), and the projected completion date for each finding requiring corrective action. The RQAM will review the Corrective Action Plan and prepare any necessary responses for discussion with the management of the reviewed organization or program. Once any outstanding issues have

been addressed and the corrective actions agreed upon by the RQAM and the reviewed organization's or program's management, a Final Report will be issued. The confirmation and implementation of the corrective actions will be done through the submittal of associated documents (e.g., a revised QMP) to the RQAM for review or through a follow-up evaluation. The QAARWP will identify the MSRs of internal programs or external organizations planned for the upcoming fiscal year.

11.2.2 Annual Program Reviews

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

11.2.3 Technical Systems Audits

Technical systems audits are a thorough, systematic, on site, qualitative audit of facilities, equipment, personnel, training, procedures, recordkeeping, data validation, data management, and reporting aspects of field and laboratory activities. Project-level documents, such as a QAPP, will specify the need for a TSA for a particular project. The Project Manager is responsible for ensuring the specified TSA is accomplished. 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.

11.2.4 Other Technical Audits

Other types of technical audits can include, but not be limited to: readiness reviews, surveillance, and audits of data quality. Project-level documents, such as a QAPP, will specify the need for these types of technical audits for a particular project. 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.

11.2.5 Response Actions

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

11.2.6 Data Quality Assessments

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

11.3   Performance Evaluations

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

Because performance evaluations are project-level evaluations, their use will be specified in a project's QAPP. It is the responsibility of the Project Manager to determine the applicability of performance evaluations for a project and to ensure they are accomplished as defined in QAPPs. The Project Manager will also be responsible for reviewing the results of performance evaluations, determining corrective actions, and confirming the implementation and effectiveness of corrective actions. 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 by the Regional Laboratory according to Region 7 SOP 2430.8, "Procurement and Preparation of Soils Used in the Preparation of Audit Samples," SOP 2430.9, "Preparation and Verification of Water and Solid/Sediment Matrix Performance Evaluation Materials," and SOP 2430.13 "Preparation of Dioxin Performance Evaluation Samples Using PUF Cartridges for Air Toxics Monitoring Support" depending on the type of performance evaluation sample requested. 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."

11.4   Dispute Resolution

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

12. QUALITY IMPROVEMENT

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

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

12.1 Internal Region 7-Wide Reviews

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

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

12.2 SOP Reviews

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

12.3   Program Reviews

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

12.4   Project Reviews

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

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

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

12.5   Quality Improvement Responsibilities

Region 7 staff, at all levels, 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 10 and 11 of this QMP. Because the supervisors, Project Managers, and other technical staff are responsible for the day-to-day operations, they typically have the most direct experience with the quality system process and are encouraged to identify opportunities for improving the quality system by contacting the RQAM directly or through discussion with their management or QAC. During interviews conducted by the Region 7 QA Team during the MSR process, the review team includes questions regarding the support received by personnel from the QA Team and from the QACs in an effort to encourage open dialogue on how the quality system can be improved to help Regional staff perform their job functions. Another process by which the QA Team actively encourages input on the quality system from Regional

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

ATTACHMENT A
ORGANIZATION CHART

REGIONAL OVERVIEW
REGION 7 ORGANIZATIONAL STRUCTURE
July 25, 2006 | Page 2 of 8
("*" = Detail, "***" = Acting)*
Customer Service Phone #: 800-223-0425 or 913-551-7122

OFFICE OF REGIONAL COUNSEL (CNSL)
Martha Steincamp
x7246
REGIONAL COUNSEL

David Cozad, x7587
DEPUTY REGIONAL COUNSEL FOR SUPERFUND

Cheryl Mocznk, x7274
DEPUTY REGIONAL COUNSEL

Becky Ingram Dolph, x7261
Leslie Humphrey, x7237
DEPUTY REGIONAL COUNSEL FOR REGULATORY PROGRAMS

Karen Flournoy
x7782
ASSOCIATE REGIONAL ADMINISTRATOR AGRICULTURE & ENVIRONMENTAL PRIORITIES

Vacant
REGIONAL ADMINISTRATOR (RGAD)

William W. Rice
x7306
DEPUTY REGIONAL ADMINISTRATOR (DRAD)

OFFICE OF POLICY AND MANAGEMENT (PLMG)
Martha Cupps
x7799
ASSISTANT REGIONAL ADMINISTRATOR

Tom Hogan, x7684
DEPUTY DIRECTOR

AIR, RCRA, AND TOXICS DIVISION (ARTD)
Vacant
DIRECTOR

Carol Kaiher, x7681
DEPUTY DIRECTOR

ENVIRONMENTAL SERVICES DIVISION (ENSV)
U. Gale Hutton
x7307
DIRECTOR

Cheryl Crisler
x7820
DEPUTY DIRECTOR

SUPERFUND DIVISION (SUPR)
Cecilia Tapia
x7733
DIRECTOR

Robert Jackson, x7952
DEPUTY DIRECTOR

WATER, WETLANDS, & PESTICIDES DIVISION (WWPD)
William Spratlin
x7401
DIRECTOR

Betty Berry
x7279
DEPUTY DIRECTOR

OFFICE OF EXTERNAL PROGRAMS (EXPR)
Patrick Bustos
x7969
DIRECTOR

Hattie Thomas
x7762
DEPUTY DIRECTOR

ENFORCEMENT COORDINATION OFFICE (ECO)
Mark Hague
x7546
DIRECTOR

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

ATTACHMENT A-1
ENSV ORGANIZATION CHART
with QA Team

PROPOSED USEPA REGION 7
Environmental Services Division

Regional Administrator

Environmental Services Division Director

Environmental Services Deputy Division Director

NEPA

Regional Quality Assurance Manager - Diane Harris

Bob Nichols

Leslye Werner

Assessment and Monitoring Branch

Field Compliance Support Branch

Regional Laboratory

——— Line of Authority
- - - - - Line of Communication

June 13, 2006

ATTACHMENT A-2
REGION 7 ORGANIZATION CHART
with QA Lines of Authority and Communication

