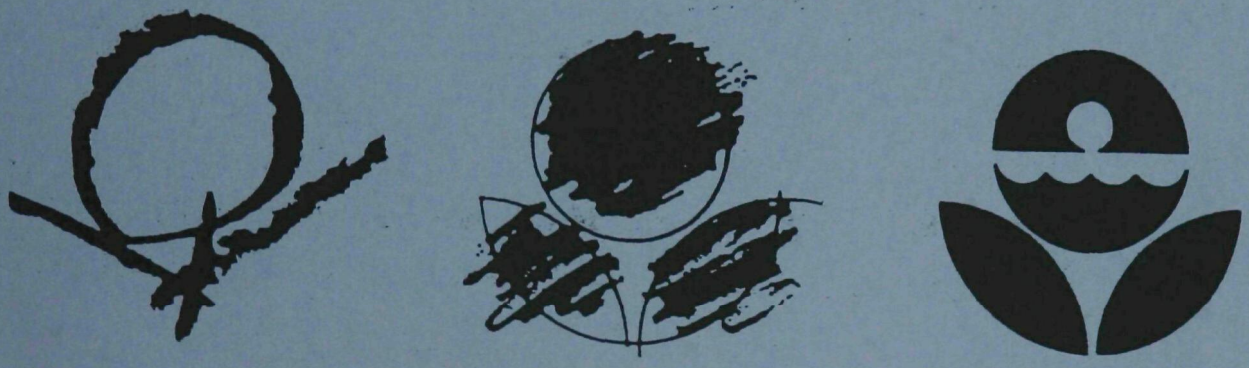
Quality Management Plan and Quality Assurance Project Plan Seminar



U.S. Environmental Protection Agency
Region 6 - Dallas, Texas
Office of Quality Assurance

TABLE OF CONTENTS

July 16, 2001

NOTES

AGENDA

Day 1 - Morning Session: 8:00 AM - 12:00 PM

8:00 - 8:30 AM	Introduction
8:30 - 9:00 AM	Quality Management Plans - General
9:00 - 10:00 AM	EPA QMP Requirements
10:00 - 12:00 PM	QMP Practical Exercise #1

Lunch: 12:00 - 12:30 PM

Afternoon Session: 12:30 - 4:30 PM

12:30 - 1:00 PM	Critique Exercise # 1
1:00 - 2:00 PM	QMP Practical Exercise # 2
2:00 - 2:30 PM	Critique Practical Exercise # 2
2:30 - 4:30 PM	ANSI/ASQC E4-1994 Part C

Day 2 - Morning Session: 8:00 AM - 12:00 PM

8:00 - 9:00 AM	QAPPs - General
9:00 - 10:00 AM	EPA QAPP Requirements
10:00 - 12:00 PM	QAPP Practical Exercise #1

Lunch: 12:00 - 12:30 PM

Afternoon Session: 12:30 - 4:30 PM

12:30 - 1:30 PM	Critique Exercise # 1
1:30 - 3:00 PM	QAPP Practical Exercise # 2
3:00 - 4:00 PM	Critique Practical Exercise # 2
4:00 - 4:30 PM	Wrap-Up & Final Comments

NOTES

COURSE OBJECTIVES

By the end of this course, participants will be able to:

- understand in detail the 10 elements of a Quality Management Plan;
- effectively evaluate the elements of a Quality Management Plan;
- determine the approvability of a Quality Management Plan;
- understand the linkage between Quality Management Plans and Quality Assurance Project Plans;
- define the review and approval process for QA Plans in EPA Region 6;
- understand in detail the 24 elements of a Quality Assurance Project Plan;
- effectively evaluate the elements of a Quality Assurance Project Plan;
- determine the approvability of a Quality Assurance Project Plan; and
- understand the relationship of the EPA's QA System to ANSI/ASQ E-4.

NOTES

QUALITY MANAGEMENT PLANS

Definition:

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

What it does:

- Ensures senior management commitment and involvement;
- Provides a blueprint of the quality program;
- Describes roles and responsibilities;
- Defines requirements for QA Project Plans;
- Provides a benchmark for evaluating progress;
- Satisfies CFR requirements for documenting quality program.

Criteria:

EPA Requirements for Quality Management Plans, EPA QA/R-2 (Replacing Guidance and Specifications for Preparing Quality Assurance Program Plans, QAMS-004/80

NOTES

United States Environmental Protection Agency | Office of Environmental Information Washington, DC 20460 | EPA/240/B-01/002 March 2001

EPA Requirements for Quality Management Plans

EPA QA/R-2

FOREWORD

The U.S. Environmental Protection Agency (EPA) has developed the Quality Management Plan as a means of documenting how an organization will plan, implement, and assess the effectiveness of its quality assurance and quality control operations applied to environmental programs. The process of planning, implementing, and assessing these management systems is called *quality management* and the product of this process is called the *Quality System*. The Quality Management Plan is part of the mandatory Agency-wide Quality System that requires all organizations performing work for EPA to develop and operate management processes and structures for assuring that data or information collected are of the needed and expected quality for their desired use.

This document provides the development and content requirements for Quality Management Plans for organizations that conduct environmental data operations for EPA through contracts, assistance agreements, and interagency agreements; however, it may be used by EPA as well. It contains the same requirements as Chapter 3 of the EPA Order 5360 A1 (2000), *EPA Quality Manual for Environmental Programs*, for EPA organizations.

This document is one of the *U.S. Environmental Protection Agency Quality System Series* documents. These documents describe the EPA policies and procedures for planning, implementing, and assessing the effectiveness of the Quality System. Questions regarding this document or other *Quality System Series* documents should be directed to the Quality Staff:

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

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

www.epa.gov/quality

ACKNOWLEDGMENTS

This document reflects the collaborative efforts of many quality management professionals who participate in the challenge for continual improvement in quality systems supporting environmental programs. These individuals, representing the EPA, other Federal agencies, State and local governments, and private industry, reflect a diverse and broad range of needs and experiences in environmental data collection programs. Their contributions and the comprehensive reviews during the development of this document are greatly appreciated.

TABLE OF CONTENTS

CHAPTER 1

INTRODUCTION

1.1 BACKGROUND

The U.S. Environmental Protection Agency (EPA) annually spends several hundred million dollars in the collection of environmental data for scientific research and regulatory decision making. In addition, non-EPA organizations may spend as much as an order of magnitude more each year to respond to Agency requirements. Furthermore, as EPA is increasingly involved in the use of environmental technology for pollution control and waste clean-up, the use of particular technologies is often specified in permits and regulations. If decision makers are to have the necessary confidence in the quality of environmental data used to support their decisions or that environmental technology successfully performed its intended role, there must be a structured process for quality in place.

A structured system that describes the policies and procedures for ensuring that work processes, products, or services satisfy stated expectations or specifications is called a quality system. All organizations conducting environmental programs funded by EPA are required to establish and implement a quality system. EPA organizations are required to document their quality system in a Quality Management Plan through EPA Order 5360.1 A2, *Policy and Program Requirements for the Mandatory Agency-wide Quality System* (EPA 2000). Non-EPA organizations funded by EPA are required to document their quality system in a Quality Management Plan (or equivalent document)[1] through:

- 48 CFR 46, for contractors;
- 40 CFR 30, 31, and 35 for assistance agreement recipients; and
- other mechanisms, such as consent agreements in enforcement actions.

A Quality Management Plan documents how an organization structures its quality system and describes its quality policies and procedures, criteria for and areas of application, and roles, responsibilities, and authorities. It also describes an organization's policies and procedures for implementing and assessing the effectiveness of the quality system. This document describes the elements of a quality system that must be documented in a Quality Management Plan to comply with EPA requirements.

---

[1]An equivalent document may not be called a Quality Management Plan but still would document an organization's quality system and address the required quality management practices described in this document.

This requirements document presents specifications and instructions for the information that must be contained in a Quality Management Plan for organizations conducting environmental programs funded by EPA. The document also discusses the procedures for review, approval, implementation, and revision of Quality Management Plans. Users of this document should assume that all of the elements described herein are required in a Quality Management Plan unless otherwise directed by EPA.

1.2 QUALITY MANAGEMENT PLANS, THE EPA QUALITY SYSTEM, AND ANSI/ASQC E4-1994

EPA Order 5360.1 A2 and the applicable Federal regulations (defined above) establish a mandatory Quality System that applies to all EPA organizations and organizations that are funded by EPA. Components of this system are illustrated in Figure 1. Organizations must ensure that data collected for the characterization of environmental processes and conditions are of the appropriate type and quality for their intended use and that environmental technologies are designed, constructed, and operated according to defined expectations. Quality system documentation (e.g., the Quality Management Plan) is a key component of the EPA Quality System as shown in Figure 1.

EPA policy is based on the national consensus standard, ANSI/ASQC E4-1994, *Specifications and Guidelines for Environmental Data Collection and Environmental Technology Programs*. The ANSI/ASQC E4-1994 standard describes the necessary management and technical elements for developing and implementing a quality system. This standard recommends using a tiered approach to a quality system. The standard recommends first documenting each organization-wide quality system in a Quality Management Plan or Quality Manual (to address requirements of *Part A: Management Systems* of the standard) and then documenting the applicability of the quality system to technical activity-specific efforts in a Quality Assurance Project Plan (QA Project Plan) or similar document (to address the requirements of *Part B: Collection and Evaluation of Environmental Data* of the standard). EPA has adopted this tiered approach for its mandatory Agency-wide Quality System. This document addresses Part A requirements of the standard.

The Quality Management Plan may be viewed as the 'umbrella' document under which individual projects are conducted. The Quality Management Plan is then supported by project-specific QA Project Plans. A QA Project Plan is the 'blueprint' by which individual projects involving environmental data are implemented and assessed and how specific quality assurance (QA) and quality control (QC) activities will be applied during a particular project. EPA requirements for QA Project Plans are defined in *EPA Requirements for Quality Assurance Project Plans (QA/R-5)* (EPA 2001). In some cases, a QA Project Plan and a Quality Management Plan may be combined into a single document that contains both organizational and project-specific elements. The QA Manager for the EPA organization sponsoring the work has the authority to determine when a single document is applicable and will define the content requirements of such a document.

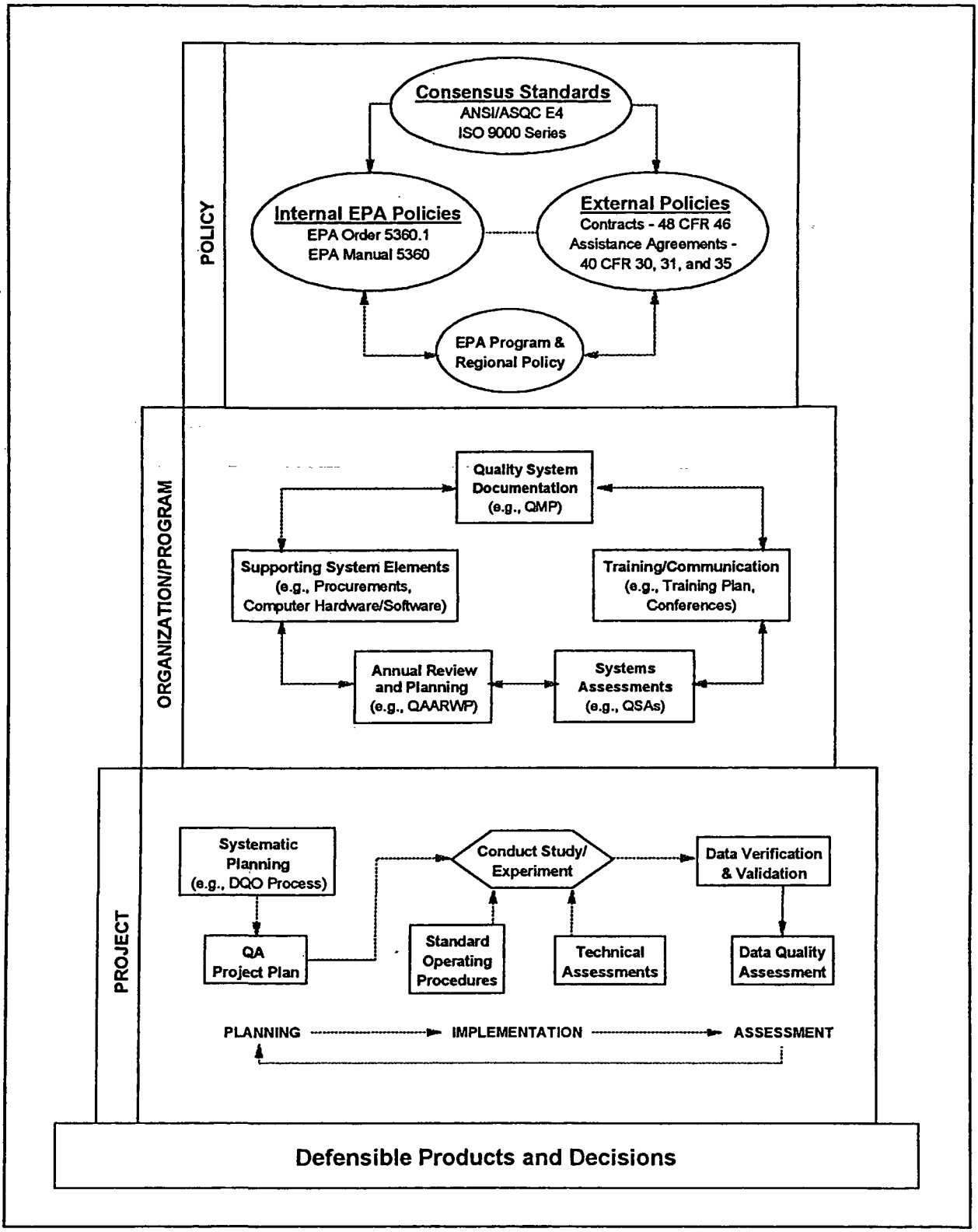


Figure 1. EPA Quality System Components and Tools

1.3 THE GRADED APPROACH AND THE EPA QUALITY SYSTEM

Implementation of the EPA Quality System is based on the principle of graded approach. This principle recognizes that a 'one size fits all' approach to quality requirements will not work in an organization as diverse as EPA so managerial controls are applied according to the scope of the program and/or the intended use of the outputs from a process. For example, the quality expectations of a fundamental research program are different from that of a regulatory compliance program because the purpose or intended use of the data is different. Applying a graded approach means that quality systems for different organizations and programs will vary according to the specific objectives and needs of the organization. The specific application of the graded approach principle to Quality Management Plans is described in Section 2.4.2.

1.4 INTENDED AUDIENCE

This document specifies the requirements for developing a Quality Management Plan for organizations that conduct environmental data operations funded by EPA through contracts, financial assistance agreements, and interagency agreements. EPA organizations may also use this document to develop their Quality Management Plans since this document is clearer and more user-friendly than the equivalent requirements defined in Section 3.3 of EPA Order 5360 A1 (EPA 2000), *The EPA Quality Manual for Environmental Programs* (an internal policy document). However, the preparation, submission, review, and approval requirements for EPA organizations are still contained in Section 3.2 of EPA Order 5360 A1 as these represent internal EPA policy.

1.5 PERIOD OF APPLICABILITY

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

1.6 ADDITIONAL RESOURCES

EPA has issued a checklist for reviewing Quality Management Plans that can be used to verify if the requirements defined in this document are satisfied. This checklist is available on the Quality Staff website, www.epa.gov/quality/tools-org.html#qmp.

1.7 SUPERSESSION

This document replaces QAMS-004/80, *Interim Guidelines and Specifications for Preparing Quality Assurance Program Plans* (EPA 1980) in its entirety.

CHAPTER 2

QUALITY MANAGEMENT PLAN REQUIREMENTS

2.1 POLICY

Quality systems supporting environmental programs involving environmental data or technology conducted by EPA organizations or by organizations funded by EPA shall be covered by an Agency-approved Quality Management Plan.

2.2 PURPOSE

A Quality Management Plan is a management tool that documents an organization's quality system for planning, implementing, documenting, and assessing the effectiveness of activities supporting environmental data operations and other environmental programs. The Quality Management Plan is used to demonstrate conformance to Part A requirements of ANSI/ASQC E4-1994.

2.3 APPLICABILITY

These requirements apply to all organizations conducting environmental programs funded by EPA that acquire, generate, compile, or use environmental data and technology. These requirements apply to all work performed through contracts, cooperative agreements, interagency agreements, State-EPA agreements, State, local, and Tribal Financial Assistants/Grants (including Performance Partnership Grants and Agreements), Research Grants, and in response to statutory or regulatory requirements and consent agreements. These requirements shall be negotiated into interagency agreements, including sub-agreements, and, in some cases, included in enforcement consent agreements and orders. Where specific Federal regulations require the application of QA and QC activities (see Section 1.1), Quality Management Plans shall be prepared, reviewed, and approved in accordance with the specifications contained in this document unless explicitly superseded by regulation.

2.4 GENERAL CONTENT AND DETAIL REQUIREMENTS

2.4.1 General Content

The Quality Management Plan documents the quality management practices which are critical to a quality system. Specific Quality Management Plan content requirements are described in Chapter 3. Each organization should evaluate these requirements for applicability to their quality system. Where a particular element is not relevant, an explanation of why it is not relevant must be provided in the Quality Management Plan. Also, if the Quality Management Plan preparer or EPA organization sponsoring the work determines that additional quality management

elements are useful or necessary for an adequate quality system, these elements should be discussed in the Quality Management Plan.

2.4.2 Level of Detail

The Quality Management Plan should describe a Quality System that is designed to support the objectives of the organization. The level of effort expended to develop a Quality Management Plan should be based on the scope of the program. For example, large grants to a State government may require a comprehensive quality system and Quality Management Plan, whereas smaller grants for programs with relatively less significant impacts may require less substantial documentation.

The Quality Management Plan must be sufficiently inclusive, explicit, and readable to enable both management and staff to understand the priority which management places on QA and QC activities, the established quality policies and procedures, and their respective quality-related roles and responsibilities. The Quality Management Plan must be written so that an assessment of the suitability and effectiveness of the organization's quality system can be accomplished. Such assessments will enable management to determine if the quality system meets the needs of the organization. The Quality Management Plan should be focused on the processes and procedures used to plan, implement, and assess the programs to which it is applied, and must include definitions of appropriate authorities and responsibilities for managers and staff.

2.5 QUALITY MANAGEMENT PLAN PREPARATION[2]

An organization's senior manager is responsible for assuring the preparation of a Quality Management Plan to cover all environmental programs supported or undertaken by the organization. Senior management, i.e., the executives and managers who are responsible and accountable for mission accomplishment and overall operations of the organization, is responsible for ensuring that the Quality Management Plan is prepared and that the quality system documented in the Quality Management Plan satisfies all EPA policy requirements and meets all statutory, contractual, and assistance agreement requirements for EPA work.

While senior management is responsible for the preparation of the Quality Management Plan, the actual preparation may be assigned to the organization's staff so long as it is assured that all managers support the effort; for example, the preparation of the Quality Management Plan may be directed by the QA Manager of the organization. However, it is essential that all management levels understand fully the content of the Quality Management Plan and concur with its implementation.

---

[2]Specific preparation, submission, review, and approval requirements for EPA organizations are contained in Section 3.2 of EPA Order 5360 A1 (EPA 2000) as these represent internal EPA policy.

2.6 QUALITY MANAGEMENT PLAN SUBMISSION AND APPROVAL

The Quality Management Plan must be approved and signed by the senior management of the organization. This will certify that the organization has conducted an internal review of the Quality Management Plan and that management has concurred with its contents.

When a Quality Management Plan is required either by statute, contractual requirement, or assistance agreement condition, the Quality Management Plan must be submitted for review and approval to the EPA official responsible for the work. The EPA official may include the contracting officer's representative (such as the project officer, work assignment manager, or delivery order project office), the award official, and the EPA QA Manager. For example, the review and approval of a State Quality Management Plan that has been submitted as part of a request for an assistance agreement may be performed by the QA Manager of the office awarding the assistance agreement.

EPA approval of a Quality Management Plan will be valid for no more than five years for State, local, and Tribal governments or the length of the extramural agreement for all other extramural agreement holders. The period for which a Quality Management Plan is valid is defined in the Quality Management Plan of the EPA organization sponsoring the work.

2.7 QUALITY MANAGEMENT PLAN REVISIONS

Each organization shall review its Quality Management Plan at least annually to reconfirm the suitability and effectiveness of the approved quality management practices. The process of developing, annually reviewing, and revising (as needed) the Quality Management Plan provides an opportunity for management and staff to clarify roles and responsibilities, address problem areas, and institutionalize improvements. Having an accurate Quality Management Plan at all times is an essential element in every quality system, thus changes in QA policy and procedures shall be documented in the Quality Management Plan in a timely fashion.

In general, a copy of any Quality Management Plan revision(s) made during the year should be submitted to EPA as a report when such changes occur. However, if significant changes have been made to the quality system that affect the performance of work for the Agency, it may be necessary to re-submit the entire Quality Management Plan to EPA for re-approval. Conditions requiring the revision of an approved Quality Management Plan include:

- expiration of the five-year life span of the Quality Management Plan;
- major changes in mission and responsibilities, such as changes in the delegation status of a program;
- re-organization of existing functions that affect programs covered by the Quality Management Plan; and
- assessment findings requiring corrective actions and response.

All appropriate personnel in the organization performing work covered by the scope of the Quality Management Plan shall be notified of changes to the quality system and the Quality Management Plan to keep them informed of the current requirements. This practice should also include active sub-contractors for relevant work.

CHAPTER 3

QUALITY MANAGEMENT PLAN ELEMENTS

3.1 CONTENT REQUIREMENTS

The Quality Management Plan documents management practices, including QA and QC activities, used to ensure that the results of technical work are of the type and quality needed for their intended use. Accordingly, the Quality Management Plan documents:

- the mission and quality policy of the organization;
- the specific roles, authorities, and responsibilities of management and staff with respect to QA and QC activities;
- the means by which effective communications with personnel actually performing the work are assured;
- the processes used to plan, implement, and assess the work performed;
- the process by which measures of effectiveness for QA and QC activities will be established and how frequently effectiveness will be measured; and
- the continual improvement based on lessons learned from previous experience.

The Quality Management Plan reflects the organization's commitment to quality management principles and practices, tailored, when appropriate, by senior management to meet the organization's needs.

The elements to be addressed in a Quality Management Plan include: management and organization; quality system description; personnel qualifications and training; procurement of items and services; documentation and records; computer hardware and software; planning; implementation of work processes; assessment and response; and quality improvement. Specific requirements for each of these elements are described below in Sections 3.2 through 3.11. Items specific to Quality Management Plans developed by EPA organizations under EPA Order 5360.1 A2 (EPA 2000) are noted by "EPA Quality Management Plans." Organizations funded by EPA do not have to address these EPA-specific items.

It is preferable, but not necessary, that the Quality Management Plan address the specifications in the same order as presented below to ensure uniformity and a consistent and complete review. If an existing, approved Quality Management Plan adequately addresses each of these topics, it should not be rewritten simply to conform to the outline provided here.

3.2 MANAGEMENT AND ORGANIZATION

Purpose – To document the overall policy, scope, applicability, and management responsibilities of the organization's quality system.

Specifications – Provide the following:

- an approval page for the signatures of the organization's management and QA manager. The approval page may be part of a title page or a separate sheet following the title page. If EPA approval of the Quality Management Plan is required, the approval page shall include a section for the signature of the EPA official (see Section 2.6). For EPA Quality Management Plans[3], the approval page shall contain the signatures of the organization's senior manager, senior line management (as appropriate), the QA Manager, the Director of the Quality Staff, and the Assistant Administrator of the Office of Environmental Information;

- a statement of the organization's policy on quality assurance, including:

  - the importance of QA and QC activities to the organization and why,
  - the general objectives and goals of the quality system, and
  - the policy for resource allocation for the quality system (EPA Quality Management Plans must discuss personnel, intramural and extramural funding, and travel resources);

- an organization chart that identifies all of the components of the organization and, in particular, the organizational position and lines of reporting for the QA Manager (or similar position such as a Quality Manager) and any QA staff;

- a discussion of the authorities of the QA Manager and any other QA staff that also:

  - documents the organizational independence of the QA Manager from groups generating, compiling, and evaluating environmental data, and
  - indicates how the organization will ensure that QA personnel will have access to the appropriate levels of management in order to plan, assess, and improve the organization's quality system;

- a discussion of the technical activities or programs that are supported by the quality system including:

  - the specific programs that require quality management controls,

[3]Organizations funded by EPA do not have to address these EPA-specific elements.

- where oversight of delegated, contracted, or other extramural programs is needed to assure data quality, and
- where and how internal coordination of QA and QC activities among the group's organizational units needs to occur;

- a discussion of how management will assure that applicable elements of the quality system are understood and implemented in all environmental programs; and

- a discussion of the organization's process for resolving disputes regarding quality system requirements, QA and QC procedures, assessments, or corrective actions (requirement for EPA Quality Management Plans only).

3.3 QUALITY SYSTEM COMPONENTS

Purpose – To document how an organization manages its quality system and defines the primary responsibilities for managing and implementing each component of the system.

Specifications – Provide the following:

- a description of the organization's quality system that includes the principal components of the system and the roles and implementation responsibilities of management and staff with regards to these components. These components include, but are not limited to:

  - quality system documentation
  - annual reviews and planning
  - management assessments
  - training
  - systematic planning of projects
  - project-specific quality documentation
  - project and data assessments;

- a list of the tools for implementing each component of the quality system. These tools include, but are not limited to:

  - Quality Management Plans (quality system documentation),
  - Quality Systems Audits (management assessments),
  - Training Plans (training),
  - QA Project Plan (project-specific quality documentation),
  - Data Verification and Validation (data assessments);

- a list of any components of the organization that develop Quality Management Plans (or equivalent document) in support of the organization's Quality System and the review and approval procedures for such documentation; and

- a discussion of how roles and responsibilities for the principal components of the Quality System are incorporated into performance standards (requirement for EPA Quality Management Plans only).