USEPA REGION 7

Regional Administrator
(RGAD)

Office of Regional Councel
(CNSL)

OFFICE OF EXTERNAL
PROGRAMS
(EXPR)

ENFORCEMENT COORDINATION
OFFICE
(ECO)

Quality Assurance
Coordinator

Quality Assurance
Coordinator

Quality Assurance
Coordinator

OFFICE OF POLICY
AND MANAGEMENT
(PLMG)

AIR,RCRA, AND TOXICS
DIVISION
(ARTD)

Environmental Services
Division
(ENSV)

SUPERFUND DIVISION
(SUPR)

WATER, WETLANDS, &
PESTICIDES DIVISION
(WWPD)

Regional Quality
Assurance Manager

Quality Assurance
Coordinator

Quality Assurance
Coordinator

Regional Quality
Assurance Team

Quality Assurance
Coordinator

Quality Assurance
Coordinator

——————— Line of Authority
- - - - - Line of Communication

ATTACHMENT B
QMP REVIEW CHECKLIST

Organization:

Question	YES	NO
General		
1. Is the QMP signed by the accountable manager who prepared the plan?		
2. Is the QMP signed by the senior QA official?		
3. Is the QMP signed by the senior management official(s)?		
4. Does the QMP include a section for the signatures of the EPA official and RQAM?		
5. Does the QMP format comply with EPA QA/R-2?		
Management and Organization		
1. Does the QMP include a statement of the organization's policy on quality assurance?		
2. Does the QMP contain organizational charts and functional statements?		
3. Is the current organizational structure of the quality system documented in the QMP reasonable?		
4. Is the QA Manager shown on the organization chart?		
5. Is an acceptable line of reporting from the QA Manager to the senior manager identified?		
6. Is the organizational independence of the QA Manager indicated?		
7. Does the QMP adequately describe the scope of the organization's environmental data collection programs?		
8. Does the QMP discuss how management will assure that applicable elements of the quality system are understood and implemented in all environmental programs?		
Quality System and Description		
1. Does the QMP describe the organization's quality system?		
2. Are the principal components of the quality system (e.g., quality system documentation, annual reviews and planning, project-specific documentation, etc.) described including the roles and implementation responsibilities of management and staff?		
3. Does the QMP list the tools (e.g., QMPs, QAPPs, training plan, etc.) for implementing each component of the quality system?		
4. Is the review and approval process for QMPs submitted by external organizations		

Question	YES	NO
acceptable?		
5. Does the QMP list any components of the organization that develop QMPs (or equivalent document) in support of the organization's quality system and the review and approval procedures for such documentation?		
Personnel Qualifications and Training		
1. Does the QMP state the organization's policy regarding training for management and staff?		
2. Does the QMP identify an acceptable process for assuring that personnel are qualified to perform the environmental data collection activities needed?		
3. Does the QMP describe an acceptable process for determining QA-related training needs and identifying the need for retraining based on changing requirements?		
4. Does the QMP identify an acceptable individual for item (3) above as well as the roles, responsibilities, and authorities of management and staff?		
Procurement of Items and Services		
1. Does the QMP describe or reference the process for reviewing and approving procurement documents or extramural agreements (grants, cooperative agreements, contracted and subcontracted activities) involving or affecting environmental programs?		
2. Does the QMP include the roles, responsibilities, and authorities of management and staff in the process in item (1) above?		
3. Does the review process include ensuring procurement documents are accurate and complete?		
4. Does the review process ensure procurement documents clearly describe the item or service needed, the technical and quality requirements, the quality system elements for which the supplier is responsible, and how the supplier's conformance to customer requirements will be verified?		
5. Does the QMP explain the review and approval of all applicable responses to solicitations to ensure these documents satisfy all technical and quality requirements?		
6. Does the process described ensure procured items and services are of acceptable quality?		
Documents and Records		
1. Does the QMP describe the process for identifying quality-related records (including electronic) requiring control?		
2. Does the QMP include the process for preparing, reviewing, approving, issuing, using, and revising documents and records?		
3. Is the process described for ensuring that records and documents accurately reflect		

Question	YES	NO
completed work?		
4. Does the QMP explain the process for maintaining documents and records including transmittal, distribution, retention, access, preservation, traceability, retrieval, removal of obsolete documentation, and disposition?		
5. Does the process ensure compliance with statutory, regulatory, and EPA requirements?		
6. Is the process explained for establishing and implementing appropriate chain of custody and confidentiality procedures for evidentiary records?		
7. Are roles, responsibilities and authorities described in the above processes?		
Computer Hardware and Software		
1. Does the QMP describe the processes for developing, installing, testing, using, maintaining, controlling, and documenting computer hardware and software used in environmental programs?		
2. Is the process described for assessing and documenting the impact of changes to user requirements and/or the hardware and software on performance?		
3. Does the QMP address the process for evaluating purchased hardware and software to ensure it meets user requirements and complies with applicable contractual requirements and standards?		
4. Is the process explained for ensuring data and information produced from or collected by computers meet applicable requirements and standards?		
5. Are roles, responsibilities, and authorities included in the above processes?		
Planning		
1. Does the QMP contain a systematic planning process for planning environmental data operations (the DQO process is not mandatory but is the recommended planning approach for many EPA data collection activities)?		
2. Does the QMP describe the process for developing, reviewing, approving, implementing, and revising QAPPs or equivalent planning document (see R-5)?		
3. Is the process for evaluating and qualifying data collected for other purposes or from other sources included in the QMP?		
4. Are the roles, responsibilities, and authorities for the above processes defined in the QMP?		
Implementation of Work Process		
1. Does the QMP contain an adequate process for ensuring that work is performed according to planning and technical documents?		
2. Does the QMP describe how operations needing procedures are identified and the process for preparation, review, approval, revision, and withdrawal of these		

Question	YES	NO
procedures?		
3. Is the policy for use of these procedures defined?		
4. Does the QMP include the process for controlling and documenting the release, change, and use of planned procedures including approval, specific times and points for implementing changes, removal of obsolete documentation from work areas, and verification that the changes are made as described?		
5. Are roles, responsibilities, and authorities of management and staff identified?		
Assessment and Response		
1. Does the QMP describe the process for assessing the adequacy of the quality system at least annually?		
2. Is the process for planning, implementing, and documenting assessments and reporting results to management included?		
3. Does the process identified in item (2) above include how to select an assessment tool, the expected frequency, and the roles and responsibilities of the assessors?		
4. Does the QMP address determining the level of competence, experience, and training necessary to ensure that assessment personnel are technically knowledgeable, have no real or perceived conflict of interest, and have no direct involvement or responsibility for the work being assessed?		
5. Does the QMP describe the process for ensuring assessment personnel have sufficient authority, access to programs, managers, documents, and records and the organizational freedom to identify quality problems and noteworthy practices, propose recommendations, and independently confirm implementation and effectiveness of solutions?		
6. Is the process for management's review of, and response to, findings defined?		
7. Does the QMP include the process for identifying how and when corrective actions are to be taken in response to assessment findings?		
8. Does the process identified in item (7) above include ensuring corrective actions are made promptly, confirming the implementation and effectiveness of any corrective action, and documenting such actions?		
9. Does the QMP describe how any disputes encountered as a result of assessments are addressed?		
10. Are roles, responsibilities, and authorities described in the above processes?		
Quality Improvements		
1. Does the QMP address the process for ensuring that conditions adverse to quality are prevented, identified promptly, corrected promptly, and actions are taken toward prevention?		

Question	YES	NO
2. Does the process identified in item (1) above include documenting all corrective actions and tracking such actions to closure?		
3. Does the QMP describe the approach for encouraging staff to establish communications between customers and suppliers, identify process improvement opportunities, and identify and propose solutions for problems?		
4. Are roles, responsibilities, and authorities included in the above processes?		

ATTACHMENT C
QAPP REVIEW CHECKLIST

Site Name: _____ Document No. _____

Site Manager: _____ Date of QAPP: _____

QAPP Author: _____ QAPP Reviewer: _____

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

A7. Quality Objectives & Criteria for Measurement Data	
States project objectives and limits, both qualitatively & quantitatively	
States & characterizes measurement quality objectives as to applicable action levels or criteria	
A8. Special Training Requirements/Certification Listed	
A9. Documentation & Records	
Lists information & records to be included in data report (e.g., raw data, field logs, results of QC checks, problems encountered)	
Describes process and responsibilities for ensuring that the most current approved version of the QAPP is available	
Specifies the level of detail of the field sampling and/or lab analysis narrative needed to completely describe difficulties encountered	
Gives retention time and location for records & reports	
B1. Sampling Process Design (Experimental Design)	
Lists samples required as to type & number	
States sampling network design & rationale	
Gives sampling locations & sampling frequency	
Identifies sample matrices	
Lists classification of each measurement parameter as either critical or needed for information only	
Gives appropriate validation study information for non-standard situations	
B2. Sampling Methods Requirements	
Identifies sample collection procedures & methods	
Lists equipment needed	
Identifies support facilities	
Identifies individuals responsible for corrective action	
Describes process for preparation and decontamination of sampling equipment	
Describes selection and preparation of sample containers and sample volumes	
Describes preservation methods and maximum holding times	
B3. Sample Handling & Custody Requirements	
Notes sample handling requirements	
Notes chain of custody procedures, if required	