3.4 PERSONNEL QUALIFICATION AND TRAINING

Purpose – To document the procedures for assuring that all personnel performing work for an organization have the necessary skills to effectively accomplish their work.

Specifications – Provide the following:

- a statement of the policy regarding training for management and staff;

- a description of the process(es), including the roles, responsibilities, and authorities of management and staff, for:

  - identifying, ensuring, and documenting that personnel have and maintain the appropriate knowledge, skill, and statutory, regulatory, professional or other certifications, accreditations, licenses, or other formal qualification necessary, and

  - identifying the need for retraining based on changing requirements.

3.5 PROCUREMENT OF ITEMS AND SERVICES

Purpose – To document the procedures for purchased items and services that directly affect the quality of environmental programs.

Specifications –

Describe or reference the process(es), including the roles, responsibilities, and authorities of management and staff, pertaining to all appropriate procurement documents or extramural agreements, including grants, cooperative agreements, and contracted and subcontracted activities, involving or affecting environmental programs, for:

- reviewing and approving procurement documents (and any changes to these documents) to ensure that procurement documents are accurate, complete, and clearly describe:

- the item or service needed,
- the associated technical and quality requirements,
- the quality system elements for which the supplier is responsible, and
- how the supplier's conformance to the customer's requirements will be verified;

- review and approval of all applicable responses to solicitations to ensure that these documents:
  - satisfy all technical and quality requirements, and
  - provide evidence of the supplier's capability to satisfy EPA quality system requirements as defined in the extramural agreement or applicable Federal Regulation (requirement for EPA Quality Management Plans only);

- ensuring that procured items and services are of acceptable quality, including the review of objective evidence of quality for applicable items and services furnished by suppliers and subcontractors, source selection, source inspections, supplier audits, and examination of deliverables;

- review and approval procedures for mandatory quality-related documentation (e.g., Quality Management Plans or QA Project Plans) from suppliers (requirement for EPA Quality Management Plans only);

- policies and criteria for delegations of EPA authority to review and approve mandatory quality-related documentation (e.g., Quality Management Plans or QA Project Plans) from suppliers consistent with Chapter 2.2 of EPA Order 5360 A1 (requirement for EPA Quality Management Plans only); and

- ensuring that EPA quality-related contracting policies, as defined by the Federal Acquisition Regulations, Office of Federal Procurement Policy, and the EPA Contracts Management Manual [EPA Order 1900 (EPA 1998)], are satisfied (requirement for EPA Quality Management Plans only).

3.6 DOCUMENTS AND RECORDS

Purpose – To document appropriate controls for quality-related documents and records determined to be important to the mission of the organization.

Specifications – Describe or reference the process(es), including the roles, responsibilities, and authorities of management and staff, for:

- identifying quality-related documents and records (both printed and electronic) requiring control;

- preparing, reviewing for conformance to technical and quality system requirements, approving, issuing, using, authenticating, and revising documents and records;

- ensuring that records and documents accurately reflect completed work;

- maintaining documents and records including transmittal, distribution, retention (including retention times), access, preservation (including protection from damage, loss, and deterioration), traceability, retrieval, removal of obsolete documentation, and disposition;

- ensuring compliance with all applicable statutory, regulatory, and EPA requirements for documents and records [EPA Quality Management Plans shall ensure compliance with EPA Order 2160 (EPA 1984) and EPA Directive 2100, Chapter 10 (EPA 1998)]; and

- establishing and implementing appropriate chain of custody and confidentiality procedures for evidentiary records.

3.7 COMPUTER HARDWARE AND SOFTWARE

Purpose – To document how the organization will ensure that computer hardware and software satisfies the organization's requirements.

Specifications – Describe or reference the process(es), including the roles, responsibilities, and authorities of management and staff, for:

- developing, installing, testing (including verification and validation), using, maintaining, controlling, and documenting computer hardware and software used in environmental programs to ensure it meets technical and quality requirements and directives from management [EPA Quality Management Plan specifications must be consistent with EPA Directive 2100 (EPA 1998)];

- assessing and documenting the impact of changes to user requirements and/or the hardware and software on performance;

- evaluating purchased hardware and software to ensure it meets user requirements and complies with applicable contractual requirements and standards;

- ensuring that data and information produced from, or collected by, computers meet applicable information resource management requirements and standards; and

- ensuring that applicable EPA requirements for information resources management are addressed [EPA Directive 2100 (EPA 1998)] including security and privacy requirements (requirement for EPA Quality Management Plans only).

Computer software covered by this requirement includes, but is not limited to, design, data handling, data analysis, modeling of environmental processes and conditions, operations, or process control of environmental technology system (including automated data acquisition and laboratory instrumentation), data bases containing environmental data.

3.8 PLANNING

Purpose – To document how individual data operations will be planned within the organization to ensure that data or information collected are of the needed and expected quality for their desired use.

Specifications – Describe or reference the process(es), including the roles, responsibilities, and authorities of management and staff, for:

- planning environmental data operations using a systematic planning process[4] which includes:
  - the identification and involvement of the project manager, sponsoring organization and responsible official, project personnel, stakeholders, scientific experts, etc. (e.g., all customers and suppliers);
  - a description of the project goal, objectives, and questions and issues to be addressed;
  - the identification of project schedule, resources (including budget), milestones, and any applicable requirements (e.g., regulatory and contractual requirements);
  - the identification of the type and quantity of data needed and how the data will be used to support the project's objectives;
  - the specification of performance criteria for measuring quality;

[4]EPA has developed a systematic planning process called the Data Quality Objectives (DQO) Process [See the *EPA Guidance for the Data Quality Objectives Process (QA/G-4)* (EPA 2000)]. While not mandatory, the DQO Process is the recommended planning approach for many EPA data collection activities.

- the specification of needed QA and QC activities to assess the quality performance criteria (e.g., QC samples for both the field and laboratory, audits, technical assessments, performance evaluations, etc.);

- a description of how, when, and where the data will be obtained (including existing data) and identification of any constraints on data collection; and

- a description of how the acquired data will be analyzed (either in the field or the laboratory), evaluated (i.e., QA review, verification, validation), and assessed against its intended use and the quality performance criteria;

- developing, reviewing, approving, implementing, and revising a QA Project Plan or equivalent planning document [see *EPA Requirements for Quality Assurance Project Plans (QA/R-5)* (EPA 2001)]; and

- evaluating and qualifying data collected for other purposes or from other sources, including the application of any statistical methods, for a new use.

3.9 IMPLEMENTATION OF WORK PROCESSES

Purpose – To document how work processes will be implemented within the organization to ensure that data or information collected are of the needed and expected quality for their desired use.

Specifications – Describe or reference the process(es), including the roles, responsibilities, and authorities of management and staff for:

- ensuring that work is performed according to approved planning and technical documents;

- identification of operations needing procedures (e.g., standardized, special, or critical operations), preparation (including form, content, and applicability), review, approval, revision, and withdrawal of these procedures; and policy for use; and

- controlling and documenting the release, change, and use of planned procedures, including any necessary approvals, specific times and points for implementing changes, removal of obsolete documentation from work areas, and verification that the changes are made as prescribed.

3.10 ASSESSMENT AND RESPONSE

Purpose – To document how the organization will determine the suitability and effectiveness of the implemented quality system and the quality performance of the environmental programs to which the quality system applies.

Specifications – Describe or reference the process(es), including the roles, responsibilities, and authorities of management and staff, pertaining to both management and technical assessments for:

- assessing the adequacy of the quality system at least annually;
- planning, implementing, and documenting assessments and reporting assessment results to management including how to select an assessment tool, the expected frequency of their application to environmental programs, and the roles and responsibilities of assessors;
- determining the level of competence, experience, and training necessary to ensure that personnel conducting assessments are technically knowledgeable, have no real or perceived conflict of interest, and have no direct involvement or responsibility for the work being assessed;
- ensuring that personnel conducting assessments have sufficient authority, access to programs, managers, documents, and records, and organizational freedom to:
  - identify both quality problems and noteworthy practices,
  - propose recommendations for resolving quality problems, and
  - independently confirm implementation and effectiveness of solutions;
- management's review and response to findings;
- identifying how and when corrective actions are to be taken in response to the findings of the assessment, ensuring corrective actions are made promptly, confirming the implementation and effectiveness of any corrective action, and documenting (including the identification of root causes, the determination of whether the problem is unique or has more generic implications, and recommendation of procedures to prevent recurrence) such actions; and
- addressing any disputes encountered as a result of assessments.

Available assessment tools include quality systems audits, management systems reviews, peer reviews, technical reviews, performance evaluations, data quality assessments, readiness reviews, technical systems audits, and surveillance.

3.11 QUALITY IMPROVEMENT

Purpose – To document how the organization will improve the organization's quality system.

Specifications – Identify who (organizationally) is responsible for identifying, planning, implementing, and evaluating the effectiveness of quality improvement activities and describe the process to ensure continuous quality improvement, including the roles and responsibilities of management and staff, for:

- ensuring that conditions adverse to quality are:
  - prevented,
  - identified promptly including a determination of the nature and extent of the problem,
  - corrected as soon as practical, including implementing appropriate corrective actions and actions to prevent reoccurrence,
  - documenting all corrective actions, and
  - tracking such actions to closure;

- encouraging staff at all levels to establish communications between customers and suppliers, identify process improvement opportunities, and identify and offer solutions to problems.

REFERENCES

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

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

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

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

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

EPA Directive 2100 (1999), *Information Resources Management Policy Manual*, U.S. Environmental Protection Agency, Washington, DC.

EPA Order 1900 (February 1998), *Contracts Management Manual*, U.S. Environmental Protection Agency, Washington, DC.

EPA Order 2160 (July 1984), *Records Management Manual*, U.S. Environmental Protection Agency, Washington, DC.

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

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

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

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

U.S. Environmental Protection Agency, 1980. *Interim Guidelines and Specifications for Preparing Quality Assurance Program Plans*, QAMS-004/80, Office of Research and Development.

(This page has been left blank intentionally.)

QMP PRACTICAL EXERCISE #1

In small groups, we will review a "Good Example" of a **"Bad Example"** of a Quality Management Plan submitted by the Commonwealth of East Carolina's Water Commission (ECWC), for it's Marine and Estuarine Division. The ECWC has total responsibility for all Environmental work on surface, subsurface and coastal waterways in the mythical Commonwealth of East Carolina. Since this "Bad Example" is comprised of bits and pieces of QMPs submitted from several organizations and states the name of the state has been changed to protect the guilty.

Spending a limited amount of time, as defined by the instructor, review the sections identified by the instructor using EPA QA/R-2 as the review criteria.

NOTES

QUALITY MANAGEMENT PLAN

FOR

MARINE AND ESTUARINE ENVIRONMENTAL MONITORING AND REMEDIAL ACTION

SUBMITTED BY EAST CAROLINA WATER COMMISSION

TABLE OF CONTENTS

Quality Management Plan for work to be performed by, or implemented by, the East Carolina Water Commission, for all efforts involving Marine and Estuarine Environmental Monitoring and Remedial Action, in the State and Coastal Waters of the Commonwealth of East Carolina.

East Carolina Water Commission Document Control Number QMP-1996-ME Div.-1

EPA Region 6 QTRAK #_____

Plan Prepared By:

Susan Daigle, ECWC Marine & Division Quality Assurance Manager — Date: 9/12/96

ECWC Concurrence:

Joan Breedon, ECWC Central Laboratory Division Director — Date: 9/12/96

Bob Gilmore, ECWC Data Processing Division Chief — Date: 9/14/96

Paul Cronin, ECWC Field Operations Division Chief — Date: 9/12/96

ECWC Approvals:

Darryl Royale, Marine and Estuarine Division Director — Date: 9/15/96

Shelia Meyers, Quality Manager ECWC — Date: 9/12/96

Barry Switchitter, ECWC Commissioner — Date: 9/15/96

EPA Approvals:

Alva L. Smith, 6EN-XQ
Regional Quality Assurance Officer — Date: _____

1. QUALITY MANAGEMENT AND ORGANIZATION

1.1 ECWC Marine and Estuarine Division Mission

The mission of ECWC Marine and Estuarine Division is to monitor and protect the environment to the extent outlined by Commonwealth of East Carolina Statutory Law and the delegated responsibilities from the U.S. Code of Federal Regulations that U.S. EPA has empowered the ECWC. A good decision for ECWC is one that follows both the spirit and letter of environmental law and regulations, protects the environment and public health, expends the least amount of resources, is made quickly and causes the least amount of disruption. Decisions made by ECWC must be based on valid scientific assumptions and good information, because those decisions impact not only the environment but public health, the regulated community and ECWC's credibility.

1.2 Quality Assurance Policy

Quality Assurance (QA) is an integrated system of management activities involving planning, implementation, assessment, reporting , and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the customer. As a matter of policy, ECWC is strongly committed to good science, and sound quality assurance practices. It is a general objective that on all work performed by the ECWC Marine and Estuarine Division that there be achievable data quality goals defined for every project in which Environmentally Related Measurements will be generated. These goals will be stated in each QAPP.

1.3 QA Structure

The ECWC Marine and Estuarine Division utilizes a decentralized QA organization, relying on each Branch and/or project within the division to be responsible for their own Quality Assurance efforts, with overall QA Management and policy coming from Marine and Estuarine Division QA Manager. Within the ECWC there is a QA Manager within each Division that is responsible for preparation, maintenance, update and implementation of their respective Division's QMP as described in the overall QMP for the ECWC. Figure 1-1 is an organization chart that shows the lines of authority in the ECWC, and specifically in the Marine and Estuarine Division.

1.4 Effective Date

This QMP becomes effective on the date finally approved by the U.S. EPA Region 6 QA Officer, and remains in effect until revised at the time required by the U.S. EPA Marine and Estuarine General Program Grant.

1.5 QMP/QAPP Policy

This QMPs follows the guidance of Quality Assurance Management Staff (QAMS) at EPA Headquarters (EPA QA/R-2). The initial review and approval of Quality Assurance Project Plans, rests with the ECWC Marine and Estuarine Division QA Manager an Division Director. Approval or disapproval and return of a QAPP to the submitter will be accomplished within 20 working days by the ECWC Marine and EstuarineEsturaine Division QA Manager. Once a QAPP is deemed acceptable it will be forwarded to the QA Managers of any other ECWC Division that has any participation in the project for concurrence. After all participating ECWC Divisions have approved/concurred on the QAPP it will be forwarded on to the ECWC QA Manager for final review/approval and forwarding to EPA Region 6. Specific written comments shall be provided when a QAPP is disapproved that assist the submitter in creating a workable QAPP. Final approval of QAPPs rests with the appropriate EPA Region 6 Division QA Officer. Once a QAPP is approved, it is in effect until the project is completed. QAPPs must follow the guidance of QAMS for QAPPs, which is EPA QAMS 005/80.

1.6 QA Plan Document Control Numbering

All QMPs and QAPPs will be assigned a document control number by the ECWC QA Manager, prior to submission to EPA. Individual tasked with responsibility for preparation or revision of a QA Plan will receive and use that document control number in that respective QA Plan. QA Plan format for ECWC defined by ECWC SOP # 5 (Appendix B) will be followed without exception in the Marine and Estuarine Division.

1.7 QA Manager

The ECWC Marine and Estuarine Division Quality Assurance Manager and staff will be responsible for the following QA activities (see Section 9 for explanation of these functions):

1.7.1 Preparation and submission of the Marine and Estuarine Division QMP;

1.7.2 Review and approval of all Marine and Estuarine Division QAPPs;

1.7.3 Laboratory audits (multimedia and program specific):

1.7.4 Certification of laboratories; and

1.7.5 Maintenance of a file system that contains a copy of all current Marine and Estuarine Division QAPPs.

FIGURE 1

ECWC MARINE AND ESTUARINE DIVISION PERSONNEL

2. QUALITY SYSTEM AND DESCRIPTION

The ECWC Marine and Estuarine Division utilizes a decentralized QA organization, relying on each project to be responsible for their own Quality Assurance efforts, with overall QA Management and policy coming from Marine and Estuarine Division QA Manager.

2.1 Project Quality Assurance Functions

Each Project Director shall be jointly responsible for the following QA activities in their respective Projects, along with the Project QA Officer:

2.1.1 Concurrence and submission of QAPPs to Region 6 Office of Quality Assurance for final approval;

2.1.2 Assignment of a QA/QC Technical Liaison between Project and Marine and Estuarine Division;

2.1.3 Providing routine technical guidance to Project Staff on implementation of the QAPPs;

2.1.4 Maintenance or oversight of a file system that contains a copy of all valid SOPs; and

2.1.5 Preparation of a quarterly QA report on each project that will be submitted to the Marine and Estuarine Division QA Officer.

2.2 Data Quality Objective (DQO) Process

The Data Quality Objective (DQO) Process is an essential tool to be used in planning all environmental data collection activities. DQOs shall be developed following all current and applicable EPA guidance (Currently EPA QA/G-4, Guidance for Planning for Data Collection in Support of Environmental Decision Making Using the Data Quality Objectives Process. Participants in the DQO process shall be those individuals that represent organizations that are involved or could be affected by the respective project. At a minimum the ECWC Marine and Estuarine Division Project Director, Project Officer and Project QA Officer will participate. A representative will be requested from the ECWC elements that will collect samples, analyze samples. At least 30 days prior to initiation of DQO Planning session the Project Director shall provide a list of proposed organizations/individuals that will be invited to participate. Region 6 EPA Project Officer will be kept apprised of DQO sessions, and invited to participate.

2.3 QA Project Plans (QAPPs)

Every project involving the collection of environmental data must have a written Quality

Assurance Project Plan (QAPPs) approved prior to initiation of data collection activities.

A QAPP presents, in specific terms, the policies, organization, objectives, functional activities, QA, and quality control (QC) activities designed to achieve the data quality objectives (DQOs) of a particular project or continuing operation. The typical characteristics of a good QAPP are:

. requirements for management and technical audits and a process for correction of deficiencies.

. a requirement for documenting sampling procedures

. the definition of specific QC activities.

EPA is responsible for policy on format and areas of coverage for QAPPs. Each QAPP will cite the specific QMP, and its effective date, that it falls under. No QAPP can be approved without an approved QMP, as the QMP is essential for defining the criteria of a QAPP.

Implementation of QAPPs will be evaluated by U.S. EPA Region 6 Office of QA through audits and other means.

2.4 In-House Projects

The ECWC Marine and Estuarine Division will prepare QAPPs for all projects that will be performed totally by ECWC personnel. All QAPPs will conform to QAMS 005/80 or EPA QA/R-5. The Project QA Officer shall evaluate the implementation of these plans.

2.5 Contracted Projects

The contractor will prepare QAPPs for all projects that will be performed totally by contractor personnel. All QAPPs will conform to EPA QA/R-5. The Contractor's QA Officer shall evaluate the implementation of these plans, and oversight of this evaluation shall be performed annually by designated ECWC Marine and Estuarine Division Staff.

2.6 Standard Operating Procedures (SOPs)

Standard Operating Procedures (SOPs) may be developed and incorporated into QMPs or QAPPs by reference and attachment. Use of SOPs is encouraged both as a method to reduce variation and to reduce costs, when a similar method or process is utilized in a number of projects or programs. All SOPs shall be written, reviewed, approved and updated in accordance with ECWC SOP # 1, revision current at time SOP is approved.

2.7 Management Systems Reviews (MSRs)

Management System Reviews shall be performed on all projects within 180 days of project completion. Staff designated to perform MSRs will be defined in the respective QAPPs. MSR reports will be prepared and submitted to respective Project Officer for review, comment and if requested, corrective action(s) within 90 days of completion of the MSR by the MSR team leader. If corrective action is requested the Project Officer shall define the necessary corrective action(s) to be taken in a response to the MSR team leader.

3. PERSONNEL QUALIFICATIONS AND TRAINING

3.1 Required certification

All ECWC sample collectors receive 32 hours of formal training an successfully complete a written and performance examination prior to collection of any samples in accordance with ECWC Samplers Certification Program, formally approved by U.S. EPA, Region 6 on July 11, 1993. After 90 days of OJT, a sample collector is fully certified if all observed work has been of an acceptable quality to the first line supervisor. All ECWC Marine and Estuarine Division Project Officers, Project and Division QA Officers, QA Coordinators, and Project Directors shall be certified for QA in accordance with ECWC Directive # 5-92 (Appendix C).

3.2 Establishing training requirements for personnel

The Project QA Officer is making plans to attend the 1994 EPA National QA Meeting, and will attend several training courses there.

At the present time, no specified training is **required** above and beyond what staff personnel are already capable of; however, training will be sought which will improve the effectiveness of the staff. Original FY 94 budget had allocated considerable funding for staff training, but had to be re-allocated to cover salaries. Some money is available for training from other sources, but it is anticipated that it will not be enough to cover all the training desirable for project personnel.

3.3 Identifying and satisfying technical and project management training needs;

Each Division of the ECWC participates in the centrally managed East Carolina Personnel Commission's annual training survey, which defines training needs by department.

3.4 Identifying and/or designing training programs to meet these needs;

Where there are existing training programs personnel requiring such training can enroll and take training at their discretion, with first line supervisor approval.

3.5 Performing introductory training and continuing training (or re-training);

U.S. EPA Region 6 will present the following courses:

1. Orientation to Quality Assurance Management,
2. Data Quality Objectives,
3. Quality Management Plans and Quality Assurance Project Plans Seminar.

3.6 Encouraging professional development beyond initial qualifications;

All ECWC staff are encouraged to take training to prepare themselves for acceptance of positions requiring higher level skills and abilities.

3.7 Documenting and maintaining training records for personnel;

The East Carolina Personnel Commission maintains all training records of East Carolina State employees. Training records are forwarded to the East Carolina Personnel Commission at the discretion of the employee, with concurrence of the first line supervisor.

3.8 Identifying qualified trainers;

All ECWC Marine and Estuarine Division staff that conduct training shall have as a minimum:

- completed any course they conduct;
- completed a course in conducting training;
- a dry and sarcastic sense of humor;
- a latent disrespect for "sacred cows";
- complete support of University of Texas Longhorns athletics.

3.9 Assessing the effectiveness of training and (where applicable) establishing a program for training and updating the instructors on training techniques and technical changes; and

Evaluations from each ECWC Marine and Estuarine Training course will be evaluated by the course instructors for areas in which improvements can be made. Supervisors of instructors will review all course evaluations also.

3.10 Reviewing and updating training materials and course content.

All training courses will be reviewed and updated annually, and more frequently if course evaluations are consistently negative, or if significant changes to documents, regulations, policy or state or federal laws that courses are based upon are changed.

4. PROCUREMENT OF ITEMS AND SERVICES

4.1 Process for defining and assuring that QA/QC requirements for all applicable acquisitions are documented for each acquisition action;

All procured items will be field tested prior to actual data collection activities to ensure they are performing properly. Project personnel will verbally inform project officer of non-conforming equipment or supplies.

4.2 Process to assure changes to procurement documents receive the same review approvals as the original documents;

Any changes to procurement documents will be approved by the Project Officer or designee.

4.3 Process to assure QA/QC requirements are adequately addressed in responses to applicable solicitations and that QA/QC is an integral criterion of the evaluation criteria;

Commonwealth of East Carolina General Services Agency creates the policy for all procurement activities, ECWC provides input into that process to assure QA/QC requirements are met.

4.4 Process for ensuring that contracted and subcontracted activities produce results of acceptable quality.

Each project QAPP will define the process by which supplies and services are accepted for the ECWC from the supplier or contractor.

5. DOCUMENTATION and RECORDS

5.1 Documentation and Procedure for Review of Quality Assurance Project Plans

The review will be conducted using EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations (EPA QA/R-5) as a standard along with this QMP. Approved Quality Assurance Project Plans will be maintained in the files of the appropriate Project Office while the approved Quality Management Plan will be maintained by the Quality Assurance Manager. Each QAPP shall cite the QMP that it falls under, including approval date.

5.3. Record Maintenance

All quality assurance documents of the ECWC Marine and Estuarine Division will be filed after action in the central ECWC file room. The documents will be maintained under the supervision of a file clerk. The file clerk will take special care to preserve the integrity of sensitive documents such as enforcement actions. This special care includes such precautions as locking these files in the absence of the file clerk. If sensitive documents are to be used at a work station, due care will be used there, too, in order to maintain the integrity of the data.

6. USE OF AUTOMATED DATA PROCESSING SYSTEM

6.1. Policy

It is an ECWC policy that data collected, analyzed, processed and maintained on all automated data processing (ADP) systems, in support of environmental studies, be accurate and of sufficient integrity to support effective environmental management.

In order to ensure the effective and efficient use of the ECWC's ADP systems, including hardware and software system design, development, implementation, and maintenance, ECWC will follow the Commonwealth of East Carolina's Information Resource Management (IRM) Policy.

6.2 Computer Hardware and Software Requirements

6.2.1 All hardware and software shall meet Commonwealth of East Carolina's Informational Resource Management Hardware and Software Standards from the Architectural Management and Planning Branch of the ECIRM's Data Processing Division.

6.2.2 All software systems shall be developed and designed according to the ECIRM's Systems and Development Guidance.

6.2.3 All software systems shall be operated and maintained according to ECIRM's Operation and Maintenance Manual.

6.2.4 For integrity of computer resident data in stand alone PC systems, the laboratories or offices which use systems for environmental effects studies shall follow the EPA Good Automated Laboratory Practices guidelines.