B4. Analytical Methods Requirements	
Identifies analytical methods to be followed (with all options) & required equipment	
Provides validation information for non-standard methods	
Identifies individuals responsible for corrective action	
Specifies needed laboratory turnaround time if important to project schedule	
B5. Quality Control Requirements	
Identifies QC procedures & frequency for each sampling, analysis, or measurement technique, as well as associated acceptance criteria & corrective action	
Referenced procedures used to calculate QC statistics (precision & bias or accuracy)	
B6. Instrument/Equipment Testing, Inspection & Maintenance Requirements	
Identifies acceptance testing of sampling & measurement systems	
Describes equipment preventive & corrective maintenance	
Notes availability & location of spare parts	
B7. Instrument Calibration & Frequency	
Identifies equipment needing calibration & frequency for such calibration	
Notes required calibration standard and/or equipment	
Cites calibration records & manner traceable to equipment	
B8. Inspection/Acceptance Requirements for Supplies & Consumables	
States acceptance criteria for supplies & consumables	
Notes responsible individuals	
B9. Data Acquisition Requirements for Non-direct Measurements	
Identifies type of data needed from non-measurement sources (e.g., computer data bases and literature files) along with acceptance criteria for their use	
Describes any limitations of such data	
Documents rationale for original collection of data and its relevance to this project	
B10. Data Management	
Describes standard record keeping, data storage, & retrieval requirements	
Checklists or standard forms attached to QAPP	

Describes data handling equipment & procedures used to process, compile, and analyze data (e.g., required computer hardware and software)	
Describes process for assuring that applicable information resource management requirements are satisfied	
C1. Assessments & Response Actions	
Lists required number, frequency, & type of assessments with approximate dates & names of responsible personnel (assessments include but are not limited to peer review, management systems review, technical systems audits, performance evaluations, and audits of data quality)	
Identifies individuals responsible for corrective actions	
C2. Reports to Management Identifies frequency & distribution of reports for:	
Project status	
Results of performance evaluations & audits	
Results of periodic data quality assessments	
Any significant QA problems	
Preparers & recipients of reports	
D1. Data Review, Validation, & Verification	
States criteria for accepting, rejecting, or qualifying data	
Includes project-specific calculations or algorithms	
D2. Validation & Verification Methods	
Describes process for data validation & verification	
Identifies issue resolution procedure & responsible individuals	
Identifies method for conveying these results to data users	
D3. Reconciliation with User Requirements	
Describes process for reconciling project results with DQOs & reporting limitations on use of data	

ATTACHMENT D
Quality Assurance Review Form

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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: _____%.

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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.

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    ___   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.)		

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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 E
STANDARD FORM 424

APPLICATION FOR FEDERAL ASSISTANCE

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

5. APPLICANT INFORMATION

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

6. EMPLOYER IDENTIFICATION (EIN):

☐☐ - ☐☐☐☐☐☐☐

7. TYPE OF APPLICANT: (enter appropriate letter here) _____

A. State   H. Independent School District
B. County   I. State Controlled Institution of Higher Learning
C. Municipal   J. Private University
D. Township   K. Indian Tribe
E. Interstate   L. Individual
F. Intermunicipal   M. Profit Organization
G. Special District   N. Other (Specify): _____

8. TYPE OF APPLICATION:

☐ New   ☐ Continuation   ☐ Revision

If Revision, enter appropriate letter(s) in box(es): ☐ ☐

A. Increase Award   B. Decrease Award
C. Increase Duration   D. Decrease Duration
Other Specify: _____

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:

☐☐ ---- ☐☐☐

TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. AREAS AFFECTED BY PROJECT (cities, counties, states, etc.):

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

15. Estimated Funding:		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

ATTACHMENT F
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 G
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. For additional information concerning quality assurance, please contact the R7 Quality Assurance Manager at (913) 551-5000.

_____   _____
Date   **Applicant Signature**

                                 _____
                                        Applicant Title

                                 _____
                                        Applicant Organization

ENSV   Revised   03/97

I-1

ATTACHMENT H
GLOSSARY

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Management - those individuals directly responsible and accountable for planning, implementing, and assessing work.

Management system - a structured, non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

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

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

Peer review - a documented critical review of work by qualified individuals (or organizations) who are independent of those who performed the work, but are collectively equivalent in technical expertise. A peer review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality

requirements. The peer review is an in-depth evaluation of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them.

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

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

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

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

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

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

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

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

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

Quality system - a structured and documented management system describing the policies,

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

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

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

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

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

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

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

ATTACHMENT I
EPA Region 7 Product Development and Approval Plan
Draft (revised April 7, 2004)

Contents

Product approval begins at the concept stage. Do not wait until a draft or final version is completed before seeking approval.

Introduction
This plan establishes Region 7 review procedures for materials published or issued through Region 7 of the U.S. Environmental Protection Agency. It does not constitute any suggestion of constraints on the free expression of EPA employees, contractors or assistance recipients. These procedures are established to:
- Assure that materials published, distributed or financed by EPA, including those financed under grants or other assistance agreements, achieve high-quality results.
- Protect the technical and scientific quality of materials distributed or financed by EPA and ensure that they are based on the best scientific and technical evidence available.

- Clarify EPA Region 7 responsibilities for information published by EPA or under an EPA contract or assistance agreement.
- Assure that translations of materials are available in non-English-speaking communities.

What is covered and tracked?

The review process described in this document is applicable to most materials designed for public distribution and created by an EPA employee, contractor, grantee or consultant, including those produced under assistance agreements to state, tribal and local governments. Items subject to product review include but are not limited to:

- Written statements needed to satisfy a statutory or regulatory requirement.

- Published or unpublished books, manuals, and research reports.

- Informational brochures or materials and newsletters or other periodic reports.

- Publications by EPA employees proposed for outside journals.

- Project reports and other materials filed with the National Technical Information Service (NTIS).