6.4 Data Management

To take full advantage of the ECWC's growing technological and data resources, there needs to be an increased emphasis on improving compatibility of data among the systems. For consistent definition of data, and to facilitate cross-media use of data, all data produced or collected by the computers shall be managed as specified in the Commonwealth of East Carolina's IRM Policy Manual. ECIRM is in the process of developing State-wide data standards, in the ECIRM Catalog of Data Policies and Standards. This catalog will summarize State data policies and standards which are the definitive list of data standards that East Carolina agency personnel and contractors must meet when developing information systems.

6.5 Information Security

It is important that the ECWC's information resources are protected from potential loss and

misuse from a variety of accidental and deliberate causes, which can take the form of destruction, disclosure, alteration, delay or undesired manipulation.

For a comprehensive, Statewide security program to safeguard the ECWC's information resources, all information resources shall be safeguarded as specified in the ECIRM ADP Disaster Recovery Plan.

6.6 Documents

For proper implementation and maintenance of the system, the appropriate offices shall have:

6.6.1 A written description of the computer system(s) hardware and a written operating procedures for routine maintenance operations;

6.6.2 A written document which contains detailed description of the software in use, including the listing of all algorithms or formulas used for data generation, processing and assessment, clear guidelines for data acceptance criteria, criteria for data validation/invalidation, data deletion/addition, and data correction; and

6.6.3 Standard Operating Procedures (SOPs) which describe the routine operation, maintenance and testing, to ensure that both the hardware and software in use is accurately performing the intended functions.

These documents shall be readily available in the areas where these procedures will be performed. Published literature or vendor documentation may be used as a supplement to software documentation if properly referenced therein. All deviations from the operational instructions for data collection systems shall be authorized by the designated responsible person. Changes in any part of the operating procedures shall be properly authorized, reviewed and accepted in writing by the designated responsible person.

6.7 Personnel

Personnel involved in computer data collection systems, hardware and software shall:

6.7.1 have adequate education, training, and experience to perform the assigned system functions;

6.7.2 have a current summary of their training, experience, and job description, including information relevant to system design and operation maintained at the facility; and

6.7.3 be of sufficient number for timely and proper conduct of the study, including timely and proper operation of the automated data collection system(s).

7. PLANNING

7.1 Customer Identification Process

The customer for the results of the work is the Environmental Conditions of the Bays and Estuaries of the Commonwealth of East Carolina.

7.2 Identification of Customer Needs and Expectations

The ECWC will use the Data Quality Objectives Process (DQO) planning methodology for all in-house projects that will exceed $ 75,000 per year. For projects to be performed by a Contractor Data Quality Objectives will be used at the discretion of the Contractor.

7.3 Creation of Quality Specifications for Data

The ECWC Marine and Estuarine Division utilizes the DQO process to define the data quality specifications for each project. Once the DQO process is accomplished for a project not only does it define data quality requirements, but it also considers any cost and schedule constraints within which project activities are required to be performed, and identifies acceptance criteria for the result or measures of performance by which customer satisfaction will be determined.

8. IMPLEMENTATION OF WORK PROCESSES

8.1 Procedures for ensuring that work is performed according to plan

All ECWC Marine and Estuarine Division environmental data operations project will be implemented in accordance with the Quality Assurance Project Plan. The ECWC Marine and Estuarine Division Director meets quarterly with all Project Managers to review implementation status of projects.

8.2 Level of management oversight and inspection

The level of oversight and inspection will be commensurate with the importance of particular projects and the intended use of the data.

8.3 Procedures for appropriate routine, standardized, special, or critical operations development and implementation

8.3.1 Identification of operations needing procedures

Operations requiring procedures are defined in the QAPP. If the procedures are standard or routine they will be covered in depth in the ECWC Sampling Handbook, which will be incorporated by reference into all QAPPs. ECWC SOPs, can be used in the same manner where applicable.

8.3.2 Preparation of procedures

All special and critical operations procedures will be defined in the applicable QAPP in detail.

8.3.3 Review and approval of procedures

All procedures will be approved by the Director ECWC Marine and Estuarine Division prior to actual use. Special and critical operations procedures will be peer reviewed by at least three Project Officers prior to submission for final approval.

9. QUALITY ASSESSMENT AND RESPONSE

Even the best QA plans are of limited value unless they are implemented. In order to ensure that QA plans are being implemented and that they are adequate, a series of technical and managerial audits are necessary. These audits comprise the major mechanism of the ECWC oversight. The QAPP must describe how and by whom assessments of environmental programs are planned, conducted, and evaluated to measure the effectiveness of the implemented quality system. The assessment tools for environmental programs encompass:

- management systems reviews,
- surveillances,
- audits,
- performance evaluations,
- audits of data quality,
- peer reviews and technical reviews,
- readiness reviews, and
- data quality assessments.

9.1 Planning, scheduling, and implementation of assessment and response to needed changes

Project Officers have total responsibility for assessments of their projects.

9.2 Definition of responsibilities, levels of participation, and authority for staff

Coverage of these items is in section 9.4.

9.3 How, when, and by whom actions will be taken in response to the findings of the assessment, and how the effectiveness of the response will be determined.

Responses to assessment findings will be the responsibility of the Project QA Officer.

9.4 Ability of personnel conducting assessments to:

- identify quality problems;
- identify and cite noteworthy practices that may be shared with others to improve the quality of their operations and products;
- propose recommendations for resolving quality problems;
- independently confirm implementation and effectiveness of solutions; and
- provide documented assurance to line management that, when problems are identified, further work performed is monitored carefully until the problems are suitably resolved.

The personnel performing in-house management assessments are trained managers with years of supervisory, managerial and administrative experience. The technical self-assessments will be performed by Project Managers and Project Officers who are intimately familiar with the goals of the project. The independent technical assessment will be performed by natural resource specialist with years of experience in their respective fields. As the assessors are fully qualified professionals in their fields, any recommendations made will be considered by the Project Managers and Project Officer of the particular project under assessment, and implemented immediately, with approval of the Director.

External assessments will be performed by U.S. EPA QAMS Staff. Recommendations made by QAMS will be considered by the Project Managers and Project Officer of the particular project under assessment, and implemented immediately, with approval of the Director.

10. QUALITY IMPROVEMENT

This section of the QMP includes a description of the ECWC Marine and Estuarine Division's management system for detecting and preventing quality problems and for ensuring continuing quality improvement.

10.1 Process and personnel responsible for identifying, planning, implementing, and evaluating the effectiveness of quality improvement activities.

In the ECWC Marine and Estuarine Division the Quality Manager has total responsibility for Quality Improvement. On each project the Project QA Officer has total responsibility for Quality Improvement.

10.2 Corrective action program.

Each QAPP will define a method to ensure that conditions adverse to quality are identified promptly and corrected as soon as practical. This Corrective Actions process shall include the identification of root causes of problems, determining if the problem is unique or has more generic implications, and recommending procedures to prevent recurrence.

APPENDIX A

TERMS AND DEFINITIONS

Terms and definitions are at the back of this book at page 247.

NOTES

QMP CLASSROOM EXERCISE #2

In our same small groups, we will now revise the **"Bad Example"** of a Quality Management Plan into a "Better Example" of a QMP.

Work in your group on the sections assigned by the instructor, using EPA QA/R-2 as the criteria document for the revision.

NOTES

QUALITY MANAGEMENT PLAN

FOR

MARINE AND ESTUARINE ENVIRONMENTAL MONITORING AND REMEDIAL ACTION

SUBMITTED BY EAST CAROLINA WATER COMMISSION

Original Table of Contents:

TABLE OF CONTENTS

Comments:

Table of Contents is not a required item for a QMP, but it certainly adds to the usefulness, especially in longer QMPs.

Original Approval Page:

Quality Management Plan for work to be performed by, or implemented by, the East Carolina Water Commission, for all efforts involving Marine and Estuarine Environmental Monitoring and Remedial Action, in the State and Coastal Waters of the Commonwealth of East Carolina.

East Carolina Water Commission Document Control Number QMP-1996-ME Div.-1

EPA Region 6 QTRAK #_____

Plan Prepared By:

_____ Date:_____
Susan Daigle, , ECWC Marine & Estuarine
Division Quality Assurance Manager

ECWC Concurrence:

_____ Date:_____
Joan Breedon, Laboratory Director

_____ Date:_____
Bob Gilmore, Data Processing Chief

_____ Date:_____
Paul Cronin, Field Operations Chief

ECWC Approvals:

_____ Date:_____
Darryl Royale, Marine and Estuarine
Division Director

_____ Date:_____
Shelia Meyers, Quality Manager ECWC

_____ Date:_____
Barry Switchitter, ECWC Commissioner

EPA Approvals:

_____ Date:_____
Alva L. Smith, Chief, 6E-Q
Quality Assurance Officer

REMEMBER- 3 COPIES ARE RECOMMENDED TO BE SUBMITTED, ALL WITH ORIGINAL SIGNATURES.

Requirement: (From Section 1 of EPA QA/R-2)

This section of the QMP shall contain or address the following management and organizational items:

- an approval page for the signatures of the accountable managers, senior line management (as appropriate), and the QA Manager/QA Officer of the organization, and for the Region 6 QA Officer, and appropriate Region 6 Program Office staff. This approval page may be part of a title page or a separate sheet following the title page.

TASK 1. GROUP ASSIGNMENT:

Revise the original organizational chart, adding or deleting at the consensus of the work group.

Original Section 1:

1. QUALITY MANAGEMENT AND ORGANIZATION

1.1 ECWC Marine and Estuarine Division Mission

The mission of ECWC Marine and Estuarine Division is to monitor and protect the environment to the extent outlined by Commonwealth of East Carolina Statutory Law and the delegated responsibilities from the U.S. Code of Federal Regulations that U.S. EPA has empowered the ECWC. A good decision for ECWC is one that follows both the spirit and letter of environmental law and regulations, protects the environment and public health, expends the least amount of resources, is made quickly and causes the least amount of disruption. Decisions made by ECWC must be based on valid scientific assumptions and good information, because those decisions impact not only the environment but public health, the regulated community and ECWC's credibility.

1.2 Quality Assurance Policy

Quality Assurance (QA) is an integrated system of management activities involving planning, implementation, assessment, reporting , and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the customer. As a matter of policy, ECWC is strongly committed to good science, and sound quality assurance practices. It is a general objective that on all work performed by the ECWC Marine and Estuarine Division that there be achievable data quality goals defined for every project in which Environmentally Related Measurements will be generated. These goals will be stated in each QAPP.

1.3 QA Structure

The ECWC Marine and Estuarine Division utilizes a decentralized QA organization, relying on each Branch and/or project within the division to be responsible for their own Quality Assurance efforts, with overall QA Management and policy coming from Marine and Estuarine Division QA Manager. Within the ECWC there is a QA Manager within each Division that is responsible for preparation, maintenance, update and implementation of their respective Division's QMP as described in the overall QMP for the ECWC. Figure 1-1 is an organization chart that shows the lines of authority in the ECWC, and specifically in the Marine and Estuarine Division.

1.4 Effective Date

This QMP becomes effective on the date finally approved by the U.S. EPA Region 6 QA Officer, and remains in effect until revised at the time required by the U.S. EPA Marine and Estuarine General Program Grant.

1.5 QMP/QAPP Policy

This QMPs follows the guidance of Quality Assurance Management Staff (QAMS) at EPA

Headquarters (EPA QA/R-2). The initial review and approval of Quality Assurance Project Plans, rests with the ECWC Marine and Estuarine Division QA Manager an Division Director. Approval or disapproval and return of a QAPP to the submitter will be accomplished within 20 working days by the ECWC Marine and Esturaine Division QA Manager. Once a QAPP is deemed acceptable it will be forwarded to the QA Managers of any other ECWC Division that has any participation in the project for concurrence. After all participating ECWC Divisions have approved/concurred on the QAPP it will be forwarded on to the ECWC QA Manager for final review/approval and forwarding to EPA Region 6. Specific written comments shall be provided when a QAPP is disapproved that assist the submitter in creating a workable QAPP. Final approval of QAPPs rests with the appropriate EPA Region 6 Division QA Officer. Once a QAPP is approved, it is in effect until the project is completed. QAPPs must follow the guidance of QAMS for QAPPs, which is EPA QAMS 005/80.

1.6 QA Plan Document Control Numbering

All QMPs and QAPPs will be assigned a document control number by the ECWC QA Manager, prior to submission to EPA. Individual tasked with responsibility for preparation or revision of a QA Plan will receive and use that document control number in that respective QA Plan. QA Plan format for ECWC defined by ECWC SOP # 5 (Appendix B) will be followed without exception in the Marine and Estuarine Division.

1.7 QA Manager

The ECWC Marine and Estuarine Division Quality Assurance Manager and staff will be responsible for the following QA activities (see Section 9 for explanation of these functions):

1.7.1 Preparation and submission of the Marine and Estuarine Division QMP;

1.7.2 Review and approval of all Marine and Estuarine Division QAPPs;

1.7.3 Laboratory audits (multimedia and program specific):

1.7.4 Certification of laboratories; and

1.7.5 Maintenance of a file system that contains a copy of all current Marine and Estuarine Division QAPPs.

Requirement: This section of the QMP shall contain or address the following management and organizational items:

a statement of the organization's policy on quality assurance, including:

the level of importance of QA/QC to the organization and why,

the general objectives/goals for QA/QC, and

the commitment of resources for QA/QC;

- an organization chart that identifies all of the components of the organization and, in particular, the organizational position of the QA Manager/QA Officer;

- a discussion of the responsibilities and authorities of the QA Manager/QA Officer and any other QA staff, including:

  - the line of reporting to senior management, and

  - the means by which management will be kept informed about quality issues;

- a discussion of the mission of each organization component, functional responsibilities of management and staff, levels of accountability and authority, and lines of communication for planning, implementing, and assessing environmental programs;

- a discussion of the QA/QC roles and responsibilities of line management, technical staff, and any other staff;

- identification of all activities to which QA/QC are to be applied;

- how management will assure that applicable elements of the Quality System are understood and are implemented in all activities under their responsibility involving environmental programs;

TASK 1. INDIVIDUAL ASSIGNMENT:

Using material from the next two pages and the instructor, develop a revised organizational chart for the ECWC Marine and Estuarine Division.

NOTES

PROJECT DIRECTOR
Cedar Bay Project
Zack Dempsey
(777) 555-1210

PROJECT OFFICER
Cedar Bay Project
Rebecca Quince
(777) 555-1211

COMMISSIONER
ECWC
Barry Switchitter
(777) 555-1200

QA OFFICER
Cedar Bay Project
Troy Achemann
(777) 555-1212

LABORATORY MANAGER
ECWC Central Lab.
Joan Breedon
(777) 555-1213

DIRECTOR
Marine & Division
Darryle Royale
(777) 555-1205

C/ECWC Mgmt. Info. Systems Branch
Bob Gilmore
(777) 555-1214

C/ECWC Field Operations Branch
Paul Cronin
(777) 555-1215

ECWC QUALITY MANAGER
Sheila Meyers
(777) 555-1204

QC/LAB
Robert Mendez
(777) 555-1216

QC/ADP
Mark Preston
(777) 555-1217

QUALITY MANAGER
Marine & Division
Susan Daigle
(777) 555-1222

QC/FIELD
Diane Jenkins
(777) 555-1218

NOTES

FIGURE 1

ECWC Marine and Estuarine DIVISION PERSONNEL

NOTES

TASK 2. GROUP ASSIGNMENT:

Each group will reach a consensus on the Organizational Chart that will be the most effective for this organization. Revise chart as required, to reach consensus.

PROJECT DIRECTOR
Cedar Bay Project
Zack Dempsey
(777) 555-1210

PROJECT OFFICER
Cedar Bay Project
Rebecca Quince
(777) 555-1211

COMMISSIONER
ECWC
Barry Switchitter
(777) 555-1200

QA OFFICER
Cedar Bay Project
Troy Achemann
(777) 555-1212

LABORATORY MANAGER
ECWC Central Lab.
Joan Breedon
(777) 555-1213

DIRECTOR
Marine & Division
Darryle Royale
(777) 555-1205

C/ECWC Mgmt. Info. Systems Branch
Bob Gilmore
(777) 555-1214

C/ECWC Field Operations Branch
Paul Cronin
(777) 555-1215

ECWC QUALITY MANAGER
Sheila Meyers
(777) 555-1204

QC/LAB
Robert Mendez
(777) 555-1216

QC/ADP
Mark Preston
(777) 555-1217

QUALITY MANAGER
Marine & Division
Susan Daigle
(777) 555-1222

QC/FIELD
Diane Jenkins
(777) 555-1218

NOTES

FIGURE 1

ECWC Marine and Estuarine DIVISION PERSONNEL

NOTES

TASK 3. GROUP ASSIGNMENT:

Once the organizational chart is complete, as a group, revise the areas of Section 1 that are not effective in the space below. Section **must** comply with requirements above.

Original Section 2:

2. QUALITY SYSTEM AND DESCRIPTION

The ECWC Marine and Estuarine Division utilizes a decentralized QA organization, relying on each project to be responsible for their own Quality Assurance efforts, with overall QA Management and policy coming from Marine and Estuarine Division QA Manager.

2.1 Project Quality Assurance Functions

Each Project Director shall be jointly responsible for the following QA activities in their respective Projects, along with the Project QA Officer:

2.1.1 Concurrence and submission of QAPPs to Region 6 Office of Quality Assurance for final approval;

2.1.2 Assignment of a QA/QC Technical Liaison between Project and Marine and Estuarine Division;

2.1.3 Providing routine technical guidance to Project Staff on implementation of the QAPPs;

2.1.4 Maintenance or oversight of a file system that contains a copy of all valid SOPs; and

2.1.5 Preparation of a quarterly QA report on each project that will be submitted to the Marine and Estuarine Division QA Officer.

2.2 Data Quality Objective (DQO) Process

The Data Quality Objective (DQO) Process is an essential tool to be used in planning all environmental data collection activities. DQOs shall be developed following all current and applicable EPA guidance (Currently EPA QA/G-4, Guidance for Planning for Data Collection in Support of Environmental Decision Making Using the Data Quality Objectives Process. Participants in the DQO process shall be those individuals that represent organizations that are involved or could be affected by the respective project. At a minimum the ECWC Marine and Estuarine Division Project Director, Project Officer and Project QA Officer will participate. A representative will be requested from the ECWC elements that will collect samples, analyze samples. At least 30 days prior to initiation of DQO Planning session the Project Director shall provide a list of proposed organizations/individuals that will be invited to participate. Region 6 EPA Project Officer will be kept apprised of DQO sessions, and invited to participate.

2.3 QA Project Plans (QAPPs)

Every project involving the collection of environmental data must have a written Quality

Assurance Project Plan (QAPPs) approved prior to initiation of data collection activities.

A QAPP presents, in specific terms, the policies, organization, objectives, functional activities, QA, and quality control (QC) activities designed to achieve the data quality objectives (DQOs) of a particular project or continuing operation. The typical characteristics of a good QAPP are:

. requirements for management and technical audits and a process for correction of deficiencies.

. a requirement for documenting sampling procedures

. the definition of specific QC activities.

EPA is responsible for policy on format and areas of coverage for QAPPs. Each QAPP will cite the specific QMP, and its effective date, that it falls under. No QAPP can be approved without an approved QMP, as the QMP is essential for defining the criteria of a QAPP.

Implementation of QAPPs will be evaluated by U.S. EPA Region 6 Office of QA through audits and other means.

2.4 In-House Projects

The ECWC Marine and Estuarine Division will prepare QAPPs for all projects that will be performed totally by ECWC personnel. All QAPPs will conform to QAMS 005/80 or EPA QA/R-5. The Project QA Officer shall evaluate the implementation of these plans.

2.5 Contracted Projects

The contractor will prepare QAPPs for all projects that will be performed totally by contractor personnel. All QAPPs will conform to EPA QA/R-5. The Contractor's QA Officer shall evaluate the implementation of these plans, and oversight of this evaluation shall be performed annually by designated ECWC Marine and Estuarine Division Staff.

2.6 Standard Operating Procedures (SOPs)

Standard Operating Procedures (SOPs) may be developed and incorporated into QMPs or QAPPs by reference and attachment. Use of SOPs is encouraged both as a method to reduce variation and to reduce costs, when a similar method or process is utilized in a number of projects or programs. All SOPs shall be written, reviewed, approved and updated in

accordance with ECWC SOP # 1, revision current at time SOP is approved.

2.7 Management Systems Reviews (MSRs)

Management System Reviews shall be performed on all projects within 180 days of project completion. Staff designated to perform MSRs will be defined in the respective QAPPs. MSR reports will be prepared and submitted to respective Project Officer for review, comment and if requested, corrective action(s) within 90 days of completion of the MSR by the MSR team leader. If corrective action is requested the Project Officer shall define the necessary corrective action(s) to be taken in a response to the MSR team leader.

Requirement: This section of the QMP shall contain or address the following items pertaining to the Quality System and the technical mission to which it applies:

- A discussion of the principal components or "tools" comprising the organization's Quality System and the process and procedures for their use. These components include, but are not limited to:

  Quality Management Plans
  Management Systems Reviews
  Data Quality Objectives Process
  QA Project Plans
  Standard Operating Procedures
  Technical Assessments (Self and Independent)
  Data Quality Assessments

The process discussion should include the roles and responsibilities for all management and staff in planning and implementing the Quality System.

- A discussion of the technical activities or programs that are supported by the Quality System and to which the QA/QC controls apply; that is, the specific programs that require extensive QA/QC controls; where oversight of delegated, contracted, or other extramural programs is needed to assure data quality; and, where internal coordination of QA/QC among the group's organizational units need to occur.

TASK 1. GROUP ASSIGNMENT:

Revise the areas of Section 2 that are not effective in the space below. Section **must** comply with requirements above.

Original Section 3:

3. PERSONNEL QUALIFICATIONS AND TRAINING

3.1 Required certification

All ECWC sample collectors receive 32 hours of formal training an successfully complete a written and performance examination prior to collection of any samples in accordance with ECWC Samplers Certification Program, formally approved by U.S. EPA, Region 6 on July 11, 1993. After 90 days of OJT, a sample collector is fully certified if all observed work has been of an acceptable quality to the first line supervisor. All ECWC Marine and Estuarine Division Project Officers, Project and Division QA Officers, QA Coordinators, and Project Directors shall be certified for QA in accordance with ECWC Directive # 5-92 (Appendix C).

3.2 Establishing training requirements for personnel

The Project QA Officer is making plans to attend the 1994 EPA National QA Meeting, and will attend several training courses there.

At the present time, no specified training is **required** above and beyond what staff personnel are already capable of; however, training will be sought which will improve the effectiveness of the staff. Original FY 94 budget had allocated considerable funding for staff training, but had to be re-allocated to cover salaries. Some money is available for training from other sources, but it is anticipated that it will not be enough to cover all the training desirable for project personnel.

3.3 Identifying and satisfying technical and project management training needs;

Each Division of the ECWC participates in the centrally managed East Carolina Personnel Commission's annual training survey, which defines training needs by department.

3.4 Identifying and/or designing training programs to meet these needs;

Where there are existing training programs personnel requiring such training can enroll and take training at their discretion, with first line supervisor approval.

3.5 Performing introductory training and continuing training (or re-training);

U.S. EPA Region 6 will present the following courses:

1. Orientation to Quality Assurance Management,
2. Data Quality Objectives,

3. Quality Management Plans and Quality Assurance Project Plans Seminar.

3.6 Encouraging professional development beyond initial qualifications;

All ECWC staff are encouraged to take training to prepare themselves for acceptance of positions requiring higher level skills and abilities.

3.7 Documenting and maintaining training records for personnel;

The East Carolina Personnel Commission maintains all training records of East Carolina State employees. Training records are forwarded to the East Carolina Personnel Commission at the discretion of the employee, with concurrence of the first line supervisor.

3.8 Identifying qualified trainers;

All ECWC Marine and Estuarine Division staff that conduct training shall have as a minimum:

- completed any course they conduct;
- completed a course in conducting training;
- a dry and sarcastic sense of humor;
- a latent disrespect for "sacred cows";
- complete support of University of Texas Longhorns athletics.

3.9 Assessing the effectiveness of training and (where applicable) establishing a program for training and updating the instructors on training techniques and technical changes; and

Evaluations from each ECWC Marine and Estuarine Training course will be evaluated by the course instructors for areas in which improvements can be made. Supervisors of instructors will review all course evaluations also.

3.10 Reviewing and updating training materials and course content.

All training courses will be reviewed and updated annually, and more frequently if course evaluations are consistently negative, or if significant changes to documents, regulations, policy or state or federal laws that courses are based upon are changed.

Requirement: The QMP must reflect management's commitment to and describe its systems for:

- identifying certifications required to perform operations for the different programs for which the organization is responsible;
- establishing training requirements for personnel;
- identifying and satisfying technical and project management training needs;
- identifying and/or designing training programs to meet these needs;
- performing introductory training and continuing training (or re-training);
- encouraging professional development beyond initial qualifications;
- documenting and maintaining training records for personnel;
- identifying qualified trainers;
- assessing the effectiveness of training and (where applicable) establishing a program for training and updating the instructors on training techniques and technical changes; and
- reviewing and updating training materials and course content.

Included in the above is the responsibility of management to identify what qualifications or certifications are necessary for personnel to perform their work safely and effectively.

TASK 1. GROUP ASSIGNMENT:

Revise the areas of Section 3 so that this QMP reflects your group's personal feelings regarding Training and Certification Requirements. Again, section **must** comply with requirements above.

TASK 1. GROUP ASSIGNMENT: (CONTINUED)

Revise the areas of Section 3 so that this QMP reflects your group's personal feelings regarding Training and Certification Requirements. Again, section **must** comply with requirements above.