- EPA-published proceedings resulting from Agency-sponsored conferences, workshops and seminars. (Papers by non-EPA employees should go through this product review process or contain an adequate disclaimer.)

- Contributions made to publications by interagency working groups where authorship is to be attributed to EPA or its employees. (These publications should go through this product review process or contain an adequate disclaimer.)

- Presentations and audiovisual materials designed for release to the general public.

- Computer software designed for release to the general public.

Exceptions are:
- Congressional testimony.
- Verbatim testimony from hearings.
- Advance notices of proposed rule makings (ANPRMs) and proposed or final regulations subject to a formal comment period.
- Press releases approved by the Office of External Programs.
- Legal opinions, briefs or memoranda, including initial, final or other decisions in quasi-judicial administrative proceedings.
- Federal Register notices.
- Notices of public hearings.
- Requests for proposals.
- Articles by EPA employees and assistance recipients submitted for publication to refereed scientific journals when the article includes a statement indicating that it might

not reflect the official views of EPA.
- Criteria documents or other similar documents subject to a formal public comment period or review by the Science Advisory Board or the Science Advisory Panel.
- Advisory committee statements and reports.
- Materials generated on an employee's own time using private facilities.
- Internal policy statements, memoranda and directives.
- Official EPA correspondence.
- Publications of the Office of the Inspector General.
- Other materials deemed appropriate for exclusion by a Region 7 product review officer.

NOTE: All new communication products must be entered into PROTRAC whether or not they require Headquarters review. See Appendix A, Guidelines for Materials Requiring Headquarters Review.

Applicability
The guidelines are applicable to employees acting in an official capacity related to their work for the Agency. They are also applicable to EPA contractors, consultants, grantees and other assistance recipients. Materials produced by EPA employees are subject to review if they are generated on Agency time or are based on materials derived from EPA-supported activities. This plan does not provide for, nor describe, all of the steps in the document production process; it is designed to outline the review procedures. This plan should not be construed to conflict with the disclosure provisions of the Freedom of Information Act. Questions as to applicability in particular cases should be submitted to a Region 7 product review officer.

Typical Steps of Product Review and Approval

1. An item subject to product review is submitted by the originator to the immediate supervisor at least five working days before approval is needed.

2. The supervisor attaches the Region 7 product review form and evaluates the item.

3. The originator and supervisor evaluate the item for general content, organization and scope; presentation and quality of data; validity of analytical techniques; soundness of conclusions; and consistency of the text with tables, figures, illustrations and maps.

4. The review process is repeated until the originator feels that the item is ready for submission to administrative review.

5. The item is submitted to the division/office director after review by whatever intervening supervisory levels are appropriate. Refusal at any level of management to approve an item may be appealed once to the next higher level of management. No appeal may be made beyond the regional administrator.

6. The product is submitted to a Region 7 product review officer.

7. The approved product is submitted to the Office of External Programs director (the

region's chief product review officer) for final approval.

Roles and responsibilities
Division/office directors are responsible for:
- Approving any items that pass to a product review officer for administrative approval.
- Assuring that their employees remain aware of and conform to the requirements contained in this plan.
- Assuring that all items generated within their areas of authority that are subject to these requirements conform to these procedures and to applicable budgetary and quality standards.
- Forwarding to the regional administrator any item subject to product review that might be "major." A major item is any one of the following:
  - Material with significant scientific or technical uncertainties.
  - Material of any cost that has policy implications.
  - A product from a project funded at $50,000 or more.
  - A single product that costs $10,000 or more to print.
  - A category or series of reports that cost $25,000 or more per year to print.
  -

Products of External Contracts and Grants

EPA encourages publication of the results of its assistance agreements.

- A contractor, consultant, grantee or other aid recipient who intends to release to the public informational materials, reports, or other products produced under an EPA contract or assistance agreement must comply with EPA's product and administrative review process.

- Three copies of the product must be submitted to the EPA project officer for review unless the product will be published with a disclaimer cited below. EPA will evaluate the documents and will provide written suggested changes, if any.

- Every effort should be made to accommodate suggestions arising from the EPA review process while preparing a revised draft. EPA reviewers must be alerted to suggestions that cannot be accommodated and to changes initiated by the originator in the revised draft.

- The following statement must be included in the product if an agreement is reached that the material is appropriate for release as an EPA or EPA-financed publication:

  "The information presented here has been funded wholly or in part by the United States Environmental Protection Agency under assistance agreement (number) to (recipient). It has been subjected to the Agency's product and administrative review and has been approved for publication as an EPA product. Mention of trade names or commercial products does not constitute endorsement or recommendation for use. "

- Originators may **independently publish and distribute a product for the originator's own use and at the originator's own expense** if agreement cannot be reached that the material is appropriate for release as an EPA or EPA-financed publication. The product must include the following statement:

  "Although the information presented here has been funded wholly or in part by the United States Environmental Protection Agency under assistance agreement (number) to (recipient), it might not necessarily reflect the views of the Agency; no official endorsement should be inferred."

EPA also encourages independent publication of reports in refereed journals at any time. The originator must submit a copy of the article to the EPA project officer when it is sent in for publication. The article must include the following statement:

  "Although the research described here has been funded wholly or in part by the United States Environmental Protection Agency under assistance agreement (number) to (recipient), it has not been subjected to the Agency's product and administrative review and therefore might not necessarily reflect the views of the Agency; no official endorsement should be inferred."

Products that are part of a recipient's regular activities are not subject to the EPA product and administrative review process, e.g., state pollution control agency-published newsletters and operation and maintenance manuals under the wastewater treatment construction grants program. However, EPA encourages other organizations to establish a similar review process before publishing such products**.** Originators may publish such products **at their own expense** only if the product includes the following statement:

  "This project has been funded wholly or in part by the United States Environmental Protection Agency under assistance agreement (number) to (recipient). The contents do not necessarily reflect the views and policies of the Environmental Protection Agency, nor does mention of trade names or commercial products constitute endorsement or recommendation for use."

All contracts, grants and other assistance agreements should clearly indicate that product review will be required when the EPA project officer believes that such assistance will result in documents to be released to the public. Such documents might include, but are not limited to, videotapes, audio tapes, slide shows, computer software, brochures, pamphlets or posters.

When questions arise about the necessity of product review for materials not covered in this plan or anticipated in an assistance agreement, the EPA project officer will decide if such materials should be submitted for product review.

Guidelines for Materials Requiring Headquarters Review

Introduction

The purpose of the EPA's product development and approval policy and guidelines, and this

implementation plan is to help plan, develop and distribute communication products that are consistent with EPA's policies and priorities. It does not replace the scientific review requirements of the Science Policy Council Peer Review Handbook or the requirements of EPA's information quality guidelines.

This plan establishes procedures and identifies the responsibilities of all who participate in creating and approving communication products. It is consistent with the mandate in the EPA administrator's January 13, 2003, memo, "Streamlining of Communication Product Development and Approval," which delegates final approval for most Region 7 products to the regional administrator.

What is covered and tracked?

The guidelines cover all media – print, Web, video, audio, CD, etc. Appendix 1 of the guidelines lists the kinds of products that are generally covered (e.g., Web sites, pamphlets, fact sheets, conference brochures, non-technical reports) and not covered (e.g., peer-reviewed technical reports, news releases, Congressional testimony). When in doubt, consult a regional product review officer.

All covered products must be entered into the product development and approval tracking system (PROTRAC). PROTRAC enables all product developers to know whether others in EPA are working on similar products, makes review and approval easier, and helps the EPA's Office of Public Affairs oversee the public outreach products as directed by the administrator.

Roles and responsibilities

The administrator's delegation of most product approval to the regional administrator may not be re-delegated. The administrator's recommendation, however, that product review and approval be coordinated by external affairs offices is being implemented in Region 7 through the Office of External Programs. As the RA's coordinators, the OEP director and product review officers – through participation, advice, training and oversight – will work with the region's management and staff to ensure that the region's outreach products bring the right messages and information to the right people and meet the Agency's product review requirements. Attachment B lists the region's product review officers, communications coordinators and Web coordinators.

__Regional administrator__   The RA is responsible and accountable for the accuracy, clarity, policy consistency and effectiveness of the region's publications. The RA will let OEP know of any categories of products that the RA wants to be personally involved with during development and approval.

__Office of External Programs__   OEP will manage and coordinate the product review process:

- Help define communication strategies and products, particularly when more than one division or office is involved.
- Provide the Region's product review officers, who will serve as advisers to the divisions and offices on all covered products.
- Serve as publication adviser during planning and drafting of outreach products.
- Train communications coordinators and Web coordinators on product review requirements.
- Ensure that the RA is informed and involved as needed in the region's communications strategies and products under development.
- Serve as principal liaison with the HQ Office of Public Affairs, including requests for OPA review of appropriate products and resolving any disagreements about what is covered or needs revision prior to publication.
- Ensure that all federal, EPA and regional requirements for use of environmentally protective paper and ink are met.

__Office of Policy and Management__   PLMG is responsible for two key parts of the region's publishing process:

1. As technical steward of information technology, PLMG ensures that
   - ❏ all technical Web requirements are met (e.g., proper use of Agency template, Sec. 508 accessibility).
   - ❏ Web training and technical support as needed to division webmasters.
2. As the office responsible for printing and contracting,
   - ❏ advises OEP and divisions on using (whether in-house or contracted) the most cost-effective printing services (e.g., photocopying vs. offset) and environmentally protective paper and ink.
   - ❏ helps OEP and divisions obtain contract assistance for design and layout, photography, video production, translation, etc.
   - ❏ ensures that product review of all covered communications products is complete before contracted printing is authorized.

Divisions and offices   As subject matter experts and "owners" of the Agency's environmental information resources, the divisions/offices – often in consultation with HQ counterparts – will plan and develop most outreach products. Specific responsibilities to ensure effective external communication include:

3.   Consulting with the RA, OEP, EPA headquarters, and state and other stakeholders when designing communication strategies and products that advise and inform the public of the Agency's priorities, initiatives, environmental protection activities, and environmental conditions and trends.
4.   Ensuring that communications products are consistent with Agency policy and effectively convey the Agency's information and messages.
5.   Involving communications and/or Web coordinators in all product planning and development and conferring with a product review officer at the concept stage to ensure that products comply with product review policy.
6.   Being alert for emerging environmental conditions and Agency responses that should be promptly publicized.
7.   Assigning well-trained people as communication and Web coordinators.
8.   Assuring that scientific peer review and information quality guidelines have been met.
9.   Considering the value of re-purposing print publications for the Web.
10.   Remaining current on Agency product review requirements and Web guidelines