Original Section 4:

4. PROCUREMENT OF ITEMS AND SERVICES

4.1 Process for defining and assuring that QA/QC requirements for all applicable acquisitions are documented for each acquisition action;

All procured items will be field tested prior to actual data collection activities to ensure they are performing properly. Project personnel will verbally inform project officer of non-conforming equipment or supplies.

4.2 Process to assure changes to procurement documents receive the same review approvals as the original documents;

Any changes to procurement documents will be approved by the Project Officer or designee.

4.3 Process to assure QA/QC requirements are adequately addressed in responses to applicable solicitations and that QA/QC is an integral criterion of the evaluation criteria;

Commonwealth of East Carolina General Services Agency creates the policy for all procurement activities, ECWC provides input into that process to assure QA/QC requirements are met.

4.4 Process for ensuring that contracted and subcontracted activities produce results of acceptable quality.

Each project QAPP will define the process by which supplies and services are accepted for the ECWC from the supplier or contractor.

Requirement: This section of the QMP shall contain discussions of or address the following issues pertaining to the procurement of items and services:

- the organization's process for assuring that QA/QC requirements are defined for all applicable acquisitions and that this assurance process is documented for each acquisition action;
- how changes to procurement documents will receive the same review approvals as the original documents;
- the organization's process for assuring that QA/QC requirements are adequately addressed in all responses to applicable solicitations and that QA/QC is an integral criterion of the evaluation criteria; and

- the organization's process for ensuring that contracted and subcontracted activities produce results of acceptable quality, including, as appropriate: procurement source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspections, supplier audits, and examination of deliverables.

TASK 1. GROUP ASSIGNMENT:

Revise the areas of Section 4 so that this QMP reflects your group's personal feelings regarding the "Best Way" to procure goods and services. Again, section **must** comply with requirements above.

Original Section 5:

5. DOCUMENTATION and RECORDS

5.1 Documentation and Procedure for Review of Quality Assurance Project Plans

The review will be conducted using EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations (EPA QA/R-5) as a standard along with this QMP. Approved Quality Assurance Project Plans will be maintained in the files of the appropriate Project Office while the approved Quality Management Plan will be maintained by the Quality Assurance Manager. Each QAPP shall cite the QMP that it falls under, including approval date.

5.3. Record Maintenance

All quality assurance documents of the ECWC Marine and Estuarine Division will be filed after action in the central ECWC file room. The documents will be maintained under the supervision of a file clerk. The file clerk will take special care to preserve the integrity of sensitive documents such as enforcement actions. This special care includes such precautions as locking these files in the absence of the file clerk. If sensitive documents are to be used at a work station, due care will be used there, too, in order to maintain the integrity of the data.

Requirement: This section of the QMP must include:

- a description of the organization's process for identifying quality-related documents and records requiring control;
- a description of the organization's process for handling documents and records to assure their accessibility, protection from damage and deterioration, and means of retention, including discussion of the roles and responsibilities for management and staff;
- a description of the process by which all technical guidance documents are prepared, reviewed, approved, issued, used, and revised; and
- a description of the process that ensures compliance with all statutory, contractual, and assistance agreement requirements for records from environmental programs and that provides adequate preservation of key records necessary to support the mission of the organization.

TASK 1. GROUP ASSIGNMENT:

Revise the areas of Section 5 so that this QMP reflects your group's personal feelings regarding the "Best Way" to do documentation and recording of QA information. Again, section **must** comply with requirements above.

Original Section 6:

6. USE OF AUTOMATED DATA PROCESSING SYSTEM

6.1. Policy

It is an ECWC policy that data collected, analyzed, processed and maintained on all automated data processing (ADP) systems, in support of environmental studies, be accurate and of sufficient integrity to support effective environmental management.

In order to ensure the effective and efficient use of the ECWC's ADP systems, including hardware and software system design, development, implementation, and maintenance, ECWC will follow the Commonwealth of East Carolina's Information Resource Management (IRM) Policy.

6.2 Computer Hardware and Software Requirements

6.2.1 All hardware and software shall meet Commonwealth of East Carolina's Informational Resource Management Hardware and Software Standards from the Architectural Management and Planning Branch of the ECIRM's Data Processing Division.

6.2.2 All software systems shall be developed and designed according to the ECIRM's Systems and Development Guidance.

6.2.3 All software systems shall be operated and maintained according to ECIRM's Operation and Maintenance Manual.

6.2.4 For integrity of computer resident data in stand alone PC systems, the laboratories or offices which use systems for environmental effects studies shall follow the EPA Good Automated Laboratory Practices guidelines.

6.4 Data Management

To take full advantage of the ECWC's growing technological and data resources, there needs to be an increased emphasis on improving compatibility of data among the systems. For consistent definition of data, and to facilitate cross-media use of data, all data produced or collected by the computers shall be managed as specified in the Commonwealth of East Carolina's IRM Policy Manual. ECIRM is in the process of developing State-wide data standards, in the ECIRM Catalog of Data Policies and Standards. This catalog will summarize State data policies and standards which are the definitive list of data standards that East Carolina agency personnel and contractors must meet when developing information systems.

6.5 Information Security

It is important that the ECWC's information resources are protected from potential loss and misuse from a variety of accidental and deliberate causes, which can take the form of destruction, disclosure, alteration, delay or undesired manipulation.

For a comprehensive, Statewide security program to safeguard the ECWC's information resources, all information resources shall be safeguarded as specified in the ECIRM ADP Disaster Recovery Plan.

6.6 Documents

For proper implementation and maintenance of the system, the appropriate offices shall have:

6.6.1 A written description of the computer system(s) hardware and a written operating procedures for routine maintenance operations;

6.6.2 A written document which contains detailed description of the software in use, including the listing of all algorithms or formulas used for data generation, processing and assessment, clear guidelines for data acceptance criteria, criteria for data validation/invalidation, data deletion/addition, and data correction; and

6.6.3 Standard Operating Procedures (SOPs) which describe the routine operation, maintenance and testing, to ensure that both the hardware and software in use is accurately performing the intended functions.

These documents shall be readily available in the areas where these procedures will be performed. Published literature or vendor documentation may be used as a supplement to software documentation if properly referenced therein. All deviations from the operational instructions for data collection systems shall be authorized by the designated responsible person. Changes in any part of the operating procedures shall be properly authorized, reviewed and accepted in writing by the designated responsible person.

6.7 Personnel

Personnel involved in computer data collection systems, hardware and software shall:

6.7.1 have adequate education, training, and experience to perform the assigned system functions;

6.7.2 have a current summary of their training, experience, and job description, including information relevant to system design and operation maintained at the facility;

and

6.7.3 be of sufficient number for timely and proper conduct of the study, including timely and proper operation of the automated data collection system(s).

Requirement: This section of the QMP shall address the use of computer hardware and software in the organization's operations. Specifically, the QMP must:

- describe the process for ensuring that computer hardware used in environmental programs meets the requirements of these programs;
- describe how changes to hardware shall be controlled to assess the impact of the change on performance;
- describe the process for developing computer software, for validating, verifying, and documenting the software for its use, and for assuring that the software meets the requirements of the user;
- describe how purchased software is evaluated to meet user requirements and to comply with applicable organizational policy regarding software proliferation and configuration management standards; and
- describe the process for ensuring that data and information produced from or collected by computers meet applicable organizational policy standards.

These descriptions shall include the roles and responsibilities assigned to management and staff.

TASK 1. GROUP ASSIGNMENT:

As a group, using the requirements from above, and the supporting rationale, revise this QMP Section.

Original Section 7:

7. PLANNING

7.1 Customer Identification Process

The customer for the results of the work is the Environmental Conditions of the Bays and Estuaries of the Commonwealth of East Carolina.

7.2 Identification of Customer Needs and Expectations

The ECWC will use the Data Quality Objectives Process (DQO) planning methodology for all in-house projects that will exceed $ 75,000 per year. For projects to be performed by a Contractor Data Quality Objectives will be used at the discretion of the Contractor.

7.3 Creation of Quality Specifications for Data

The ECWC Marine and Estuarine Division utilizes the DQO process to define the data quality specifications for each project. Once the DQO process is accomplished for a project not only does it define data quality requirements, but it also considers any cost and schedule constraints within which project activities are required to be performed, and identifies acceptance criteria for the result or measures of performance by which customer satisfaction will be determined.

Requirement: This section of the QMP shall document how and by whom work shall be planned by the organization. Minimally, the QMP shall describe the system or process used to:

- identify the customer for whom the work is to be performed,
- identify the needs and expectations of the customer in terms of both technical and quality goals,
- translate the customer's needs into specifications to produce the desired result,
- consider any cost and schedule constraints within which project activities are required to be performed, and
- identify acceptance criteria for the result or measures of performance by which customer satisfaction will be determined.

All projects involving the generation, acquisition and use of environmental data shall be planned using a systematic planning process such as the Data Quality Objective process as defined by the current revision of Guidance for Planning for Data Collection in Support of Environmental Decision Making Using the Data Quality Objectives Process, EPA QA/G-4, or acceptable alternate, and shall be documented in a Quality Assurance Project Plan (QAPP), as

defined by the current revision of EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations, EPA QA/R-5, and approved by authorized QA personnel for implementation.

TASK 1. GROUP ASSIGNMENT:

As a group, using the requirements from above, and the supporting rationale, revise this QMP Section.

Original Section 8:

8. IMPLEMENTATION OF WORK PROCESSES

8.1 Procedures for ensuring that work is performed according to plan

All ECWC Marine and Estuarine Division environmental data operations project will be implemented in accordance with the Quality Assurance Project Plan. The ECWC Marine and Estuarine Division Director meets quarterly with all Project Managers to review implementation status of projects.

8.2 Level of management oversight and inspection

The level of oversight and inspection will be commensurate with the importance of particular projects and the intended use of the data.

8.3 Procedures for appropriate routine, standardized, special, or critical operations development and implementation

8.3.1 Identification of operations needing procedures

Operations requiring procedures are defined in the QAPP. If the procedures are standard or routine they will be covered in depth in the ECWC Sampling Handbook, which will be incorporated by reference into all QAPPs. ECWC SOPs, can be used in the same manner where applicable.

8.3.2 Preparation of procedures

All special and critical operations procedures will be defined in the applicable QAPP in detail.

8.3.3 Review and approval of procedures

All procedures will be approved by the Director ECWC Marine and Estuarine Division prior to actual use. Special and critical operations procedures will be peer reviewed by at least three Project Officers prior to submission for final approval.

Requirement: This section of the QMP shall describe the process of how and by whom work shall be implemented by or on behalf of the organization. Minimally, the QMP must describe:

- the procedures for ensuring that work is performed according to plan;
- the needed level of management oversight and inspection that will be commen-

Original Section 8:

8. IMPLEMENTATION OF WORK PROCESSES

8.1 Procedures for ensuring that work is performed according to plan

All ECWC Marine and Estuarine Division environmental data operations project will be implemented in accordance with the Quality Assurance Project Plan. The ECWC Marine and Estuarine Division Director meets quarterly with all Project Managers to review implementation status of projects.

8.2 Level of management oversight and inspection

The level of oversight and inspection will be commensurate with the importance of particular projects and the intended use of the data.

8.3 Procedures for appropriate routine, standardized, special, or critical operations development and implementation

8.3.1 Identification of operations needing procedures

Operations requiring procedures are defined in the QAPP. If the procedures are standard or routine they will be covered in depth in the ECWC Sampling Handbook, which will be incorporated by reference into all QAPPs. ECWC SOPs, can be used in the same manner where applicable.

8.3.2 Preparation of procedures

All special and critical operations procedures will be defined in the applicable QAPP in detail.

8.3.3 Review and approval of procedures

All procedures will be approved by the Director ECWC Marine and Estuarine Division prior to actual use. Special and critical operations procedures will be peer reviewed by at least three Project Officers prior to submission for final approval.

Requirement: This section of the QMP shall describe the process of how and by whom work shall be implemented by or on behalf of the organization. Minimally, the QMP must describe:

- the procedures for ensuring that work is performed according to plan;
- the needed level of management oversight and inspection that will be commen-

surate with the importance of the particular project and the intended use of the project results; and

- how procedures for appropriate routine, standardized, special, or critical operations are developed and implemented, including the policies and procedures that address, but are not limited to:

  - identification of operations needing procedures;
  - preparation of procedures, including form, content, and applicability; and
  - review and approval of procedures.

The QMP must stress that environmental data operations project will be implemented in accordance with the Quality Assurance Project Plan. The QMP shall consider those activities, policies, and procedures that are common to all projects of the specific organization. It must also emphasize the importance of documenting activities including any exceptions to the QA Project Plan.

The organization shall describe how appropriate measures for controlling the release, change, and use of planned procedures are implemented. These measures shall provide for the necessary approvals, specific times and points for implementing changes, removal of obsolete documentation from work areas, and verification that the changes are made as prescribed.

TASK 1. GROUP ASSIGNMENT:

As a group, using the requirements from above, and the supporting rationale, revise this QMP Section.

Original Section 9:

9. QUALITY ASSESSMENT AND RESPONSE

Even the best QA plans are of limited value unless they are implemented. In order to ensure that QA plans are being implemented and that they are adequate, a series of technical and managerial audits are necessary. These audits comprise the major mechanism of the ECWC oversight. The QAPP must describe how and by whom assessments of environmental programs are planned, conducted, and evaluated to measure the effectiveness of the implemented quality system. The assessment tools for environmental programs encompass:

- management systems reviews,
- surveillances,
- audits,
- performance evaluations,
- audits of data quality,
- peer reviews and technical reviews,
- readiness reviews, and
- data quality assessments.

9.1 Planning, scheduling, and implementation of assessment and response to needed changes

Project Officers have total responsibility for assessments of their projects.

9.2 Definition of responsibilities, levels of participation, and authority for staff

Coverage of these items is in section 9.4.

9.3 How, when, and by whom actions will be taken in response to the findings of the assessment, and how the effectiveness of the response will be determined.

Responses to assessment findings will be the responsibility of the Project QA Officer.

9.4 Ability of personnel conducting assessments to:

- identify quality problems;
- identify and cite noteworthy practices that may be shared with others to improve the quality of their operations and products;
- propose recommendations for resolving quality problems;
- independently confirm implementation and effectiveness of solutions; and
- provide documented assurance to line management that, when problems are identified, further work performed is monitored carefully until the problems are suitably resolved.

The personnel performing in-house management assessments are trained managers with years of supervisory, managerial and administrative experience. The technical self-assessments will be performed by Project Managers and Project Officers who are intimately familiar with the goals of the project. The independent technical assessment will be performed by natural resource specialist with years of experience in their respective fields. As the assessors are fully qualified professionals in their fields, any recommendations made will be considered by the Project Managers and Project Officer of the particular project under assessment, and implemented immediately, with approval of the Director.

External assessments will be performed by U.S. EPA QAMS Staff. Recommendations made by QAMS will be considered by the Project Managers and Project Officer of the particular project under assessment, and implemented immediately, with approval of the Director.

Requirement: Assessments are evaluations intended to increase the user's understanding of the program or system being assessed, and to provide a basis for improving such programs or systems. This section of the QMP must describe how and by whom assessments of environmental programs are planned, conducted, and evaluated to measure the effectiveness of the implemented quality system. This section of the QMP shall also describe how management determines during planning which type of assessment activity is appropriate for a particular project and which assessment tool is to be used. The assessment tools for environmental programs encompass:

- management systems reviews,
- surveillances,
- audits,
- performance evaluations,
- audits of data quality,
- peer reviews and technical reviews,
- readiness reviews, and
- data quality assessments.

This section shall contain or address the following items pertaining to management assessment of the effectiveness of the organization's Quality System:

- how the process for the planning, scheduling, and implementation of assessments works, as well as how the organization will respond to needed changes;

- definition of responsibilities, levels of participation, and authorities for all management and staff for the assessment process; and

- discussion of how, when, and by whom actions will be taken in response to the findings of the assessment, and how the effectiveness of the response will be determined.

Personnel conducting assessments shall be qualified based on project-specific requirements to perform the assigned assessment. The QMP must describe how the level of competence, experience, and training necessary to ensure the capability of personnel conducting assessments is determined. The QMP must document how persons conducting assessments must have sufficient authority, access to programs and managers, access to documents and records, and organizational freedom to:

- identify quality problems;
- identify and cite noteworthy practices that may be shared with others to improve the quality of their operations and products;
- propose recommendations for resolving quality problems;
- independently confirm implementation and effectiveness of solutions; and
- provide documented assurance to line management that, when problems are identified, further work performed is monitored carefully until the problems are suitably resolved.

The QMP must clearly define the responsibilities and authorities of personnel conducting assessments, particularly in regard to authority to suspend or stop work in progress upon detection and identification of an immediate adverse condition affecting the quality of results or the health and safety of personnel.

The QMP must describe how management will respond to the findings and recommendations from assessments in a timely manner. When conditions needing corrective action are identified, the appropriate response must be made promptly. The QMP should indicate how follow-up action shall be taken and documented to confirm the implementation and effectiveness of the response action.

Environmental data must be qualified according to the intended use of the data. Data obtained from sources that did not use, or fully comply with, a QA Project Plan (or equivalent planning document) for data collection must also be qualified. Data shall be qualified according to procedures documented in the QMP. These procedures shall document the decision process and factors used in arriving at the choice of the particular qualification method. This process shall include the correct application of statistical methods during the assessment process. The decision to qualify the data for their intended use shall be based on reconciliation with the performance measures for the project defined by the data quality requirements. Any limitations on data use shall be identified quantitatively to the extent practicable and fully documented.

The QMP shall also describe how project reports containing data or reporting the results of environmental data operations shall be reviewed independently to confirm that the data or results are presented correctly. The QMP shall describe the process used for these reviews and the approval authority required prior to the publication or distribution of any reports.

The QMP shall also describe the process by which periodic assessments of environmental programs are planned, scheduled and implemented. Line management is responsible for

overseeing assessments and for responding to their findings. Scheduling of assessments and allocation of resources are to be based on the status, risk and complexity of the sampling and analytical activities.

TASK 1. GROUP ASSIGNMENT:

As a group, using the requirements from above, and the supporting rationale, revise this QMP Section.

Original Section 10:

10. QUALITY IMPROVEMENT

This section of the QMP includes a description of the ECWC Marine and Estuarine Division's management system for detecting and preventing quality problems and for ensuring continuing quality improvement.

10.1 Process and personnel responsible for identifying, planning, implementing, and evaluating the effectiveness of quality improvement activities.

In the ECWC Marine and Estuarine Division the Quality Manager has total responsibility for Quality Improvement. On each project the Project QA Officer has total responsibility for Quality Improvement.

10.2 Corrective action program.

Each QAPP will define a method to ensure that conditions adverse to quality are identified promptly and corrected as soon as practical. This Corrective Actions process shall include the identification of root causes of problems, determining if the problem is unique or has more generic implications, and recommending procedures to prevent recurrence.

Requirement: This section of the QMP shall include a description of the organization's management system for detecting and preventing quality problems and for ensuring continuing quality improvement. Accordingly, this section shall describe:

- the management process and identify who (organizationally) is responsible for identifying, planning, implementing, and evaluating the effectiveness of quality improvement activities;

- a corrective action program to ensure that conditions adverse to quality are identified promptly and corrected as soon as practical.

Corrective actions shall include the identification of root causes of problems, determining if the problem is unique or has more generic implications, and recommending procedures to prevent recurrence.

TASK 1. GROUP ASSIGNMENT:

As a group, using the requirements from above, and the supporting rationale, revise this QMP Section.

Part C - Design, Construction, and Operation of Environmental Technology

Part C – E4 Workshop

(0) General

Part C elements used in conjunction with Part A for design, construction, operation of environmental technology

Quality system elements for environmental technology that

- **remediate contamination in environment**
- **prevent / remove pollutants from discharge**
- **dispose of / store contaminants**

(0) General (cont'd)

Environmental technology includes

— pollution control devices/systems

— waste treatment processes/storage facilities

— site remediation technology

Does not include

— in-process pollution prevention/control devices

— process modification

(0) General (cont'd)

Program elements

- **planning**
- **design of systems**
- **construction/fabrication of systems and components**
- **operation of systems**
- **quality assessment and response**
- **verification and acceptance of systems**

(1) Planning – Specifications

All activities and projects for design, construction, operation of environmental technology shall be

- **— planned**
- **— documented**

must involve key users, customers of system and technical staff

Planning/design subject to review for conformance to technical and quality requirements

Part C - E4 Workshop

(1) Planning – Specifications (cont'd)

Project planning – coordinate among organizations

– following elements

- **acceptable criteria for completed systems**
- **delivery, handling, storage, identification, inspection,**
- **testing, installation requirements**
- **notify involved organization in project and role in**
- **design, construction, operation, assessment**
- **personnel, equipment required**
- **program/task scope and objectives**
- **reviews, assessments**
- **QA/project records**
- **technical, performance, regulatory quality standards**

Part C – E4 Workshop

(1) Planning – Specifications (cont'd)

Document project planning in work plans, QAPPs, design criteria, schedules, drawings

(2) Design of Systems

- **Purpose and Background**
  - To provide quality management practices and criteria for the design of environmental technology systems
  - Goal is to ensure that the technology systems are designed using sound engineering and scientific principles and appropriate standards
  - Derived primarily from ISO-9004 and ASME NQA-1

(2) Design of Systems (cont'd)

- Specifications
  - The results of the design (including changes) shall be defined, controlled to the extent required, verified, and documented
  - Design documents shall specify necessary technical and quality acceptance criteria as well as the inspections and tests needed to verify acceptable construction and operation

(2) Design of Systems (cont'd)

- Specifications (cont'd)
  - Final design shall be verified formally and documented, and design adequacy verified by independent authorities
  - Readiness reviews shall be performed prior to implementation of the design

(2) Design of Systems (cont'd)

- The design process shall ensure that the control of design inputs, processes, outputs, configuration changes, interfaces (coordination), and records provide for
  - ability of components and systems to perform under expected conditions of use
  - ability of components and systems to safely respond to unexpected conditions (such as accidents and equipment failures), including consideration of redundant systems or other safeguards
  - acceptance/rejection criteria for components and systems

(2) Design of Systems (cont'd)

- The design process shall ensure that the control of design inputs, processes, outputs, configuration changes, interfaces (coordination), and records provide for
  - agreement of customer needs expressed during planning with technical specifications for materials, items, and services, including delivery documentation requirements any constraints of cost or schedule that apply
  - compliance with regulatory requirements, national standards and codes, and organizational engineering practices

(2) Design of Systems (cont'd)

- The design process shall ensure that the control of design inputs, processes, outputs, configuration changes interfaces (coordination), and records provide for
  - considerations of unintended uses and misuses
  - effective coordination and interfacing of organizations participating in the design process

(2) Design of Systems (cont'd)

- The design process shall ensure that the control of design inputs, processes, outputs, configuration changes, interfaces (coordination), and records provide for
  - production of verified, reviewed, and approved design outputs in a timely manner
  - safety, reliability, serviceability, and maintainability requirements

(2) Design of Systems (cont'd)

- Guidelines
  - The design review process should ensure that all necessary design documents, drawings, guides, instructions, specifications, and data sheets are documented and reviewed, approved by authorized personnel, and are distributed to personnel performing the work
  - The design review should identify anticipated problems or inadequacies and corrective actions

(2) Design of Systems (cont'd)

- Guidelines (cont'd)
  - Design verification should be conducted prior to subsequent critical stages of development to ensure timely correction of deficient conditions

(3) Construction/Fabrication of Systems and Components

- **Purpose and Scope**
  - **To provide quality management practices and criteria for the construction and fabrication of systems and components based on the design documents provided**
  - **Goal is to ensure that items, systems, components meet the needs and function as defined in design documents**
  - **Derived primarily from ISO-9004 and ASME NQA-1**

(3) Construction/Fabrication of Systems and Components (cont'd)

- Specifications
  - Construction shall be performed
    - — under appropriate controlled conditions
    - — in accordance with approved drawings and specifications
  - Only qualified and accepted items and services shall be used and installed as indicated by design
  - Items shall be identified as to their acceptability (directly or indirectly)
  - Inspections and tests shall be performed during construction/fabrication to assure conformity to design

(3) Construction/Fabrication of Systems and Components (cont'd)

- Specifications (cont'd)
  - Handling, storage, cleaning, packaging, shipping and preservation of equipment shall be controlled to prevent loss damage or deterioration
  - Periodic preventative and corrective maintenance shall be performed in accordance with design or manufacturer's specifications during construction and fabrication to ensure satisfactory performance

(3) Construction/Fabrication of Systems and Components (cont'd)

- Specifications (cont'd)
  - M&TE used during construction shall be
    - of the proper type, range and accuracy
    - calibrated and maintained
  - The basis for calibration shall be documented
  - Documentation of calibration shall be maintained and traceable to the equipment calibrated
  - M&TE found unsatisfactory shall be repaired, recalibrated, and certified within tolerances prior to being used
    - The validity of measurements made without calibration equipment shall be evaluated and repeated as required

(3) Construction/Fabrication of Systems and Components (cont'd)

- Specifications (cont'd)
  - Inspection and test procedures shall include test objectives, test personnel requirements, test equipment, acceptance criteria, and disposition of unacceptable items
  - The results of tests and inspections, including the applicable procedures, shall be documented and maintained

(3) Construction/Fabrication of Systems and Components (cont'd)

- Guidelines
  - Items in storage subject to time-based deterioration should be checked periodically to detect possible deterioration and corrective action performed as appropriate
  - As-built drawings should be prepared when such information is required for operation
  - Calibration and control measures may not be required for M&TE when normal commercial availability provides required accuracy (rulers, tape measures, levels, ...)
  - Traceability to nationally recognized performance standards (not required) should be maintained when they are used

(4) Operation of Systems

- **Purpose and Scope**
  - **To provide quality management practices and criteria for the operation of systems and components based on the design documents provided**
  - **Goal is to ensure that items, systems, components are operated and function as defined in design documents**
  - **Derived primarily from ISO-9004 and ASME NQA-1**

(4) Operation of Systems (cont'd)

- Specifications
  - Environmental technology shall be operated in accordance with design document requirements and operating instructions and guides. Operating guides include
    - material controls
    - configuration management
    - operating procedures, including control limits and safety limits
    - process control during abnormal and fault conditions
    - special environmental conditions
    - personnel skill, capability, knowledge, and proficiency requirements

(4) Operation of Systems (cont'd)

- Specifications (cont'd)
  - Auxiliary materials, utilities, and consumables shall be controlled and verified periodically when required to ensure uniformity and quality
  - Status indicators shall be provided indicating operating status and limits.
  - Status indicators shall be used to prevent inadvertent operation or removal from operation when such actions
    - affect operational safety
    - present an environmental hazard
    - violate state or regulatory requirements
    - jeopardize the goals of a project (such situations include loss of data that are difficult or expensive to reproduce)
  - Items shall be identified as to their acceptability (directly or indirectly)

(5) Assessment and Response

- **Purpose and Background**
  - **To provide quality management practices and criteria for the assessment of activities during the design, construction, and operation of environmental technology**
  - **Goal is to ensure that approved planning requirements, design specifications, and operating guides are implemented as prescribed**
  - **Derived primarily from ISO-9004 and ASME NQA-1**

Part C – E4 Workshop

(5) Assessment and Response (cont'd)

- **Specifications**
  - **Assessments shall be performed regularly during design, construction, and operation**
  - **Appropriate corrective actions must be taken in response to findings and their adequacy verified and documented**

Part C – E4 Workshop

(5) Assessment and Response (cont'd)

- **Guidelines**
  - **Assessments may include surveillances, peer reviews, readiness reviews, and audits**
  - **Frequency of assessments should be appropriate to the circumstances or as required in the planning documentation**

(6) Verification and Acceptance of Systems

- **Purpose and Background**
  - **To provide quality management practices and criteria for the verification and acceptance of environmental technology following design and construction and prior to operation**
  - **Goal is to ensure that environmental technology performs as prescribed in the design specifications and is acceptable for its intended use**
  - **Derived primarily from ISO-9004 and ASME NQA-1**

(6) Verification and Acceptance of Systems (cont'd)

- **Specifications**
  - **Performance of environmental technology shall be verified prior to its routine use**
  - **When performance measurement involves environmental data operations, the requirements of Part B shall be followed**
  - **Deficiencies shall be corrected and the effectiveness of the corrective actions confirmed and documented**

QUALITY ASSURANCE PROJECT PLANS

Definition:

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.

What it does:

- **Ensures project management commitment and involvement;**
- **Provides a specific plan of QA/QC requirements for the project;**
- **Assures project is implemented as planned;**
- **Defines oversight requirements for a project;**
- **Defines assessment requirements for a project;**
- **Provides for a continuous improvement capability;**
- **Satisfies CFR requirements for a QAPP.**

Criteria:

EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5

(Replacing Guidance and Specifications for Preparing Quality Assurance Project Plans, QAMS-005/80

United States Environmental Protection Agency | Office of Environmental Information Washington, DC 20460 | EPA/240/B-01/003 March 2001

EPA Requirements for Quality Assurance Project Plans

EPA QA/R-5

FOREWORD

The U.S. Environmental Protection Agency (EPA) has developed the Quality Assurance Project Plan (QA Project Plan) as a tool for project managers and planners to document the type and quality of data needed for environmental decisions and to describe the methods for collecting and assessing those data. The development, review, approval, and implementation of the QA Project Plan is part of EPA's mandatory Quality System. The EPA Quality System requires all organizations to develop and operate management structures and processes to ensure that data used in Agency decisions are of the type and quality needed for their intended use. The QA Project Plan is an integral part of the fundamental principles and practices that form the foundation of the EPA Quality System.

This document provides the QA Project Plan requirements for organizations that conduct environmental data operations on behalf of EPA through contracts, financial assistance agreements, and interagency agreements; however, it may be used by EPA as well. It contains the same requirements as Chapter 5 of EPA Order 5360 A1 (EPA 2000), *The EPA Quality Manual for Environmental Programs*, which has been developed for internal use by EPA organizations. A companion document, *EPA Guidance for Quality Assurance Project Plans (QA/G-5)* (EPA 1998) provides suggestions for both EPA and non-EPA organizations on preparing, reviewing, and implementing QA Project Plans that satisfy the requirements defined in this document.

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

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

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

www.epa.gov/quality

ACKNOWLEDGMENTS

This document reflects the collaborative efforts of many quality management professionals who participate in the challenge for continual improvement in quality systems supporting environmental programs. These individuals, representing the EPA, other Federal agencies, State and local governments, and private industry, reflect a diverse and broad range of needs and experiences in environmental data collection programs. Their contributions and the comprehensive reviews during the development of this document are greatly appreciated.

TABLE OF CONTENTS

FIGURES

TABLES

CHAPTER 1

INTRODUCTION

1.1 BACKGROUND

Environmental programs conducted by or funded by the U.S. Environmental Protection Agency (EPA) involve many diverse activities that address complex environmental issues. The EPA annually spends several hundred million dollars in the collection of environmental data for scientific research and regulatory decision making. In addition, non-EPA organizations may spend as much as an order of magnitude more each year to respond to Agency requirements. If decision makers (EPA and otherwise) are to have confidence in the quality of environmental data used to support their decisions, there must be a structured process for quality in place.

A structured system that describes the policies and procedures for ensuring that work processes, products, or services satisfy stated expectations or specifications is called a quality system. All organizations conducting environmental programs funded by EPA are required to establish and implement a quality system. EPA also requires that all environmental data used in decision making be supported by an approved Quality Assurance Project Plan (QA Project Plan). This requirement is defined in EPA Order 5360.1 A2 (EPA 2000), *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, for EPA organizations. Non-EPA organizations funded by EPA are required to develop a QA Project Plan through:

- 48 CFR 46, for contractors;
- 40 CFR 30, 31, and 35 for assistance agreement recipients; and
- other mechanisms, such as consent agreements in enforcement actions.

The QA Project Plan integrates all technical and quality aspects of a project, including planning, implementation, and assessment. The purpose of the QA Project Plan is to document planning results for environmental data operations and to provide a project-specific "blueprint" for obtaining the type and quality of environmental data needed for a specific decision or use. The QA Project Plan documents how quality assurance (QA) and quality control (QC) are applied to an environmental data operation to assure that the results obtained are of the type and quality needed and expected.

The ultimate success of an environmental program or project depends on the quality of the environmental data collected and used in decision-making, and this may depend significantly on the adequacy of the QA Project Plan and its effective implementation. Stakeholders (i.e., the data users, data producers, decision makers, etc.) shall be involved in the planning process for a program or project to ensure that their needs are defined adequately and addressed. While time spent on such planning may seem unproductive and costly, the penalty for ineffective planning

includes greater cost and lost time. Therefore, EPA requires that a systematic planning process be used to plan all environmental data operations. To support this requirement, EPA has developed a process called the Data Quality Objectives (DQO) Process. The DQO Process is the Agency's preferred planning process and is described in the *Guidance for the Data Quality Objectives Process (QA/G-4)* (EPA 2000b). The QA Project Plan documents the outputs from systematic planning.

This requirements document presents specifications and instructions for the information that must be contained in a QA Project Plan for environmental data operations funded by EPA. The document also discusses the procedures for review, approval, implementation, and revision of QA Project Plans. Users of this document should assume that all of the elements described herein are required in a QA Project Plan unless otherwise directed by EPA.

1.2 QA PROJECT PLANS, THE EPA QUALITY SYSTEM, AND ANSI/ASQC E4-1994

EPA Order 5360.1 A2 and the applicable Federal regulations (defined above) establish a mandatory Quality System that applies to all EPA organizations and organizations funded by EPA. Components of the EPA Quality System are illustrated in Figure 1. Organizations must ensure that data collected for the characterization of environmental processes and conditions are of the appropriate type and quality for their intended use and that environmental technologies are designed, constructed, and operated according to defined expectations. The QA Project Plan is a key project-level component of the EPA Quality System.

EPA policy is based on the national consensus standard, ANSI/ASQC E4-1994, *Specifications and Guidelines for Environmental Data Collection and Environmental Technology Programs*. The ANSI/ASQC E4-1994 standard describes the necessary management and technical elements for developing and implementing a quality system. This standard recommends using a tiered approach to a quality system. This standard recommends first documenting each organization-wide quality system in a Quality Management Plan or Quality Manual (to address requirements of *Part A: Management Systems* of the standard) and then documenting the applicability of the quality system to technical activity-specific efforts in a QA Project Plan or similar document (to address the requirements of *Part B: Collection and Evaluation of Environmental Data* of the standard). EPA has adopted this tiered approach for its mandatory Agency-wide Quality System. This document addresses Part B requirements of the standard.

A Quality Management Plan, or equivalent Quality Manual, documents how an organization structures its quality system, defines and assigns QA and QC responsibilities, and describes the processes and procedures used to plan, implement, and assess the effectiveness of the quality system. The Quality Management Plan may be viewed as the "umbrella" document under which individual projects are conducted. EPA requirements for Quality Management Plans are defined in *EPA Requirements for Quality Management Plans (QA/R-2)* (EPA 2001). The

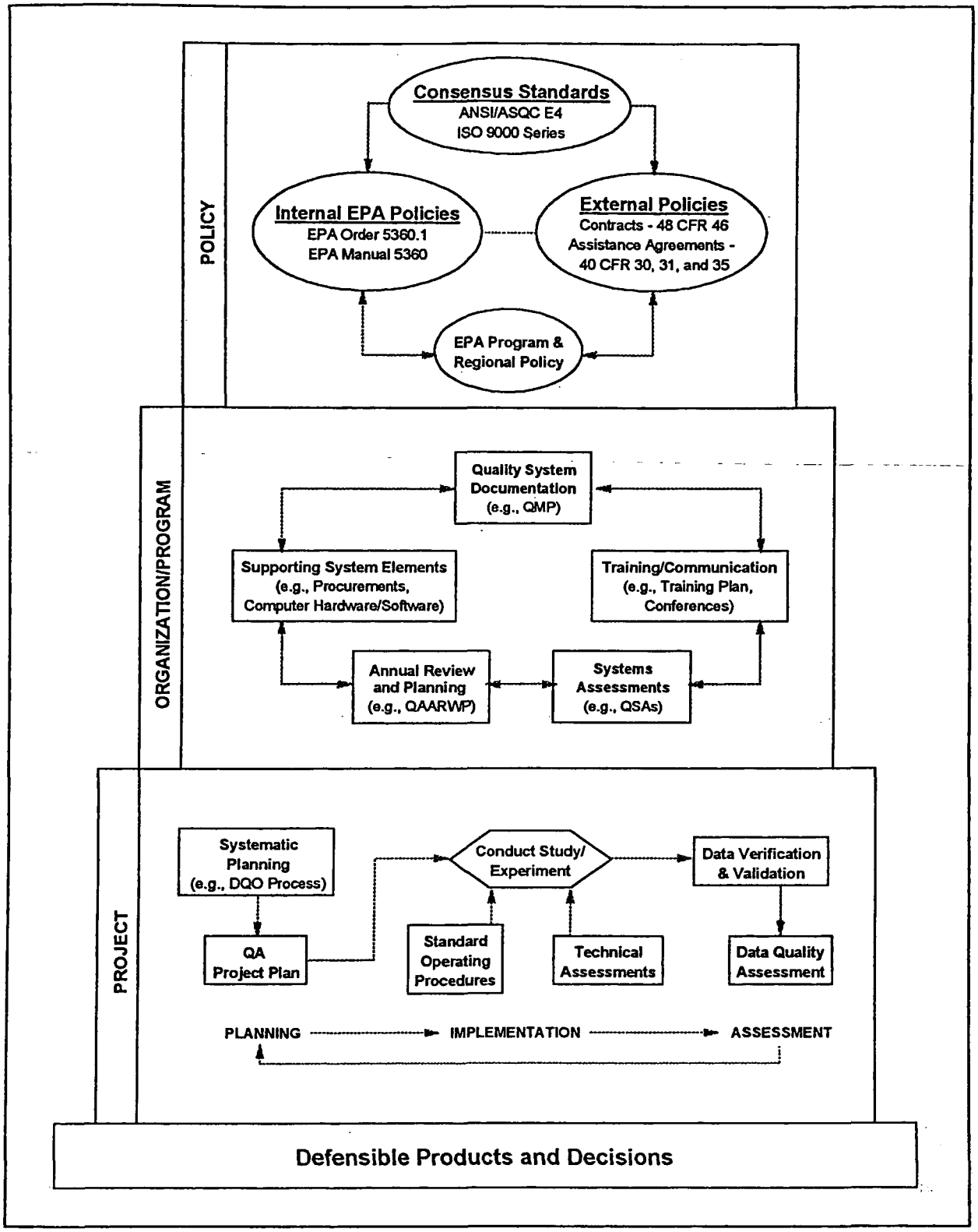


Figure 1. EPA Quality System Components and Tools

Quality Management Plan is then supported by project-specific QA Project Plans. In some cases, a QA Project Plan and a Quality Management Plan may be combined into a single document that contains both organizational and project-specific elements. The QA Manager for the EPA organization sponsoring the work has the authority to determine when a single document is applicable and will define the content requirements of such a document.

1.3 THE GRADED APPROACH AND THE EPA QUALITY SYSTEM

Recognizing that a "one size fits all" approach to quality requirements will not work in organizations as diverse as EPA, implementation of the EPA Quality System is based on the principle of graded approach. Applying a graded approach means that quality systems for different organizations and programs will vary according to the specific objectives and needs of the organization. For example, the quality expectations of a fundamental research program are different from that of a regulatory compliance program because the purpose or intended use of the data is different. The specific application of the graded approach principle to QA Project Plans is described in Section 2.4.2.

1.4 INTENDED AUDIENCE

This document specifies the requirements for developing QA Project Plans for organizations that conduct environmental data operations funded by EPA through contracts, financial assistance agreements, and interagency agreements. EPA organizations may also use this document to develop QA Project Plans since this document is clearer and more user-friendly than the equivalent requirements defined in Section 5.3 of EPA Order 5360 A1 (EPA 2000), *The EPA Quality Manual for Environmental Programs* (an internal policy document). However, the preparation, submission, review, and approval requirements for EPA organizations are still contained in Section 5.2 of EPA Order 5360 A1 as these represent internal EPA policy.

1.5 PERIOD OF APPLICABILITY

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

1.6 ADDITIONAL RESOURCES

Guidance on preparing QA Project Plans may be found in a companion document, *EPA Guidance for Quality Assurance Project Plans (QA/G-5)* (EPA 1998). This guidance discusses the application of the QA Project Plan requirements and provides examples. Other documents that provide guidance on activities critical to successful environmental data operations and complement the QA Project Plan preparation effort include:

- *Guidance for the Data Quality Objectives Process (QA/G-4)*, (EPA 2000b)
- *Guidance for the Preparation of Standard Operating Procedures for Quality-Related Documents (QA/G-6)*, (EPA 1995)
- *Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA/G-9)*, (EPA 2000a)

1.7 SUPERSESSION

This document replaces QAMS-005/80, *Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans* (EPA 1980) in its entirety.

(This page is intentionally blank.)

CHAPTER 2

QA PROJECT PLAN REQUIREMENTS

2.1 POLICY

All work funded by EPA that involves the acquisition of environmental data generated from direct measurement activities, collected from other sources, or compiled from computerized data bases and information systems shall be implemented in accordance with an approved QA Project Plan. The QA Project Plan will be developed using a systematic planning process based on the graded approach. No work covered by this requirement shall be implemented without an approved QA Project Plan available prior to the start of the work except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.

2.2 PURPOSE

The QA Project Plan documents the planning, implementation, and assessment procedures of, and how specific QA and QC activities will be applied during a particular project. The QA Project Plan demonstrates conformance to Part B requirements of ANSI/ASQC E4-1994.

2.3 APPLICABILITY

These requirements apply to all environmental programs funded by EPA that acquire, generate, or compile environmental data including work performed through contracts, work assignments, delivery orders, task orders, cooperative agreements, interagency agreements, State-EPA agreements, State, local and Tribal Financial Assistance/Grants, Research Grants, and in response to statutory or regulatory requirements and consent agreements. These requirements are negotiated into interagency agreements, including sub-agreements, and, in some cases, are included in enforcement settlement and consent agreements and orders. Where specific Federal regulations require the application of QA and QC activities (see Section 1.1), QA Project Plans shall be prepared, reviewed, and approved in accordance with the specifications contained in this document unless explicitly superseded by the regulation.

2.4 GENERAL CONTENT AND DETAIL REQUIREMENTS

2.4.1 General Content

The QA Project Plan must be composed of standardized, recognizable elements covering the entire project from planning, through implementation, to assessment. Chapter 3 of this document describes specific elements to address for QA Project Plans submitted to EPA. In some cases, it may be necessary to add special requirements to the QA Project Plan. The EPA organization sponsoring the work has the authority to define any special requirements beyond

those listed in this document. If no additional requirements are specified, the QA Project Plan shall address all required elements. Each EPA organization defines their organizational-specific requirements for QA Project Plan documentation in their Quality Management Plan. All applicable elements defined by the EPA organization sponsoring the work must be addressed.

While most QA Project Plans will describe project- or task-specific activities, there may be occasions when a *generic* QA Project Plan may be more appropriate. A generic QA Project Plan addresses the general, common activities of a program that are to be conducted at multiple locations or over a long period of time; for example, it may be useful for a large monitoring program that uses the same methodology at different locations. A generic QA Project Plan describes, in a single document, the information that is not site or time-specific but applies throughout the program. Application-specific information is then added to the approved QA Project Plan as that information becomes known or completely defined. A generic QA Project Plan shall be reviewed periodically to ensure that its content continues to be valid and applicable to the program over time.

2.4.2 Level of Detail

The level of detail of the QA Project Plan should be based on a graded approach so that the level of detail in each QA Project Plan will vary according to the nature of the work being performed and the intended use of the data. As a result, an acceptable QA Project Plan for some environmental data operations may require a qualitative discussion of the experimental process and its objectives while others may require extensive documentation to adequately describe a complex environmental program.

2.5 QA PROJECT PLAN PREPARATION AND APPROVAL

The QA Project Plan may be prepared by an EPA organization, a contractor, an assistance agreement holder, or another Federal agency under an interagency agreement. Except where specifically delegated in the Quality Management Plan of the EPA organization sponsoring the work, all QA Project Plans prepared by non-EPA organizations must be approved by EPA before implementation.

The QA Project Plan shall be reviewed and approved by an authorized EPA reviewer to ensure that the QA Project Plan contains the appropriate content and level of detail. The authorized reviewer, for example the EPA project manager[1] with the assistance and approval of the EPA QA Manager or by the EPA QA Manager alone, are defined by the EPA organization's Quality Management Plan. In some cases, the authority to review and approve QA Project Plans is delegated to another part of the EPA organization covered by the same Quality Management

[1] This term refers to the EPA official responsible for the project. This individual may also be called Project Officer, Delivery Order Project Officer, Work Assignment Manager, or Principal Investigator.

Plan. In cases where the authority to review and approve QA Project Plans is delegated in writing by EPA to another organization (i.e., a Federal agency or a State under an EPA-approved Quality Management Plan when the environmental data operation itself has been delegated to that organization for implementation), it is possible that the EPA project manager and EPA QA Manager may not be involved in the review and approval steps.

2.6 QA PROJECT PLAN IMPLEMENTATION

None of the environmental work addressed by the QA Project Plan shall be started until the QA Project Plan has been approved and distributed to project personnel except in situations requiring immediate action to protect human health and the environment or operations conducted under police powers. Subject to these exceptions, it is the responsibility of the organization performing the work to assure that no environmental data are generated or acquired before the QA Project Plan is approved and received by the appropriate project personnel. However, EPA may grant conditional approval to a QA Project Plan to permit some work to begin while non-critical deficiencies in the QA Project Plan are being resolved.

The organization performing the work shall ensure that the QA Project Plan is implemented as approved and that all personnel involved in the work have direct access to a current version of the QA Project Plan and all other necessary planning, implementation, and assessment documents. These personnel should understand the requirements prior to the start of data generation activities.

2.7 QA PROJECT PLAN REVISION

Although the approved QA Project Plan must be implemented as prescribed; it is not inflexible. Because of the complex and diverse nature of environmental data operations, changes to original plans are often needed. When such changes occur, the approving official shall determine if the change significantly impacts the technical and quality objectives of the project. When a substantive change is warranted, the originator of the QA Project Plan shall modify the QA Project Plan to document the change and submit the revision for approval by the same authorities that performed the original review. Only after the revision has been received and approved (at least verbally with written follow-up) by project personnel, shall the change be implemented.

For programs or projects of long duration, such as multi-year monitoring programs or projects using a generic QA Project Plan, the QA Project Plans shall be reviewed at least annually by the EPA Project Manager (or authorized representative). When revisions are necessary, the QA Project Plan must be revised and resubmitted for review and approval.

(This page is intentionally blank.)

CHAPTER 3

QA PROJECT PLAN ELEMENTS

3.1 CONTENT REQUIREMENTS

The QA Project Plan is 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. The QA Project Plan must provide sufficient detail to demonstrate that:

- the project technical and quality objectives are identified and agreed upon;
- the intended measurements, data generation, or data acquisition methods are appropriate for achieving project objectives;
- assessment procedures are sufficient for confirming that data of the type and quality needed and expected are obtained; and
- any limitations on the use of the data can be identified and documented.

Most environmental data operations require the coordinated efforts of many individuals, including managers, engineers, scientists, statisticians, and others. The QA Project Plan must integrate the contributions and requirements of everyone involved into a clear, concise statement of what is to be accomplished, how it will be done, and by whom. It must provide understandable instructions to those who must implement the QA Project Plan, such as the field sampling team, the analytical laboratory, modelers, and the data reviewers. In all aspects of the QA Project Plan, the use of national consensus standards and practices are encouraged.

In order to be effective, the QA Project Plan must specify the level or degree of QA and QC activities needed for the particular environmental data operations. Because this will vary according to the purpose and type of work being done, EPA believes that the graded approach should be used in planning the work. This means that the QA and QC activities applied to a project will be commensurate with:

- the purpose of the environmental data operation (e.g., enforcement, research and development, rulemaking),
- the type of work to be done (e.g., pollutant monitoring, site characterization, risk characterization, bench level proof of concept experiments), and
- the intended use of the results (e.g., compliance determination, selection of remedial technology, development of environmental regulation).

The QA Project Plan shall be composed of standardized, recognizable elements covering the entire project from planning, through implementation, to assessment. These elements are presented in that order and have been arranged for convenience into four general groups. The four groups of elements and their intent are summarized as follows:

A Project Management - The elements in this group address the basic area of project management, including the project history and objectives, roles and responsibilities of the participants, etc. These elements ensure that the project has a defined goal, that the participants understand the goal and the approach to be used, and that the planning outputs have been documented.

B Data Generation and Acquisition - The elements in this group address all aspects of project design and implementation. Implementation of these elements ensure that appropriate methods for sampling, measurement and analysis, data collection or generation, data handling, and QC activities are employed and are properly documented.

C Assessment and Oversight - The elements in this group address the activities for assessing the effectiveness of the implementation of the project and associated QA and QC activities. The purpose of assessment is to ensure that the QA Project Plan is implemented as prescribed.

D Data Validation and Usability - The elements in this group address the QA activities that occur after the data collection or generation phase of the project is completed. Implementation of these elements ensures that the data conform to the specified criteria, thus achieving the project objectives.

All applicable elements, including the content and level of detail under each element, defined by the EPA organization sponsoring the work must be addressed in the QA Project Plan. If an element is not applicable, state this in the QA Project Plan. Documentation, such as an approved Work Plan, Standard Operating Procedures, etc., may be referenced in response to a particular required QA Project Plan element to reduce the size of the QA Project Plan. Current versions of all referenced documents must be attached to the QA Project Plan itself or be placed on file with the appropriate EPA office and available for routine referencing when needed. The QA Project Plan shall also address related QA planning documentation (e.g., Quality Management Plans) from suppliers of services critical to the technical and quality objectives of the project or task.

3.2 GROUP A: PROJECT MANAGEMENT

The elements in this group (Table 1) address project management, including project history and objectives, roles and responsibilities of the participants, etc. These elements document

that the project has a defined goal, that the participants understand the goal and the approach to be used, and that the planning outputs have been documented.

Table 1. Group A: Project Management Elements	
A1	Title and Approval Sheet
A2	Table of Contents
A3	Distribution List
A4	Project/Task Organization
A5	Problem Definition/Background
A6	Project/Task Description
A7	Quality Objectives and Criteria
A8	Special Training/Certification
A9	Documents and Records

3.2.1 A1 - Title and Approval Sheet

On the Title and Approval Sheet, include the title of the plan, the name of the organization(s) implementing the project, the effective date of the plan, and the names, titles, signatures, and approval dates of appropriate approving officials. Approving officials may include:

- Organization's Project Manager
- Organization's QA Manager
- EPA Project Manager
- EPA QA Manager
- Others, as needed (e.g., field operations manager, laboratory managers, State and other Federal agency officials)

3.2.2 A2 - Table of Contents

Provide a table of contents for the document, including sections, figures, tables, references, and appendices. Apply a document control format (Figure 2) on each page following the Title and Approval Sheet when required by the EPA Project Manager and QA Manager.