Typical Steps of Product Development and Approval

While the circumstances affecting individual products might require varying the process, the steps outlined in the product review policy and guidelines and summarized here should be followed:

1.   Someone decides that, in support of a communication strategy, a communication product should be produced. Initial planning takes place in one or more divisions, involving subject experts, managers, communication coordinators and, as needed, Web coordinators. It is important at this concept stage to learn what is being planned by HQ counterparts and other regions. (division/office)

2.   Coordinate with a product review officer to discuss preliminary plans and decide if the planned product is covered by PROTRAC (division/office and OEP)

3.   Enter plans, at the concept stage, into PROTRAC. (division/office)

4.   The OEP product review officer reviews PROTRAC information, clarifies any concerns with originator or program manager, and submits a recommendation to OPA. (OEP)

5.   If HQ OPA approval is needed, OEP coordinates any OPA concerns with division/office and makes sure that the OPA review is timely. (OEP) OEP works with division/office if

contractors are needed for design, photography, video production, translation, etc.
(division/office, OEP)

6.   Draft the product, paying special attention to policy consistency, plain language,
scientific clarity, use of graphics that support the main points, and benefits of
coordinating print and Web versions as appropriate. (division/office)

7.   Transmit the draft via PROTRAC to OEP for review and advice and submit a checklist
certification to OEP showing that information quality guidelines have been met. The
OEP product review officer, when satisfied, will submit approval to HQ OPA for
additional review. (division/office, OEP)

8.   Final product is produced and/or posted to the Web. Printing officer ensures that OEP has
approved products that require outside printing. Final entry is made in PROTRAC.
(division/office, printing officer, OEP)

Web topical approach and content coordination   The administrator's January 11, 2002 memo,
"One Agency, One Voice," directed that EPA reorganize its Web site around topics and
geography rather than organization. An implementation plan for "Topics Lite" Web
reorganization will guide this effort. A tangible result will be a more coherent, usable Web site
with minimal duplication, more comprehensive information, national information on national
Web pages and regional/state/local information on regional Web pages. This multi-year
reorganization requires a substantial level of effort from OEP as coordinator and the
divisions/offices. PROTRAC will track this process, and an Intranet site will include the
implementation plan and a list of topics being coordinated.

Attachment B

Product Review Officers and Division Product Development Coordinators

Product Development and Approval Participants

Office of External Programs

Director   Patrick Bustos
Deputy Director   Hattie Thomas

Product Review Officers:
Superfund   Beckie Himes
                         Debbie Kring
                         Belinda Young

ENSV and EJ   LaTonya Sanders

Brownfields   Belinda Young

Water   Martin Kessler

Air   Kris Lancaster

RCRA   Shawntell Martin

CBEP   Kathleen Fenton

ECO and PLMG   Hattie Thomas

OTHER   Dale Armstrong

Division/Office Product Development and Approval Coordinators		
Division/Office	**Communication Coordinator**	**Web Coordinator**
ARTD	Christine Schmaltz	Christine Schmaltz
ECO	Andri Jovan	Andri Jovan
ENSV	Diane Harris	Diane Harris
Policy & Management	Jeff Wandtke	Jeff Wandtke
Regional Counsel	Kathy Robinson	Kathy Robinson
Superfund	Jude Roach	Jude Roach
Water	Reggie Kidwell	Reggie Kidwell

Attachment C

R7 Product Review Form

A single form is now used for all product review: Web, print, electronic, etc. This form is available on R7@Work at http://r7atwork.r07.epa.gov/intranet/proceduresforms/ under Miscellaneous Procedures and Forms. However, products should conform to the appropriate Information Quality Guidelines checklist in Attachment D.

This is a regional approval form only. A scientific product might still need approval under the requirements of the Science Policy Council Peer Review Handbook. Most products will have to be submitted through PROTRAC on the Internet.

R7 PRODUCT REVIEW FORM

Office of External Programs

(See reverse for further instructions and lists of materials subject to or exempt from review)

SUBMISSION DATE: _____

ORIGINATOR: _____

Originating Office and Division:
_____

PRODUCT TITLE:
_____

TYPE OF PRODUCT (i.e. brochure, Internet page, slide show, etc.):
_____

AUDIENCE:
_____

PURPOSE:
_____

MOST NEW PRODUCTS REQUIRE HQ REVIEW. **Go to** *R7@Work* → **Office Procedures and Forms** → **Miscellaneous Procedures & Forms** → **"Product Development and Approval Plan" for Region 7 product review guidance. If your product needs HQ review, <u>STOP HERE</u> and consult your division's product review representative and/or OEP's product review officer. Continue with this form after HQ has approved the concept and draft of your product through PROTRAC.**

All new products not specifically exempted should be entered into PROTRAC whether they require HQ review or not, so they're available throughout the Agency.

☐ **This product conforms to the appropriate Information Quality Guidelines checklist in Attachment D of the Product Development and Approval Plan.**

<u>CONCURRENCES</u>

Originator: _____   Date: _____

Supervisor: _____   Date: _____

Division/Office Director: _____   Date: _____

OEP Reviewer: _____   Date: _____

OEP Authorizing Official: _____   Date: _____

GENERAL INSTRUCTIONS

Originator should attach a hard copy of submission to product review form and get approval signatures from supervisors. Submit package to OEP office manager, who will log it in and assign to an OEP reviewer. OEP authorizing official (director/deputy director) will give final approval. OEP office manager will log out submission and return package to originator (or to OEP reviewer for Internet submissions). ***See reverse for additional instructions on Web submissions.***

We strongly recommend that you consult with your division's product review representative and/or OEP's product review officer (as listed in the Product Development and Approval Plan) at the **concept stage** of your product.