Section No. _____ Revision No. _____ Date _____ Page ___ of ___

Figure 2. Example Document Control Format

3.2.3 A3 - Distribution List

List the individuals and their organizations who need copies of the approved QA Project Plan and any subsequent revisions, including all persons responsible for implementation (e.g., project managers), the QA managers, and representatives of all groups involved. Paper copies need not be provided to individuals if equivalent electronic information systems can be used.

3.2.4 A4 - Project/Task Organization

Identify the individuals or organizations participating in the project and discuss their specific roles and responsibilities. Include the principal data users, the decision makers, the project QA manager, and all persons responsible for implementation. The project quality assurance manager must be independent of the unit generating the data. (This does not include being independent of senior officials, such as corporate managers or agency administrators, who are nominally, but not functionally, involved in data generation, data use, or decision making.) Identify the individual responsible for maintaining the official, approved QA Project Plan.

Provide a concise organization chart showing the relationships and the lines of communication among all project participants. Include other data users who are outside of the organization generating the data, but for whom the data are nevertheless intended. The organization chart must also identify any subcontractor relationships relevant to environmental data operations, including laboratories providing analytical services.

3.2.5 A5 - Problem Definition/Background

State the specific problem to be solved, decision to be made, or outcome to be achieved. Include sufficient background information to provide a historical, scientific, and regulatory perspective for this particular project.

3.2.6 A6 - Project/Task Description

Provide a summary of all work to be performed, products to be produced, and the schedule for implementation. Provide maps or tables that show or state the geographic locations of field tasks. This discussion need not be lengthy or overly detailed, but should give an overall picture of how the project will resolve the problem or question described in A5.

3.2.7 A7 - Quality Objectives and Criteria

Discuss the quality objectives for the project and the performance criteria to achieve those objectives. EPA requires the use of a systematic planning process to define these quality objectives and performance criteria.

3.2.8 A8 - Special Training/Certification

Identify and describe any specialized training or certifications needed by personnel in order to successfully complete the project or task. Discuss how such training will be provided and how the necessary skills will be assured and documented.

3.2.9 A9 - Documents and Records

Describe the process and responsibilities for ensuring the appropriate project personnel have the most current approved version of the QA Project Plan, including version control, updates, distribution, and disposition.

Itemize the information and records which must be included in the data report package and specify the reporting format for hard copy and any electronic forms. Records can include raw data, data from other sources such as data bases or literature, field logs, sample preparation and analysis logs, instrument printouts, model input and output files, and results of calibration and QC checks.

Identify any other records and documents applicable to the project that will be produced, such as audit reports, interim progress reports, and final reports. Specify the level of detail of the field sampling, laboratory analysis, literature or data base data collection, or modeling documents or records needed to provide a complete description of any difficulties encountered.

Specify or reference all applicable requirements for the final disposition of records and documents, including location and length of retention period.

3.3 GROUP B: DATA GENERATION AND ACQUISITION

The elements in this group (Table 2) address all aspects of data generation and acquisition to ensure that appropriate methods for sampling, measurement and analysis, data collection or generation, data handling, and QC activities are employed and documented. The following QA Project Plan elements describe the requirements related to the actual methods or methodology to be used for the:

collection, handling, and analysis of samples;

- data obtained from other sources (e.g., contained in a computer data base from previous sampling activities, compiled from surveys, taken from the literature); and

- the management (i.e., compiling, handling) of the data.

The methods described in these elements should have been summarized earlier in element A6. The purpose here is to provide detailed information on the methods. If the designated methods are well documented and are readily available to all project participants, citations are adequate; otherwise, detailed copies of the methods and/or SOPs must accompany the QA Project Plan either in the text or as attachments.

Table 2. Group B: Data Generation and Acquisition Elements	
B1	Sampling Process Design (Experimental Design)
B2	Sampling Methods
B3	Sample Handling and Custody
B4	Analytical Methods
B5	Quality Control
B6	Instrument/Equipment Testing, Inspection, and Maintenance
B7	Instrument/Equipment Calibration and Frequency
B8	Inspection/Acceptance of Supplies and Consumables
B9	Non-direct Measurements
B10	Data Management

3.3.1 B1- Sampling Process Design (Experimental Design)

Describe the experimental data generation or data collection design for the project, including as appropriate:

- the types and numbers of samples required,
- the design of the sampling network,
- the sampling locations and frequencies,
- sample matrices,
- measurement parameters of interest, and
- the rationale for the design.

3.3.2 B2 - Sampling Methods

Describe the procedures for collecting samples and identify the sampling methods and equipment, including any implementation requirements, sample preservation requirements, decontamination procedures, and materials needed for projects involving physical sampling. Where appropriate, identify sampling methods by number, date, and regulatory citation. If a method allows the user to select from various options, then the method citations should state exactly which options are being selected. Describe specific performance requirements for the method. For each sampling method, identify any support facilities needed. The discussion should also address what to do when a failure in the sampling or measurement system occurs, who is responsible for corrective action, and how the effectiveness of the corrective action shall be determined and documented.

Describe the process for the preparation and decontamination of sampling equipment, including the disposal of decontamination by-products; the selection and preparation of sample containers, sample volumes, and preservation methods; and maximum holding times to sample extraction and/or analysis.

3.3.3 B3 - Sample Handling and Custody

Describe the requirements for sample handling and custody in the field, laboratory, and transport, taking into account the nature of the samples, the maximum allowable sample holding times before extraction or analysis, and available shipping options and schedules for projects involving physical sampling. Sample handling includes packaging, shipment from the site, and storage at the laboratory. Examples of sample labels, custody forms, and sample custody logs should be included.

3.3.4 B4 - Analytical Methods

Identify the analytical methods and equipment required, including sub-sampling or extraction methods, laboratory decontamination procedures and materials (such as in the case of hazardous or radioactive samples), waste disposal requirements (if any), and any specific performance requirements for the method. Where appropriate, analytical methods may be identified by number, date, and regulatory citation. Address what to do when a failure in the analytical system occurs, who is responsible for corrective action, and how the effectiveness of the corrective action shall be determined and documented. Specify the laboratory turnaround time needed, if important to the project schedule.

List any method performance standards. If a method allows the user to select from various options, then the method citations should state exactly which options are being selected. For non-standard method applications, such as for unusual sample matrices and situations, appropriate method performance study information is needed to confirm the performance of the

method for the particular matrix. If previous performance studies are not available, they must be developed during the project and included as part of the project results.

3.3.5 B5 - Quality Control

Identify QC activities needed for each sampling, analysis, or measurement technique. For each required QC activity, list the associated method or procedure, acceptance criteria, and corrective action. Because standard methods are often vague or incomplete in specifying QC requirements, simply relying on the cited method to provide this information is usually insufficient. QC activities for the field and the laboratory include, but are not limited to, the use of blanks, duplicates, matrix spikes, laboratory control samples, surrogates, or second column confirmation. State the frequency of analysis for each type of QC activity, and the spike compounds sources and levels. State or reference the required control limits for each QC activity and corrective action required when control limits are exceeded and how the effectiveness of the corrective action shall be determined and documented.

Describe or reference the procedures to be used to calculate applicable statistics (e.g., precision and bias). Copies of the formulas are acceptable as long as the accompanying narrative or explanation specifies clearly how the calculations will address potentially difficult situations such as missing data values, "less than" or "greater than" values, and other common data qualifiers.

3.3.6 B6 - Instrument/Equipment Testing, Inspection, and Maintenance

Describe how inspections and acceptance testing of instruments, equipment, and their components affecting quality will be performed and documented to assure their intended use as specified. Identify and discuss the procedure by which final acceptance will be performed by independent personnel (e.g., personnel other than those performing the work) and/or by the EPA project manager. Describe how deficiencies are to be resolved, when re-inspection will be performed, and how the effectiveness of the corrective action shall be determined and documented.

Describe or reference how periodic preventive and corrective maintenance of measurement or test equipment or other systems and their components affecting quality shall be performed to ensure availability and satisfactory performance of the systems. Identify the equipment and/or systems requiring periodic maintenance. Discuss how the availability of critical spare parts, identified in the operating guidance and/or design specifications of the systems, will be assured and maintained.

3.3.7 B7 - Instrument/Equipment Calibration and Frequency

Identify all tools, gauges, instruments, and other sampling, measuring, and test equipment used for data generation or collection activities affecting quality that must be controlled and, at

specified periods, calibrated to maintain performance within specified limits. Describe or reference how calibration will be conducted using certified equipment and/or standards with known valid relationships to nationally recognized performance standards. If no such nationally recognized standards exist, document the basis for the calibration. Identify the certified equipment and/or standards used for calibration. Indicate how records of calibration shall be maintained and be traceable to the instrument.

3.3.8 B8 - Inspection/Acceptance of Supplies and Consumables

Describe how and by whom supplies and consumables (e.g., standard materials and solutions, sample bottles, calibration gases, reagents, hoses, deionized water, potable water, electronic data storage media) shall be inspected and accepted for use in the project. State acceptance criteria for such supplies and consumables.

3.3.9 B9 - Non-direct Measurements

Identify any types of data needed for project implementation or decision making that are obtained from non-measurement sources such as computer data bases, programs, literature files, and historical data bases. Describe the intended use of the data. Define the acceptance criteria for the use of such data in the project and specify any limitations on the use of the data.

3.3.10 B10 - Data Management

Describe the project data management process, tracing the path of the data from their generation to their final use or storage (e.g., the field, the office, the laboratory). Describe or reference the standard record-keeping procedures, document control system, and the approach used for data storage and retrieval on electronic media. Discuss the control mechanism for detecting and correcting errors and for preventing loss of data during data reduction, data reporting, and data entry to forms, reports, and databases. Provide examples of any forms or checklists to be used.

Identify and describe all data handling equipment and procedures to process, compile, and analyze the data. This includes procedures for addressing data generated as part of the project as well as data from other sources. Include any required computer hardware and software and address any specific performance requirements for the hardware/software configuration used. Describe the procedures that will be followed to demonstrate acceptability of the hardware/software configuration required. Describe the process for assuring that applicable information resource management requirements are satisfied.

Describe the process for assuring that applicable Agency information resource management requirements (EPA Directive 2100) are satisfied (EPA QA Project Plans only). If other Agency data management requirements are applicable, such as the Chemical Abstract Service Registry Number Data Standard (EPA Order 2180.1), Data Standards for the Electronic

Transmission of Laboratory Measurement Results (EPA Order 2180.2), the Minimum Set of Data Elements for Ground-Water Quality (EPA Order 7500.1A), or new data standards as they are issued by EPA, discuss how these requirements are addressed.

3.4 GROUP C: ASSESSMENT AND OVERSIGHT

The elements in this group (Table 3) address the activities for assessing the effectiveness of project implementation and associated QA and QC activities. The purpose of assessment is to ensure that the QA Project Plan is implemented as prescribed.

Table 3. Group C: Assessment and Oversight Elements	
C1	Assessments and Response Actions
C2	Reports to Management

3.4.1 C1 - Assessments and Response Actions

Describe each assessment to be used in the project including the frequency and type. Assessments include, but are not limited to, surveillance, management systems reviews, readiness reviews, technical systems audits, performance evaluations, audits of data quality, and data quality assessments. Discuss the information expected and the success criteria (i.e., goals, performance objectives, acceptance criteria specifications, etc.) for each assessment proposed. List the approximate schedule of assessment activities. For any planned self-assessments (utilizing personnel from within the project groups), identify potential participants and their exact relationship within the project organization. For independent assessments, identify the organization and person(s) that shall perform the assessments if this information is available. Describe how and to whom the results of each assessment shall be reported.

Define the scope of authority of the assessors, including stop work orders, and when assessors are authorized to act.

Discuss how response actions to assessment findings, including corrective actions for deficiencies and other non-conforming conditions, are to be addressed and by whom. Include details on how the corrective actions will be verified and documented.

3.4.2 C2 - Reports to Management

Identify the frequency and distribution of reports issued to inform management (EPA or otherwise) of the project status; for examples, reports on the results of performance evaluations and system audits; results of periodic data quality assessments; and significant quality assurance

problems and recommended solutions. Identify the preparer and the recipients of the reports, and any specific actions recipients are expected to take as a result of the reports.

3.5 GROUP D: DATA VALIDATION AND USABILITY

The elements in this group (Table 4) address the QA activities that occur after the data collection phase of the project is completed. Implementation of these elements determines whether or not the data conform to the specified criteria, thus satisfying the project objectives.

Table 4. Group D: Data Validation and Usability Elements	
D1	Data Review, Verification, and Validation
D2	Verification and Validation Methods
D3	Reconciliation with User Requirements

3.5.1 D1 - Data Review, Verification, and Validation

State the criteria used to review and validate -- that is, accept, reject, or qualify -- data, in an objective and consistent manner.

3.5.2 D2 - Verification and Validation Methods

Describe the process to be used for verifying and validating data, including the chain-of-custody for data throughout the life of the project or task. Discuss how issues shall be resolved and the authorities for resolving such issues. Describe how the results are conveyed to data users. Precisely define and interpret how validation issues differ from verification issues for this project. Provide examples of any forms or checklists to be used. Identify any project-specific calculations required.

3.5.3 D3 - Reconciliation with User Requirements

Describe how the results obtained from the project or task will be reconciled with the requirements defined by the data user or decision maker. Outline the proposed methods to analyze the data and determine possible anomalies or departures from assumptions established in the planning phase of data collection. Describe how reconciliation with user requirements will be documented, issues will be resolved, and how limitations on the use of the data will be reported to decision makers.

(This page is intentionally blank.)

REFERENCES

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

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

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

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

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

EPA Directive 2100 (1998), *Information Resources Management Policy Manual*, U.S. Environmental Protection Agency, Washington, DC.

EPA Order 2180.1 (June 1987), *Chemical Abstract Service Registry Number Data Standard*, U.S. Environmental Protection Agency, Washington, DC.

EPA Order 2180.2 (December 1988), *Data Standards for the Electronic Transmission of Laboratory Measurement Results*, U.S. Environmental Protection Agency, Washington, DC.

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

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

EPA Order 7500.1A (October 1992), *Minimum Set of Data Elements for Ground-Water Quality*, U.S. Environmental Protection Agency, Washington, DC.

U.S. Environmental Protection Agency, 2001. *EPA Requirements for Quality Management Plans (QA/R-2)*, EPA/240/B-01/002, Office of Environmental Information.

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

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

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

U.S. Environmental Protection Agency, 1995. *Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents (QA/G-6)*, EPA/600/R-96/027, Office of Research and Development.

U.S. Environmental Protection Agency, 1980. *Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans,* QAMS-005/80, Office of Research and Development.

APPENDIX A

CROSSWALKS AMONG QUALITY ASSURANCE DOCUMENTS

A.1 BACKGROUND

This appendix contains crosswalks between this document and other QA planning documents. The first crosswalk compares this requirements document with its predecessor document, QAMS 005/80, *Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans* (EPA 1980). The second crosswalk compares the elements of the QA Project Plan defined in this document with the steps defined in *Guidance for the Data Quality Objectives Process (QA/G-4)* (EPA 2000b), the Agency's preferred systematic planning process for environmental decision making. This crosswalk is provided to assist the reader in determining how the outputs from the DQO Process can be integrated into a QA Project Plan.

A.2 CROSSWALK BETWEEN EPA QA/R-5 AND QAMS-005/80

QAMS-005/80 ELEMENTS		QA/R-5 ELEMENTS	
1.0	Title Page with Provision for Approval Signatures	A1	Title and Approval Sheet
2.0	Table of Contents	A2	Table of Contents
3.0	Project Description	A5	Problem Definition/Background
		A6	Project/Task Description
4.0	Project Organization and Responsibility	A3	Distribution List
		A4	Project/Task Organization
		A8	Special Training/Certification
		A9	Documents and Records
5.0	QA Objectives for Measurement Data (PARCC)	A7	Quality Objectives and Criteria
6.0	Sampling Procedures	B1	Sampling Process Design
		B2	Sampling Methods
7.0	Sample Custody	B3	Sample Handling and Custody
8.0	Calibration Procedures and Frequency	B7	Instrument/Equipment Calibration and Frequency

QAMS-005/80 ELEMENTS		QA/R-5 ELEMENTS	
9.0	Analytical Procedures	B4	Analytical Methods
10.0	Data Reduction, Validation, and Reporting	D1	Data Review, Verification, and Validation
		D2	Verification and Validation Methods
		B9	Non-direct Measurements
		B10	Data Management
11.0	Internal Quality Control Checks and Frequency	B5	Quality Control
12.0	Performance and Systems	C1	Assessments and Response Actions
13.0	Preventive Maintenance	B6	Instrument/Equipment Testing, Inspection, and Maintenance
14.0	Specific Routine Procedures Measurement Parameters Involved	D3	Reconciliation with User Requirements
15.0	Corrective Action	C1	Assessments and Response Actions
16.0	QA Reports to Management	C2	Reports to Management

A.3 CROSSWALK BETWEEN THE DQO PROCESS AND THE QA PROJECT PLAN

Elements	Requirements	DQO Overlap
PROJECT MANAGEMENT		
A1 Title and Approval Sheet	Title and approval sheet.	N/A
A2 Table of Contents	Document control format.	N/A
A3 Distribution List	Distribution list for the QA Project Plan revisions and final guidance.	Step 1: State the Problem
A4 Project/Task Organization	Identify individuals or organizations participating in the project and discuss their roles, responsibilities and organization.	Step 1: State the Problem
A5 Problem Definition/ Background	1) State the specific problem to be solved or the decision to be made. 2) Identify the decision maker and the principal customer for the results.	Step 1: State the Problem Step 2: Identify the Decision
A6 Project/Task Description	1) Hypothesis test, 2) expected measurements, 3) ARARs or other appropriate standards, 4) assessment tools (technical audits), 5) work schedule and required reports.	Step 1: State the Problem Step 2: Identify the Decision Step 3: Identify the Inputs to the Decision Step 6: Specify Limits on Decision Errors
A7 Quality Objectives and Criteria	Decision(s), population parameter of interest, action level, summary statistics and acceptable limits on decision errors. Also, scope of the project (domain or geographical locale).	Step 4: Define the Boundaries Step 5: Develop a Decision Rule Step 6: Specify Limits on Decision Errors
A8 Special Training/ Certification	Identify special training that personnel will need.	N/A
A9 Documents and Records	Itemize the information and records that must be included in a data report package, including report format and requirements for storage, etc.	Step 3: Identify the Inputs to the Decision Step 7: Optimize the Design for Obtaining Data

Elements	Requirements	DQO Overlap
DATA GENERATION AND ACQUISITION		
B1 Sampling Process Design (Experimental Design)	Outline the experimental design, including sampling design and rationale, sampling frequencies, matrices, and measurement parameter of interest.	Step 5: Develop a Decision Rule Step 7: Optimize the Design for Obtaining Data
B2 Sampling Methods	Sample collection method and approach.	Step 7: Optimize the Design for Obtaining Data
B3 Sample Handling and Custody	Describe the provisions for sample labeling, shipment, chain-of-custody forms, procedures for transferring and maintaining custody of samples.	N/A
B4 Analytical Methods	Identify analytical method(s) and equipment for the study, including method performance requirements.	Step 3: Identify the Inputs to the Decision Step 7: Optimize the Design for Obtaining Data
B5 Quality Control	Describe quality control procedures that should be associated with each sampling and measurement technique. List required checks and corrective action procedures.	Step 3: Identify the Inputs to the Decision
B6 Instrument/Equipment Testing, Inspection, and Maintenance	Discuss how inspection and acceptance testing, including the use of QC samples, must be performed to ensure their intended use as specified by the design.	Step 3: Identify the Inputs to the Decision
B7 Instrument/Equipment Calibration and Frequency	Identify tools, gauges and instruments, and other sampling or measurement devices that need calibration. Describe how the calibration should be done.	Step 3: Identify the Inputs to the Decision
B8 Inspection/Acceptance of Supplies and Consumables	Define how and by whom the sampling supplies and other consumables will be accepted for use in the project.	N/A

Elements	Requirements	DQO Overlap
B9 Non-direct Measurements	Define the criteria for the use of non-measurement data, such as data that come from databases or literature.	Step 1: State the Problem Step 7: Optimize the Design for Obtaining Data
B10 Data Management	Outline the data management scheme including the path and storage of the data and the data record-keeping system. Identify all data handling equipment and procedures that will be used to process, compile, and analyze the data.	Step 3: Identify the Inputs to the Decision Step 7: Optimize the Design for Obtaining Data
ASSESSMENT AND OVERSIGHT		
C1 Assessments and Response Actions	Describe the assessment activities needed for this project.	Step 7: Optimize the Design for Obtaining Data
C2 Reports to Management	Identify the frequency, content, and distribution of reports issued to keep management informed.	N/A
DATA VALIDATION AND USABILITY		
D1 Data Review, Verification, and Validation	State the criteria used to accept or reject the data based on quality.	Step 7: Optimize the Design for Obtaining Data
D2 Verification and Validation Methods	Describe the process to be used for verifying and validating data, including the chain-of-custody for data throughout the lifetime of the project.	Step 3: Identify the Inputs to the Decision
D3 Reconciliation With User Requirements	Describe how results will be evaluated to determine if performance criteria have been satisfied.	Step 7: Optimize the Design for Obtaining Data

(This page is intentionally blank.)

QAPP CLASSROOM PRACTICAL EXERCISE #1

In small groups, we will review a "Good Example" of a **"Bad Example"** of a Quality Assurance Project Plan submitted by the Commonwealth of East Carolina's Water Commission (ECWC), by it's Marine and Estuarine Division. The QAPP is being submitted as part of a Grant Application Package by the ECWC to seek $350,000.00 to determine the cause of recent Fish and Shellfish Kills in Cedar Bay. Watch the video tape for additional information, keeping in mind two things:

1. What is the purpose of the proposed project?

2. What is the primary motive behind the Governor's involvement in this project?

Spending a limited amount of time, as defined by the instructor, review the sections identified by the instructor using EPA QA/R-5 as the review criteria, list the things in those sections that are incorrect.

NOTES

QUALITY ASSURANCE PROJECT PLAN

FOR

DETERMINING ENVIRONMENTALLY RELATED CAUSES OF FISH KILLS IN CEDAR BAY FY 1994

PROJECT OFFICER:	Rebecca Quince
QUALITY ASSURANCE OFFICER:	Bob Gilmore
PROJECT DIRECTOR:	Zack Dempsey

NOTES

TABLE OF CONTENTS

Revision 0, October 15, 1996

LIST OF TABLES

LIST OF FIGURES

APPENDICES

I Distribution List

Following individuals will receive copies of approved QAPP.

Project Personnel:

Zack Dempsey
Bob Gilmore
Rebecca Quince
Joan Breedon
Paul Cronin
Robert Mendez
Mark Preston
Diane Jenkins

U.S. EPA Region 6 Personnel:

Alva Smith, 6EN-XQ
Charles Ritchey, 6EN-XQ
Russell Bowen, 6WQ-AG
Petra Sanchez, 6PD-L
Linda Raye Chapman, 6WQ-EW
Karen Alverez, 6PD-S
Steffanie Barnett, 6WQ-EM
Pam Mintz, 6WQ-AG

Other Personnel/Organizations:

Governors Office
Chairman, State Water Management Board
President, State Shellfishermans Association
President, Cedar Bay Homebuilders Association
President, Cedar Bay Chamber of Commerce
President, Cedar Bay Farmers Cooperative
President, Cedar Bay Realators Association
Director AAA-Ace Environmental Sampling and Analytical Laboratory (3 Copies)

Each copy of the QAPP will be serial numbered, and a receipt will be signed and returned to the QA Officer. Example of the receipt document is Appendix A of this document. Recipients are responsible for assuring they have a current and correct copy of the applicable QAPP.

II Project/Task Organization

The individuals responsible for the major aspects of the project are provided in Figure 1.

III Problem Definition/Background

This project was developed by the State Water Management Board, in conjunction with the Cedar Bay Technical Institute, to determine the environmental causes of recent fish and shellfish kills in the area. There is only minimal background studies and information known to exist for environmental concerns in Cedar Bay, primarily a DDT Study was performed in 1977, by the State Agriculture Department, funded by the U.S.D.A., that indicated a level of DDT present that was far below any level of concern. A limited study was performed in December of 1993, for Total Suspended Solids (TSS), by the AAA-Ace Environmental Sampling and Analytical Laboratory, funded by the Cedar Bay Homebuilders Association. Results are not considered valid due to Laboratory not being able to show traceability of results to sampling events or locations.

IV Project Task Description

This project is to define the nature and extent of contamination or pollution that may be present in Cedar Bay by:

* The collection and analysis of samples to determine water quality;

* Define the types of chemicals and fertilizers being used in agricultural land management processes;

* Determine presence of contamination or pollution caused by construction;

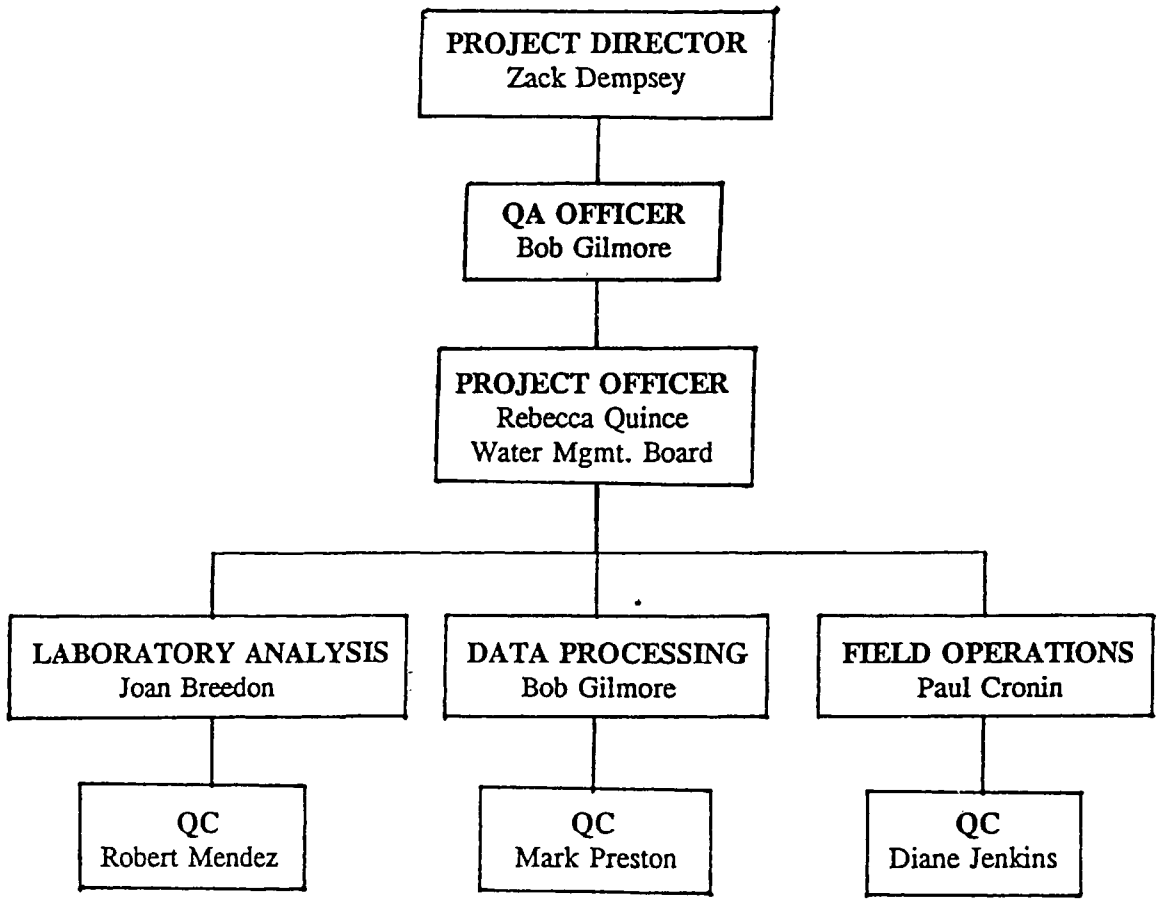
* Collect biological specimens for fish and shellfish tissue samples.

All project records and QA/QC data will be retained for at least 5 years after completion of the project.

All sample collection will be completed within 45 days of the start of the project, and all analytical work and data validation completed within 60 days of the start of the project. Project will start within 30 days of receipt of funding.

FIGURE 1

RESPONSIBILITIES OF PERSONNEL



Water Quality Lab
Cedar Bay Technical Institute
42 Catskill Lane
Benton, EC 79797

Agriculture Engineering Department
Cedar Bay Technical Institute
249 Plantation Drive
Benton, EC 79797

V Data Quality Objectives for Measurement Data

The Data Quality Objectives Process is not required for this project, as the Data must be of the highest quality possible from the analytical equipment available at the laboratories performing the analytical work. To that end the data quality requirements are specified in Table 1, and were based on the best available advice of several experienced staff members of the Water Resources Board.

VI Special Training Requirements/Certification

Sampling Personnel

Since much of the sample collection will be from boats all personnel that are responsible for actual boat operation must successfully complete a U.S.C.G. Safe Boating course. All sample collectors will be briefed on the correct methods to take samples, prior to start of sample collection operations. At least one person in each boat will possess a current Red Cross Lifesaving Certification. All personnel working in and around the boats shall have successfully passed Red Cross First Aid and CPR Training courses within the past 3 years.

Analytical Personnel

All analytical chemists will have, at a minimum, a B.S. in Chemistry, and at least two years experience in Analytical Chemistry.

All biologists will have, at a minimum, a B.S. in Marine Biology or Microbiology, as applicable, and at least two years experience in their field.

Other Personnel

All other personnel will be qualified for their positions.

VII Documentation and Records

All field samplers will maintain an accurate field log that describes as specifically as possible the location where the sample was collected, its appearance, its sample tag number, and any information that would be beneficial to the analyst. If a sampling plan cannot be followed exactly the sampler is to notify the Project Officer, who will issue verbal instructions to the sampler.

TABLE 1

QUALITY ASSURANCE REQUIREMENTS

Parameter	Sample Matrix	Detection Limit	Quantitation Limit	Estimated Accuracy	Estimated Precision
TSS	All	0.01 mg/l	---	1% relative error	±1 mg/l
COD	All	5 mg/l	15 mg/l	1% relative error	±1 mg/l
BOD	All	5 mg/l	15 mg/l	1% relative error	±1 mg/l
NH_3-N	All	0.02 mg/l	1 mg/l	99-107% recovery	±0.01 mg/l
NO_3-N	All	0.2 mg/l	1 mg/l	96-100% recovery	±0.01 mg/l
T-P	All	0.1 mg/l	5 mg/l	86-96% recovery	±0.01 mg/l
TKN	All	0.1 mg/l	5 mg/l	bias %-25%	±0.01 mg/l
PO_4	All	0.02 mg/l	1 mg/l	89-96% recovery	±0.01 mg/l
Pesticides	All	0.012 mg/l	0.02 mg/l	75-150% recovery	±0.2 ug/l

Records of samples sent for analysis will be maintained by the samplers and receipt will be verified with the analytical laboratory.

Laboratories will provide all analytical data in written format. All individual data sheets will be dated and signed/initialed by the analyst, the data validator, and the appropriate supervisor. Data validation will be performed on all data, and both validated and raw data will be provided to the Project Officer for review, evaluation and approval.

All QA/QC data will be filed.

VIII Sampling Process Design (Experimental Design)

All sampling procedures and monitoring equipment has been tested to ensure the collection of valid data.

The frequency of monitoring parameters in this project is uniform. Due to the nature and extent of the study, collection activities will take place only once.

Grab samples for surface runoff will be collected with a bucket and immediately stored in water-tight containers for shipping. Two types of biological samples will be collected and compared for lab analysis. The first set will come from the dead fish/shellfish at the kill sites; the second set will be living organisms accumulated with netting from Cedar Bay. The tissues from each set will be tested and analyzed for pesticides and chemicals. The composite water samples will be collected at intervals using a submersible pump. The results from the 3-foot interval and the 6-foot interval will then be mixed together in one container. All air samples will be analyzed for temperature. Also, engine emission pollutants from hydrocarbons will be measured using an organic vapor analyzer (OVA). As water samples are collected they will be stored on ice until delivery to a laboratory for analysis.

IX Sampling Methods Requirements

Sampling locations were chosen to best represent the area of the largest number of fish/shellfish kills. Figure 2 shows the locations of the data collection sites, and Table 2 lists the sample types, matrix, monitoring parameters, and frequency of collection at each site.

Because of the nature and extent of the project, only one sampling event per site and sample type will occur during the confines of the study.

Instantaneous grab samples for surface runoff will be collected at stations CB1-CB3, and will be representative of contaminants from nearby farm lands. At stations CB4-CB6, composite

FIGURE 2

DATA COLLECTION SITES ON CEDAR BAY

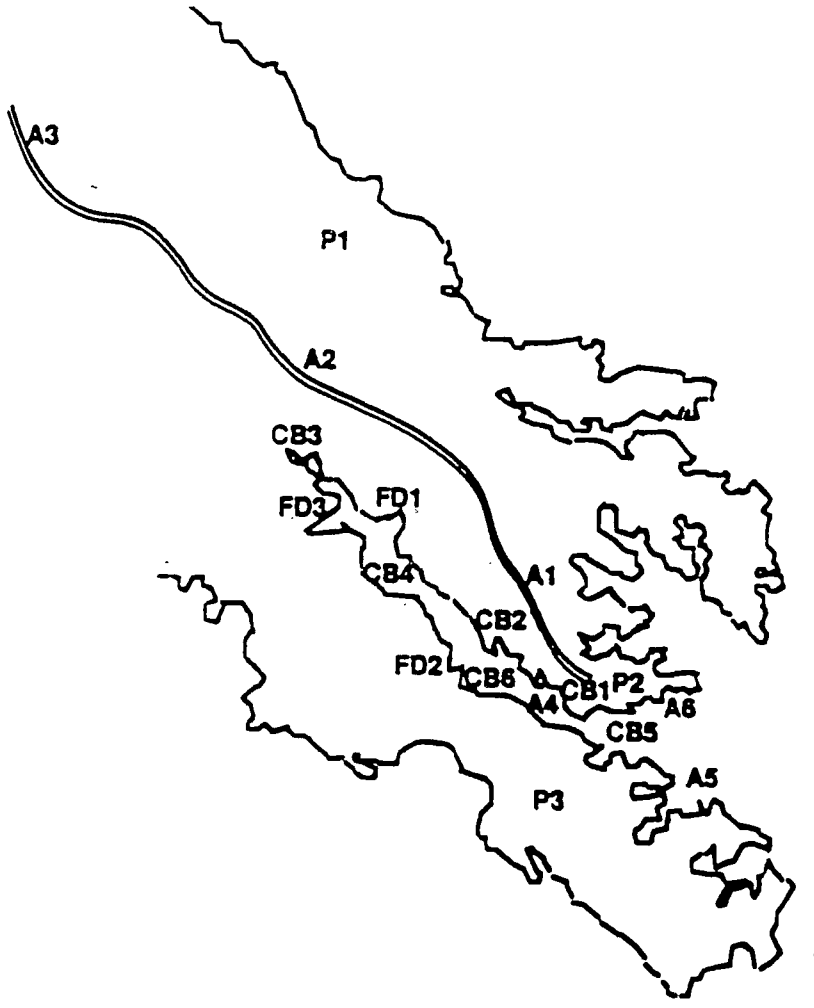


TABLE 2

MONITORING PARAMETERS

SITE	TYPE OF SAMPLE	MATRIX	PARAMETERS	FREQUENCY
CB1-CB3	Grab	Surface Runoff	TSS Nitrate Ammonia TKN Total Nitrogen Ortho -P Total -P Filterable Total -P Ch. Oxygen Demand Bio. Oxygen Demand Pesticides	1 Event
CB4-CB6	Composite	Cedar Bay Water Sample -3ft interval -6ft interval	TSS Nitrate Ammonia TKN Total Nitrogen Ortho -P Total -P Filterable Total -P Ch. Oxygen Demand Bio. Oxygen Demand Pesticides	1 Event
CB1-CB6	Grab	Air	Temperature	1 Event
FD1-FD2	Grab	Biological (Fish)	Pesticides	1 Event
P1-P3	Controlled	Rainfall	Quantity Intensity	10 min. 10 min.
A1-A3	Grab	Air	Temperature	1 Event
A4-A6	Grab	Air	Temperature Engine Emission	1 Event

water samples from Cedar Bay will be collected at various depths to determine contaminant characteristics at various depths. Air samples will be taken at stations CB1-CB6. Air monitoring stations will be located near the main highway and in areas where extensive boating activity occurs to assess possible pollutants from exhaust emissions.

Random temperature readings from air samples will be taken and recorded in the field log books. Grab samples for biological testing will be collected at stations FD1-FD2 to determine if pesticides are present in tissue samples. Stations P1-P3 will collect controlled rainfall samples to determine quantity and intensity.

X Sample Handling and Custody Requirements

Samples will be delivered to the designated laboratory within 24 hours of each sampling event and stored in a freezer onsite at 10 degrees celsius. The sampling tracking sheet (example at Appendix B) included with the samples must be checked upon arrival to ensure that all required information is included, such as sample date, location sampled, type of sample, number of samples, and the name of the person who sent the samples. Samples will not be discarded until all analyses have been completed and confirmed.

XI Analytical Methods Requirements

Table 3 provides references for each analytical method that will be used in the project.

XII Quality Control Requirements

Table 4 contains precision/accuracy protocol for QC checks. A comprehensive plan for the field has been prepared and is available from the QA officer.

XIII Instrument/Equipment Testing, Inspecting, and Maintenance Requirements

All field and analytical instruments and equipment will be inspected and tested daily, prior to operation. Any instruments and equipment not passing the daily inspection and test will not be used unless there are no alternates available. Operation and preventative maintenance for field equipment can be found in the manufacturer's instructions of each piece of equipment. Laboratory preventative maintenance procedures are provided in the laboratory QA Project Plan.

TABLE 3

ANALYTICAL METHODS

Parameter	Number of Samples	Sample Matrix	Method Reference
TSS	All	Water	209C[1]
COD	All	Water	508C[1]
BOD	All	Water	507[1]
NH_3-N	All	Water	417G[1]
NO_3-N	All	Water	00630[2]
T-P	All	Water	00625[2]
TKN	All	Water	00669[2]
PO_4	All	Water	424G[1]
Pesticides	All	Water Fish tissue	8080[3]
Temperature	All	Water	212[1]
Conductivity	All	Water	205[1]

[1] Standard Methods for Examination of Water and Wastewater, 16th ed., 1985, American Public Health Association, Washington, D.C.

[2] Manual for Chemical Analysis of Water and Wastes, 1974, U.S. Environmental Protection Agency, Washington, D.C.

[3] SW 846

TABLE 4

QC CHECKS FOR PRECISION AND ACCURACY

Parameter	Sample	Precision/Accuracy Protocol
TSS	All	1 duplicate/20 samples 1 standard/day
COD	All	1 duplicate/5 samples 6 standards/40 samples
BOD	All	1 duplicate/5 samples 6 standards/40 samples
NH_3-N	All	5 standards/30 samples 1 NBS standard/day
NO_3-N	All	4 standards/30 samples 1 NBS standard/day
T-P	All	5 standards/30 samples 1 NBS standard/day
TKN	All	4 standards/30 samples 1 NBS standard/day
PO_4	All	6 standards/30 samples 1 NBS standard/day
Pesticides	All	3 standards/30 samples 1 NBS standard/day

XIV Instrument Calibration and Frequency

All thermometers are precalibrated by the National Institute of Science and Technology. The organic vapor analyzer will be calibrated according to the manufacturer's instructions prior to each sampling event.

Laboratory calibration procedures are defined in the laboratory QA Project Plan.

XV Inspection/Acceptance Requirements for Supplies and Consumables

All supplies and consumables, upon receipt, will be verified with shipping/receiving documents, and purchase order to verify quantity ordered equals quantity received. Incorrect quantity shipments will be reported to purchasing agent for resolution with the supplier. Incorrect items will be evaluated by receiving clerk for suitability of use.

XVI Data Acquisition Requirements (Non-direct Measurements)

Existing data from the limited study performed for Total Suspended Solids (TSS), by the AAA-Ace Environmental Sampling and Analytical Laboratory, funded by the Cedar Bay Homebuilders Association has been evaluated and results are not considered valid due to Laboratory not being able to show traceability of results to sampling events or locations. If reconstruction of samplers logs is accomplished that provides traceability of sample location to analytical results, those individual data are considered acceptable for use as background material.

XVII Data Management

The data management system used by the laboratory performing the analytical work shall be described in the laboratory QA Project Plan.

XVIII Assessments and Response Actions

Performance and systems audits will occur in the field and the laboratory. Field audits will consist of the staff overseeing all sampling procedures. Laboratory audits will include double blind performance evaluation samples to assess the efficiency of laboratory staff. The results will be given to Rebecca Quince for review.

XIX Reports to Management

Interim QA reports will be issued bi-weekly during the course of the study. A final report will be issued at the termination of the project, and is the responsibility of the Project Director.

XX Data Review, Validation, and Verification Requirements

All data reduction procedures will follow the method specifications for performing calculations, found in Bloch et al (1986). All data will be reviewed 100%. Data validation processes will include verification that all QA criteria have been met. Data reporting procedures will ensure that all data outlined have been evaluated to determine if data quality is adequate.

REFERENCES

Bloch, S. Conducting Field Research in Agricultural Hydrology, Agricultural Handbook No. 95. Washington, D.C.: U.S. Department of Agriculture, 1986.

QAPP CLASSROOM PRACTICAL EXERCISE #2

In our same small groups, we will now revise the **"Bad Example"** of a Quality Assurance Project Plan into a "Better Example" of a QAPP.

Work in your group on the sections assigned by the instructor, using EPA QA/R-5 as the criteria document for the revision.

NOTES

Original Cover Page (Compressed):

QUALITY ASSURANCE PROJECT PLAN

FOR

DETERMINING ENVIRONMENTALLY RELATED CAUSES OF

FISH KILLS IN CEDAR BAY FY 1994

PROJECT OFFICER: Rebecca Quince

QUALITY ASSURANCE OFFICER: Bob Gilmore

PROJECT DIRECTOR: Zack Dempsey

Comments: Title Page/Element A1: Missing required signatures of Project Personnel, missing names and signatures of EPA personnel. Name of organization implementing project not provided.

Requirement: **A1** **Title and Approval Sheet**

Include:

- Title of the plan
- Name of the organization(s) implementing the project
- Names, titles, signatures of appropriate approving officials and approval dates for:

  Organization's Project Manager (Required)
  Organization's Quality Assurance Manager (Required)
  Project Subordinate Supervisors Concurrence (Optional)
  Region 6 EPA Project Manager *(Required)*
  Region 6 EPA Approving Official *(Required)*[8]
  Others, as needed (e.g., State, other Federal Agency)

- Title and Region 6 QTRAK number of the approved Quality Management Plan applicable to submitted QAPP

Submission of at least two original approval pages is recommended.

---

[8] "EPA Approving Official" is the Region 6 Program Office Manager or staff person designated and authorized by Certification of the Region 6 QA Officer to approve QAPPs. If the EPA Project Manager/Officer is unable to determine the approving official, contact the Office of Quality Assurance.

(Revised Title Page)

QUALITY ASSURANCE PROJECT PLAN

FOR

DETERMINING ENVIRONMENTALLY RELATED CAUSES OF FISH KILLS IN CEDAR BAY FY 1994

SUBMITTED BY EAST CAROLINA WATER COMMISSION

(New Approval Page)

Quality Assurance Project Plan for Determining Environmentally Related Causes of Fish Kills in Cedar Bay FY 1994

Plan is prepared by, and work to be implemented by, the East Carolina Water Commission, under the East Carolina Water Commission Quality Management Plan for Marine and Estuarine Environmental Monitoring and Remedial Action, EPA Region 6 QTRAK # Q-94-069.

Plan Prepared By:

_____ Date:_____
Rebecca Quince, ECWC Project Officer

ECWC Concurrence:

_____ Date:_____
Joan Breedon, Laboratory Director

_____ Date:_____
Bob Gilmore, Data Processing Chief

_____ Date:_____
Paul Cronin, Field Operations Chief

ECWC Approvals:

_____ Date:_____
Troy Achemann, Project QA Officer

_____ Date:_____
Rebecca Quince, Project Officer

_____ Date:_____
Zack Dempsey, Project Director

EPA Approvals:

_____ Date:_____
Steffanie Barnett, Project Officer

_____ Date:_____
Richard Hoppers, Chief, 6W-Q

Original Table of Contents:

TABLE OF CONTENTS
Revision 0, October 15, 1996

LIST OF TABLES

LIST OF FIGURES

APPENDICES

Comments: Table of Contents/Element A2: Acceptable, recommend use of document control format on this page to be consistent throughout the QAPP.

Revised Table of Contents:

TABLE OF CONTENTS
Revision 0, October 15, 1996

LIST OF TABLES

LIST OF FIGURES

APPENDICES

TASK 1: MODIFY TABLE OF CONTENTS AS REQUIRED.

Original Section I:

I Distribution List

Following individuals will receive copies of approved QAPP.

Project Personnel:

Zack Dempsey
Bob Gilmore
Rebecca Quince
Joan Breedon
Paul Cronin
Robert Mendez
Mark Preston
Diane Jenkins

U.S. EPA Region 6 Personnel:

Alva Smith, 6EN-XQ
Charles Ritchey, 6EN-XQ
Russell Bowen, 6WQ-AG
Petra Sanchez, 6PD-L
Linda Raye Chapman, 6WQ-EW
Karen Alverez, 6PD-S
Steffanie Barnett, 6WQ-EM
Pam Mintz, 6WQ-AG

Other Personnel/Organizations:

Governors Office
Chairman, State Water Management Board
President, State Shellfishermans Association
President, Cedar Bay Homebuilders Association
President, Cedar Bay Chamber of Commerce
President, Cedar Bay Farmers Cooperative
President, Cedar Bay Realators Association
Director AAA-Ace Environmental Sampling and Analytical Laboratory (3 Copies)

Each copy of the QAPP will be serial numbered, and a receipt will be signed and returned to the QA Officer. Example of the receipt document is Appendix A of this document. Recipients are responsible for assuring they have a current and correct copy of the applicable QAPP.

Comments: Section I/Element A3: Revise to indicate responsibility for assuring all QAPP recipients have a current copy of the QAPP rests with project, not with recipients. Appendix A referred to in this section is missing from the QAPP. Recommend addition of titles beside names of project personnel.

Requirement: **A3** **Distribution List**

List the individuals and their organizations who will receive copies of the approved QAPP and any subsequent revisions. Include all managers who are responsible for implementing the plan, as well as the QA managers and representatives of all groups involved.

Revised Section I:

I Distribution List

Following individuals will be provided copies of approved QAPP, and all changes to the QAPP, once approved.

Project Personnel:

Zack Dempsey, ECWC Project Director
Troy Achemann, ECWC Quality Assurance Officer
Bob Gilmore, ECWC Data Processing Supervisor
Rebecca Quince, ECWC Project Officer
Joan Breedon, ECWC Laboratory Director
Paul Cronin, ECWC Field Operations Supervisor
Robert Mendez, QC Coordinator
Mark Preston, QC Coordinator
Diane Jenkins, QC Coordinator

U.S. EPA Region 6 Personnel:

Russell Bowen, 6WQ-AG
Linda Raye Chapman, 6WQ-EW
Steffanie Barnett, 6WQ-EM
Pam Mintz, 6WQ-AG

Other Personnel/Organizations:

Governors Office
Chairman, State Water Management Board
President, State Shellfishermans Association
President, Cedar Bay Homebuilders Association
President, Cedar Bay Chamber of Commerce
President, Cedar Bay Farmers Cooperative
President, Cedar Bay Realators Association

Each copy of the QAPP will be serial numbered, and mailed via "return receipt" mail. The PS Form 3811, upon its return to the QA Officer, will be maintained as proof of receipt. Recipients are responsible for assuring the ECWC, Cedar Bay Project Office, has at all times their current mailing address. The ECWC will maintain records to assure traceability of QAPPs, by serial number.

Original Section II:

II Project/Task Organization

The individuals responsible for the major aspects of the project are provided in Figure 1.

Comments: Section II/Element A4: Two organizations are listed at bottom of organizational chart, it is not clear which organization has what if any responsibility in this effort, clarification is required. If personnel are from different entities they should be defined as to which organization they work for. Possible conflict of interest situation exists for Bob Gilmore, requires clarification. Specific responsibilities are not defined in the QAPP. Organization chart indicates the QA Officer has supervisory control over the Project Officer. There is no direct communication between the QC staff and the QA Officer. Recommend listing phone numbers of key staff for ease of access.

Requirements: **A4** **Project/Task Organization** (DQO)

Identify the individuals or organizations participating in the project and discuss their specific roles and responsibilities. Include the principal data users and the decision-makers. The project quality assurance manager **shall be** independent of the unit generating the data. This does not include senior officials, such as corporate managers or agency administrators, who are nominally but not functionally involved in data generation, data use, or decision-making. The QAPP should also identify the person(s) responsible for approving and accepting final products and deliverables.

Provide a concise **organization chart showing** the relationships and the lines of communication **among** all project participants. Include other data users who are outside of the organization generating the data, but for whom the data are nevertheless intended; e.g., modelers, risk assessors, design engineers, toxicologists, etc. Where direct contact between project managers and data users does not occur, such as, between a project consultant for a Potentially Responsible Party and EPA risk assessment staff, the organization chart should show the route by which information is exchanged. The organization chart should also identify any subcontractor relationships relevant to environmental data operations. This chart should be realistic and practical, and should reflect only actual lines of authority and communication for the project described. Names of current incumbent occupying a position is essential, as is the identification of vacant positions.

Revised Section II:

TASK 1. INDIVIDUAL ASSIGNMENT:

Using next page and material from the instructor, create an organizational chart for the Cedar Bay Project, with the assumption that all efforts will be performed by ECWC personnel.

TASK 2. GROUP ASSIGNMENT:

Each group will reach a consensus on the Organizational Chart that will be the most effective for this project. Revise chart as required, to reach consensus.

TASK 3. GROUP ASSIGNMENT:

Once the organizational chart is complete, as a group, write Section II, in the space below. Section **must** comply with requirements above.

II Project/Task Organization

II Project/Task Organization (Continued)

PROJECT DIRECTOR
Zack Dempsey
(777) 555-1210

PROJECT OFFICER
Rebecca Quince
(777) 555-1211

QA OFFICER
Troy Achemann
(777) 555-1212

LABORATORY MANAGER
Joan Breedon
(777) 555-1213

DATA PROCESSING
Bob Gilmore
(777) 555-1214

FIELD OPERATIONS
Paul Cronin
(777) 555-1215

QC
Robert Mendez
(777) 555-1216

QC
Mark Preston
(777) 555-1217

QC
Diane Jenkins
(777) 555-1218

NOTES

II Project/Task Organization (Continued)

Original Section III:

III Problem Definition/Background

This project was developed by the State Water Management Board, in conjunction with the Cedar Bay Technical Institute, to determine the environmental causes of recent fish and shellfish kills in the area. There is only minimal background studies and information known to exist for environmental concerns in Cedar Bay, primarily a DDT Study, was performed in 1977, by the State Agriculture Department, funded by the U.S.D.A., that indicated a level of DDT present that was far below any level of concern. A limited study was performed in December of 1993, for Total Suspended Solids (TSS), by the AAA-Ace Environmental Sampling and Analytical Laboratory, funded by the Cedar Bay Homebuilders Association. Results are not considered valid due to Laboratory not being able to show traceability of results to sampling events or locations.