Originators are responsible for notifying their supervisors of any significant revisions made by OEP. The originator should also send the final approved version to the OEP reviewer.

ADDITIONAL INSTRUCTIONS − Web Submissions

For Internet (R7 Home Page): Once the OEP authorizing official gives final approval, the OEP office manager will log out submission and return package to OEP reviewer. The OEP reviewer will request the electronic version of the final approved submission from the originator, along with a recommended Internet location. The OEP reviewer will then forward the completed submission package, the final electronic version, and the Internet address to IRMB for posting on the R7 Home Page. *(For minor grammatical revisions, the OEP reviewer may elect to make those revisions to the electronic version before posting, if agreed to by the reviewer and the originator.)*

For Intranet (*R7@Work*):   Division director approval is usually sufficient. OEP review is required if more than one division is involved.

For LAN Bulletin Board: Supervisor approval is sufficient.

Attachment D-1

Region 7
Information Quality Guidelines Checklist
Influential Information

Title of product reviewed:

Influential Information has or will have a clear and substantial impact on important public policies or private sector decisions. (Includes OMB economically significant actions, peer reviewed documents, top Agency policy documents, and other actions on a case-by-case basis.)

❏   The information to be disseminated is covered under the guidelines.

❏   The information is in compliance with EPA's Quality System and other related policies.

❏   The information is in compliance with Region 7's Quality Management Plan.

❏   The information is consistent with the OMB definition of "quality," meaning the information has a high level of objectivity, utility, and integrity.
      ❏   Objectivity: information is presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased.
      ❏   Integrity: the information cannot be compromised through corruption or falsification because it is secure from unauthorized access or revision.
      ❏   Utility: the information is useful to the intended users.

❏   The information meets "reproducibility" standard.
The information and its accompanying documentation has a higher degree of transparency regarding the following:
      ❏   The source of the data used
      ❏   The various assumptions employed
      ❏   The analytic methods applied
      ❏   The statistical procedures employed

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Division/Office Director's Signature & Date

**If your information does not comply with any of these items, please attach brief explanation of any omissions. Please include a copy of this document when you submit your draft product to OEP.

Attachment D-2

Region 7
Information Quality Guidelines Checklist
Influential Risk Assessment Information

Title of Product Reviewed:
Influential scientific risk assessment information has or will have a clear and substantial impact on important public policies or private sector decisions. (Includes OMB economically significant actions, peer reviewed documents, top Agency policy documents, and other actions on a case-by-case basis.)

❏   The information to be disseminated is covered under the guidelines.
❏   The information is in compliance with EPA's and Region 7's Quality System and other related policies.
❏   The information is consistent with the OMB definition of "quality," meaning the information has a high level of objectivity, utility, and integrity.
   ❏   Objectivity: information is presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased.
   ❏   Integrity: the information cannot be compromised through corruption or falsification because it is secure from unauthorized access or revision.
   ❏   Utility: the information is useful to the intended users.
❏   The information meets "objectivity" standard.
   ❏   The information is accurate, reliable, and unbiased:
        -best available science and supporting studies conducted using sound and objective scientific practices, including peer reviewed studies
        -data were collected by accepted methods or best available methods (if the method's reliability nature of the decision justifies the use of the data)
   ❏   Presentation of information on human health, safety, or environmental risks, consistent with the purpose of the information, is comprehensive, informative, and understandable. Each of the following must be specified:
        -each population addressed by the risk or each risk assessment endpoint addressed by any estimate of applicable ecological risk
        -expected risk or central estimate for the specific populations affected or the ecological assessment endpoints
        -upper-bound and lower-bound estimate of risk
        -significant uncertainties identified, and studies that would assist in resolving uncertainties
        -peer reviewed studies known to the regional administrator that support, are directly relevant to, or fail to support any estimate of risk and the methodology used to reconcile inconsistencies in the scientific data

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Division/Office Director's Signature & Date

**If your information does not comply with any of these items, please attach brief explanation of any omissions. Please include a copy of this document when you submit your draft product to OEP.

Attachment D-3

Region 7
Information Quality Guidelines Checklist
Non-Influential Information

Title of Product Reviewed:

❏   The information to be disseminated is covered under the guidelines

❏   The information is in compliance with EPA's and Region 7's Quality System and other
       related policies.

❏   The information is consistent with the OMB definition of "quality," meaning the informa-
       tion has a high level of objectivity, utility, and integrity.
   ❏   Objectivity: information is presented in an accurate, clear, complete, and
          unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased.
   ❏   Integrity: the information cannot be compromised through corruption or falsifica-
          tion because it is secure from unauthorized access or revision.
   ❏   Utility: the information is useful to the intended users.

❏   Meets "transparency" quality standard: the public can understand how conclusions were
       reached on the information.

_____
Division/Office Director's Signature & Date

**If your information does not comply with any of these items, please attach brief explanation of
any omissions. Please include a copy of this document when you submit your draft product to
OEP.