Comments: Section III/Element A5: Area is too vague to define what problem is to be solved or decision is to be made.

Requirement: **A5** **Problem Definition/Background** (DQO)

State the specific problem to be solved or decision to be made. Include sufficient background information to provide a historical perspective for this particular project. For example, this would include the regulatory or alleged toxic exposure situation that led to the need for this project. The discussion must include enough information about the problem, the past history, any previous work or data, and any regulatory or legal context to allow a technically-trained reader to make sense of the project objectives and activities. This discussion also identifies the decision maker(s) and the principal customer(s) for the results. (When the Data Quality Objectives [DQO] process has been used, this information should be readily available.)

Revised Section III:

TASK 1. **GROUP ASSIGNMENT:** **State the Problem:** Concisely describe the problem to be studied. Review prior studies and existing information to gain an acceptable understanding of the problem.

TASK 2. **GROUP ASSIGNMENT:** **Identify the Decision:** Identify the decision that will solve the problem using new data.

TASK 3. **GROUP ASSIGNMENT:** **Identify the Inputs to the Decision:** Identify the information that needs to be learned and the measurements that need to be taken in order to resolve the decision.

TASK 4. **GROUP ASSIGNMENT:** **Define the Study Boundaries:** Specify the conditions (spatial, time, event related) to which decisions will apply, and within which the data should be collected.

TASK 5. **GROUP ASSIGNMENT:** **Develop a Decision Rule:** Integrate the outputs from previous steps into an **"if....then...."** statement that defines the conditions that would cause the decision maker to choose among alternative actions.

TASK 6. **GROUP ASSIGNMENT:** **Specify Acceptable Limits on Decision Errors:** Define the Decision Maker's acceptable decision error rates based on the consequences of making an incorrect decision based on data that inaccurately estimate the true state.

TASK 7. **GROUP ASSIGNMENT:** **Optimize the design:** Evaluate information from the previous steps and generate alternative sampling designs. Choose the most resource-efficient design that meets all DQOs.

Now that the DQOs are completed we can revise Section III.

TASK 8. GROUP ASSIGNMENT: Revise Section III:

Original Section IV:

IV Project Task Description

This project is to define the nature and extent of contamination or pollution that may be present in Cedar Bay by:

* The collection and analysis of samples to determine water quality;

* Define the types of chemicals and fertilizers being used in agricultural land management processes;

* Determine presence of contamination or pollution caused by construction;

* Collect biological specimens for fish and shellfish tissue samples.

All project records and QA/QC data will be retained for at least 5 years after completion of the project.

All sample collection will be completed within 45 days of the start of the project, and all analytical work and data validation completed within 60 days of the start of the project. Project will start within 30 days of receipt of funding.

Comments: Section IV/Element A6: Types of measurements described are not complete, use of the DQO process would clarify types of data required for a decision. Quality standards, that would also come from DQO process are not defined. No special personnel/equipment requirements are defined, list any required or state none are required. No assessment tools are defined. Where or who retains records is not defined.

Requirements: **A6** **Project/Task Description** (DQO)

Provide a description of the work to be performed. This discussion may not need to be lengthy or overly detailed, but it should give a overall picture of how the project will resolve the problem or question described in A5. Describe in general terms the following, as needed:

- Measurements that are expected during the course of the project and the approach that will be used.

- Applicable technical, regulatory, or program-specific quality standards, criteria, or objectives.

- Any special personnel and equipment requirements that may indicate the complexity of the project.

- The assessment tools needed (i.e., program technical reviews, peer reviews, surveillances, and technical audits as needed and/or specified by the QMP) for the project.

- A schedule for the work to be performed.

- Project and quality records required, including the types of reports needed.

Now that the DQOs are completed we can revise Section IV.

TASK 1. GROUP ASSIGNMENT: Revise Section IV:

IV Project Task Description

Original Section V:

V Data Quality Objectives for Measurement Data

The Data Quality Objectives Process is not required for this project, as the Data must be of the highest quality possible from the analytical equipment available at the laboratories performing the analytical work. To that end the data quality requirements are specified in Table 1, and were based on the best available advice of several experienced staff members of the Water Resources Board.

Comments: Section V/Element A7: Data Quality Objectives are essential requirements for QAPPs in Region 6, and are required by EPA Order 5360.1. This project, due to its wide open possibilities, is in need of structured planning prior to data collection activities.

Requirements: **A7 Quality Objectives and Criteria for Measurement Data** (DQO)

Any QAPP must include a statement of the project quality objectives and measurement performance criteria. EPA recommends that a graded approach be used in planning, such as the Data Quality Objectives (DQO) Process. Even in those cases in which the formal DQO Process is not needed, a statement of the project quality objectives and measurement performance criteria is needed. The DQO process provides quality objectives based on several factors chosen by the user of the data. For details on the DQO Process and when it should be used, please see the EPA guidance document (QA/G-4)[9].

The project quality objectives should be stated in quantitative terms to the extent possible:

> Example: UV Treatment of Contaminated Groundwater. "The purpose of this project is to demonstrate whether or not the residual trichlorethene concentration in the treated water is less than 0.5 μg/L at a confidence level of 95 percent.

Without such quantitative goals, it is difficult to know whether the selected analytical method is sufficiently sensitive or precise, or whether a sufficient number of samples are being collected. Sometimes, of course, project objectives must be stated somewhat less quantitatively, particularly in those situations when the use of the formal DQO Process is not needed.

---

9 EPA QA/G-4 is Guidance for Planning for Data Collection in Support of Environmental Decision Making Using the Data Quality Objectives Process.

Example: Oil Spill Remediation. "One objective of this project is to determine whether the populations of clams, mussels, and sand fleas recover more rapidly in the treated than the untreated area."

Example: Epidemiology Study. "The purpose of this project is to determine whether the concentrations of indoor NO_2 and soot are greater in the residences of lung cancer patients than in the residences of healthy persons."

The section on project quality objectives and measurement performance criteria should address, as appropriate, the following:

- the **scope** of the project; that is, the domain (geographical locale and boundaries, environmental medium, time period, etc.) over which conclusions and decisions will apply;
- the time, resource, or other constraints on the measurement project;
- the intended uses of the data, in order of importance and the expected users of the data;
- the specific data needed: type, quantity, matrices involved;
- the action levels or standards upon which decisions will be made, including the detection limits and data reporting units, and the source(s) of this information;
- the population parameter(s) of interest; e.g., mean, maximum, or range, which specify the form the data will be in when compared against action levels or standards;
- the acceptable level of confidence in the data needed for the stated purposes or the acceptable amount of uncertainty;
- the quantitative **sensitivity**, **precision**, **bias**, and **completeness** criteria for each major measurement planned (including all pollutant and process measurements) for each sample matrix, based on the DQO statements;
- the units of expression of the precision and bias goals, which should correspond to the methods selected to assess data precision and bias; and
- the goals for achieving data **representativeness** and **comparability**, and the planning considerations for attaining these goals (unlike precision, bias, and completeness, these objectives are not usually expressed or assessed quantitatively);

Data quality or measurement performance criteria may be typically specified in terms of detection or quantitation limits, precision, bias, and comparability. However, simply listing requirements for precision, bias, and completeness without further discussion is not sufficient. Even statements such as "bias will be measured as percent recovery of a matrix spike sample" are of marginal help. In specifying data quality, it is thus essential to specify exactly how such quality will be measured and interpreted.

> Example: A possible statement of bias requirement. "Bias will be measured a minimum of five times throughout this project by the analysis of standard reference materials No. 956B. Recovery of TCE from this SRM should average 85 percent or greater, with a relative standard deviation of no more than 20 percent."

Data specifications should also be distinguished from the specific QC procedures that are routinely carried out as part of each measurement. QC procedures are used while carrying out specific procedures; data specifications are used for selecting the appropriate methods and QC criteria.

The QAPP may need to define different types of sensitivity (i.e., qualitative, quantitative, screening, etc.) that may be appropriate for different parts of the project.

The quantitative goals should reflect the *total measurement*, if possible, or address the field, laboratory, and data handling components separately. In the event there is no basis for defining data quality goals for the project, goals may be estimated based on prior knowledge of the measurement system, and on method validation studies (using replicates, spikes, standards, recovery, studies, etc.) Explain the circumstances under which these goals were established.

If defining quantitative goals is not relevant for certain measurements, indicate this and state the reason.

Data representativeness is the degree to which the environmental samples truly reflect the population or material in the real world. It can be affected by the time, place, and manner by which the samples are collected.

Data comparability is dependent upon consistency in sampling conditions, selection of sampling procedures, sample preservation methods, analytical methods, and data reporting units, throughout the project, and with previous projects with which these results will be compared.

The DQO Process for compliance and/or enforcement projects in the Regions may not be within the control of the EPA project manager and QA manager.

The measurement performance criteria are specified in regulations, permits, or orders. Whether or not those criteria satisfy the requirements of this document, they are absolutely required. Often the results of the DQO Process are not expressible in the terms stated here, such as precision, bias, or comparability. The affected source is simply required to follow a specified method. In such cases, it is sufficient for the portion of the QAPP addressing the DQO Process to state that the testing will satisfy the regulatory requirements specified. This does not, however, relieve the project manager or QA manager from their responsibility to comply with all other applicable QAPP requirements in this document.

Now that the DQOs are completed we can revise Section V.

TASK 1. GROUP ASSIGNMENT: Revise Section V:

V Data Quality Objectives for Measurement Data

Original Section VI:

VI Special Training Requirements/Certification

Sampling Personnel

Since much of the sample collection will be from boats all personnel that are responsible for actual boat operation must successfully complete a U.S.C.G. Safe Boating course. All sample collectors will be briefed on the correct methods to take samples, prior to start of sample collection operations. At least one person in each boat will possess a current Red Cross Lifesaving Certification. All personnel working in and around the boats shall have successfully passed Red Cross First Aid and CPR Training courses within the past 3 years.

Analytical Personnel

All analytical chemists will have, at a minimum, a B.S. in Chemistry, and at least two years experience in Analytical Chemistry.

All biologists will have, at a minimum, a B.S. in Marine Biology or Microbiology, as applicable, and at least two years experience in their field.

Other Personnel

All other personnel will be qualified for their positions.

Comments: Section VI/Element A9: Courses cited are related to Health and Safety much more than Data Quality, however they are acceptable. What would be beneficial would be a statement that none of the work performed would exceed the general knowledge criteria for field sampling personnel, as defined in the current approved Quality Management Plan. Is the criteria for analytical personnel acceptable? Other personnel "will be qualified" but qualifications are lacking, as is the responsible party for that decision.

Requirements: **A9** **Special Training Requirements/Certification**

Identify and describe any specialized training or certification requirements for personnel in order to successfully complete the project or task. Discuss how such training will be provided and how the necessary skills will be assured and documented.

Now that the DQOs are completed we need to consider revision of Section VI.

TASK 1. GROUP ASSIGNMENT: Revise Section VI:

VI Special Training Requirements/Certification

Original Section VII:

VII Documentation and Records

All field samplers will maintain an accurate field log that describes as specifically as possible the location where the sample was collected, its appearance, its sample tag number, and any information that would be beneficial to the analyst. If a sampling plan cannot be followed exactly the sampler is to notify the Project Officer, who will issue verbal instructions to the sampler.

Records of samples sent for analysis will be maintained by the samplers and receipt will be verified with the analytical laboratory.

Laboratories will provide all analytical data in written format. All individual data sheets will be dated and signed/initialed by the analyst, the data validator, and their appropriate supervisor. Data validation will be performed on all data, and both validated and raw data will be provided to the Project Officer for review, evaluation and approval.

All QA/QC data will be filed.

Comments: Section VII/Element A10: Verbal "documentation" is no documentation, and not acceptable. While flexibility is needed at times in field operations, obtaining this "flexibility" should be through a structured process that documents the deviations thoroughly. QA/QC data being "filed" is not fully acceptable. Filed and retained, with a specific retention time, an assignment of responsibility for record retention, and perhaps even access procedures may be required. An SOP could be used here easily, or if a governmental agency, citing the regulatory or policy document is acceptable.

Requirements: **A10** **Documentation and Records**

Itemize the information and records which must be included in a data report package for the project or task, and specify the reporting format, if desired. Documentation can include raw data, filed logs, instrument printouts, and results of calibration and QC checks. Specify the laboratory data reporting turnaround time. Specify whether a field sampling and/or laboratory analysis "case narrative"[10] is required to provide a complete description of any difficulties encountered during sampling or analysis.

Specify any requirements for the final disposition of records and documents from the project, including location and length of retention period.

---

[10]"Case Narrative" refers to an annotated summary of the analytical work performed by a laboratory that describes in narrative form what activities were performed and identifies any problems encountered. The case narrative provides additional information to user in interpreting the data received.

Now that the DQOs are completed we need to consider revision of Section VII.

TASK 1. GROUP ASSIGNMENT: Revise Section VII:

VII Documentation and Records

Original Section VIII:

VIII Sampling Process Design (Experimental Design)

All sampling procedures and monitoring equipment has been tested to ensure the collection of valid data.

The frequency of monitoring parameters in this project is uniform. Due to the nature and extent of the study, collection activities will take place only once.

Grab samples for surface runoff will be collected with a bucket and immediately stored in water-tight containers for shipping. Two types of biological samples will be collected and compared for lab analysis. The first set will come from the dead fish/shellfish at the kill sites; the second set will be living organisms accumulated with netting from Cedar Bay. The tissues from each set will be tested and analyzed for pesticides and chemicals. The composite water samples will be collected at intervals using a submersible pump. The results from the 3-foot interval and the 6-foot interval will then be mixed together in one container. All air samples will be analyzed for temperature. Also, engine emission pollutants from hydrocarbons will be measured using an organic vapor analyzer (OVA). As water samples are collected they will be stored on ice until delivery to a laboratory for analysis.

Comments: Section VIII/Element B1: Section is unacceptable in total. The experimental design of the project is not defined, and those requirements stated are not validated by any specific criteria. Measurements are not identified as to their criticality. Sampling methods are not well defined by applicable standard method. Process conditions are lacking totally.

Requirements: **B1** **Sampling Process Design (Experimental Design)** (DQO)

Outline in general terms the experimental design of the project and the anticipated project activities, including the types of samples required, sampling network design, sampling frequencies, sample matrices, measurement parameters of interest, and the rationale for the design. If individual sampling plans will be developed for discrete project phases, include their preparation schedule.

Describe techniques or guidelines to be followed in selecting sampling points and frequencies, well installation design (when applicable), field decontamination procedures and materials needed, and sampling equipment. When field screening techniques will be used to identify samples for laboratory analysis, describe the criteria for sample selection. Similarly, when locational data are to be collected, stored, and transmitted, the method(s) used must be specified and described (or referenced). Key elements to be addressed include how locations and their bias are determined.

All measurements should be classified as critical (i.e., required to achieve project objectives) or non-critical (informational purposes only). Critical measurements will undergo closer scrutiny during the review and data gathering process, and will have first-claim on limited budget resources.

For non-standard methods or unusual sample matrices and situations, appropriate method validation study information is needed to confirm the performance of the method for the particular matrix. Such validation studies may included round-robin studies performed by other organizations. If previous validation studies are not available, they must be developed during the project and included as part of the project results. It is very important for this element to include complete documentation and validation of both the sampling and analytical methodologies. Identifying standard methods by number, date, and regulatory citation (as appropriate) is often sufficient. However, many published (and even regulatory) methods allow the user to select from various options. The method citations should state *exactly* which options are being selected.

Measurement of process conditions is often essential to a project (e.g., industrial plant or control equipment operation associated with a compliance test, meteorological parameters associated with impoundment volatization). In such cases, the experimental design must include the design and validation techniques as described above.

Now that the DQOs are completed we can revise Section VIII.

TASK 1. GROUP ASSIGNMENT: Revise Section VIII:

VIII Sampling Process Design (Experimental Design)

VIII Sampling Process Design (Experimental Design) Continued

An alleged "GOOD EXAMPLE" from a previous class for this section is as follows:

VIII. Sampling Process Design (Experimental Design)

Sampling Activities

The project sampling activities will be divided into two phases. Phase I will be designed as a Pilot Study. The Pilot Study will be conducted as a one time sampling event and will be completed within 10 days of the start of the project. Appropriate biological, physical and chemical samples will be taken simultaneously at each site during the sampling event. The rationale behind conducting the Pilot Study is to eliminate those parameters which did not contribute to the death of the crabs and to determine the possible causes of death. After conclusive results of Phase I determine the biological, physical or chemical parameter(s) of concern (causing the death of the crabs), the project sampling design will enter Phase 11. Phase 11 will be designed as a Surveillance Strategy. The selection of sample sites will be based on the possible sources of the specific contaminant(s) and areas where the Pilot Study samples exhibited the highest contaminant concentrations. All sampling collection will be completed within 45 days of the start of the project.

Pilot Study Biological Sampling Activities

The biological sampling network will be random sampling throughout the kill sites designated in Figure 2. Data Collection Sites on Cedar Bay and a reference site. Triplicate samples shall be taken from each site. Living organisms will be netted. Individual organisms will be assigned a unique number and identified as to species, location, and general physical condition.

NECROPSY of live and morbid crabs/fish from the kill site will be conducted to determine the biological and toxicological causes of death or effects on the living organisms. Two types of biological samples will be collected from the kill site. They will be histological and bacteriological samples. Specific organs from the live and morbid crabs/fish will be collected for histological examination. Bacteriological samples will be taken from shell surface and internal organs. The toxicological tests will be conducted on whole crab/fish samples for tissue concentrations of specific chemicals and metals. Tissues will be collected from dead, live and morbid organisms.

Pilot Study Chemical Sampling Activities

Water samples will be taken from the same sites as those described above in the biological sampling activities. Water samples will also be taken from the surface runoff from construction and farming sites up to three miles upstream from the kill sites. A sample will be taken from a three mile upstream reference site to determine background concentrations of chemical parameters. Triplicate samples shall be taken from each site. Sample types will be determined by the chemical analysis to be performed on each sample as listed on Table 3.

Pilot Study Physical Sampling Activities

Sediment samples will be taken from the same sites as those described above in the biological sampling network. Sediment samples will also be taken from the areas of introduction of runoff from the construction and farming sites described above in the chemical sampling activities. Triplicate samples shall be taken from each site.

Original Section IX:

IX Sampling Methods Requirements

Sampling locations were chosen to best represent the area of the largest number of fish/shellfish kills. Figure 2 shows the locations of the data collection sites, and Table 2 lists the sample types, matrix, monitoring parameters, and frequency of collection at each site.

Because of the nature and extent of the project, only one sampling event per site and sample type will occur during the confines of the study.

Instantaneous grab samples for surface runoff will be collected at stations CB1-CB3, and will be representative of contaminants from nearby farming lands. At stations CB4-CB6, composite water samples from Cedar Bay will be collected at various depths to determine contaminant characteristics at various depths. Air samples will be taken at stations CB1-CB6. Air monitoring stations will be located near the main highway and in areas of extensive boating activities to assess possible pollutants from exhaust emissions.

Random temperature readings from air samples will be taken and recorded in the field log books. Grab samples for biological testing will be collected at stations FD1-FD2 to determine if pesticides are present in tissue samples. Stations P1-P3 will collect controlled rainfall samples to determine quantity and intensity.

Comments: Section IX/Element B2: First sentence too vague. Figure 2, sampling map, has no scale, no North arrow, is difficult to determine land from water. One sampling event may not provide all required data, without DQOs it is not easy to determine data requirements.

Requirements: **B2** **Sampling Methods Requirements**

Describe the procedures for collecting samples. Identify the required sampling methods (and/or equipment, if automated), including any implementation requirements, decontamination procedures and materials needed, and any specific performance requirements for the method. For each sampling method, identify any support facilities needed. The discussion should also address what to do if there is a failure in the sampling or measurement system and who is responsible for corrective action.

Describe the preparation and decontamination of sampling equipment, including disposal of decontamination by-products; the selection and preparation of sample containers, sample volumes, preservation methods, and maximum holding times to sample extraction and/or analysis. A tabular presentation format is strongly recommended, particularly when two or more sample matrices are involved.

Now that the DQOs are completed we need to consider revision of Section IX.

TASK 1. GROUP ASSIGNMENT: Revise Section IX:

IX Sampling Methods Requirements

An alleged "GOOD EXAMPLE" from a previous class for this section is as follows:

IX. Sampling Method Requirements

Sampling Locations and Techniques

Preliminary sampling points have been chosen for sample collection and are depicted in Figure 2. Table 2 lists the sampling points that will be selected according to each sampling network design under biological, chemical and physical sampling activities. Locations will be determined by the possibility of greatest impact on the death of the crabs based on observation and proximity to shoreline. Sampling types (grab or composite) and techniques will be in accordance with the procedures described for each specific analysis to be performed on the biological, chemical and physical parameters as listed in Table 2. All biological, chemical and physical measurements are critical and take equal priority in determining the death of the crabs. Sampling protocol will follow QA methods described in each of the analytical procedures listed in Table 3 and include QC checks listed in Table 4.

Changes to Figure 2. include a key to identify the north direction and mileage scale, demarkation between land and water, identification of sample locations and contoured areas to denote the locations of greatest crab/fish kills, identification of local roadways, and the agricultural and construction areas contributing to surface runoff. Tributaries that are within three miles of the kill sites should be denoted. Any changes in sampling locations should be reflected on Table 2.

Sampling Performance Requirements

Each sample will be collected according to the corresponding EPA published methodology including preservation and implementation requirements, decontamination procedures, and specific performance requirements. Support facilities for attaining sample containers, sampling equipment and ice will be arranged through the Carolina Water Commission as needed for each sampling method.

The Project Officer shall review the techniques that the contract sampling and analytical laboratory plan to use for sampling equipment preparation, decontamination, disposal of decontaminated by-products, sample containers, sample volume, preservation methods, holding times and analytical methods. These shall conform to the methods cited in Table 3.

Should a failure in sampling occur, the contract sampling and analytical laboratory will inform the Project Officer. The Project Officer shall decide the corrective action.

Original Section X:

X Sample Handling and Custody Requirements

Samples will be delivered to the designated laboratory within 24 hours of each sampling event and stored in a freezer onsite at 10 degrees celsius. The sampling tracking sheet (example at Appendix B) included with the samples must be checked upon arrival to ensure that all required information is included, such as sample date, location sampled, type of sample, number of samples, and the name of the person who sent the samples. Samples will not be discarded until all analyses have been completed and confirmed.

Comments: Section X/Element B3: How are samples delivered to the laboratory? Holding times, while contained in the cited Standard Methods, are not listed separately, which would be of benefit to samplers and others that may not have access to or time to determine holding times. Sample Tracking Sheet, Appendix B, is not provided. Sample receiving and custody at the laboratory is not defined. Temperature cites are suspect, and not specific as to media.

Requirements: **B3** **Sample Handling and Custody Requirements**

Describe the provisions for sample handling and shipment, taking into account the nature of the samples and the maximum allowable sample holding times before extraction or analysis. Describes the following provisions for sample custody, in both the field and the laboratory:

- Forms, notebooks and procedures to record the exact location and ambient conditions associated with sample collection, possession and analysis. In the laboratory, a sample custody log should be maintained.
- Examples of sample documentation forms, such as sample labels, custody seals, and chain-of-custody forms.
- Labeling procedures and information entered on the forms, including sample preservation, if any, and dates and times of sample transfer and analysis.
- Procedures for transferring and maintaining custody of samples.

Now that the DQOs are completed we need to consider revision of Section X.

TASK 1. GROUP ASSIGNMENT: Revise Section X:

X Sample Handling and Custody Requirements

An alleged "GOOD EXAMPLE" from a previous class for this section is as follows:

X. Sample Handling and Custody Requirements

Sample Preservation

Samples will be delivered to the contract laboratory within 24 hours of the sampling event or within the holding times specified by the analytical method. Sufficient ice or a freezer shall be used to ensure proper temperature for preservation described by each analytical method.

Sample Tracking

Each sample will have an attached sample tracking sheet. When sampling personnel deliver the sample to the laboratory, the tracking sheet shall be checked to ensure that all the required information is included, such as a sample identification number, sample date, location, type, analysis to be performed, holding times, and special handling instructions. This tracking sheet will also serve as a Chain-Of-Custody form. The sampling personnel will sign and date the Chain-Of-Custody form when they relinquish the sample to the laboratory personnel. The laboratory personnel will sign and date the Chain-Of-Custody form as they receive the sample and every time the sample changes custody. The laboratory will maintain its own sample custody procedures, including a sample custody log book, that will be defensible in a court of law.

Field Sampling Procedures

Sampling personnel will maintain a field notebook to record the sample identification number, sample type, location, date, ambient conditions including Ph and dissolved oxygen, and observations of meteorological conditions. Each sample will have a custody seal.
The Project Officer will review the contract laboratory's sample Chain-Of-Custody and field sampling procedures. Samples will not be discarded until all analyses have been performed and results reviewed by the Project Officer.

Original Section XI:

XI Analytical Methods Requirements

Table 3 provides references for each analytical method that will be used in the project.

Comments: Section XI/Element B4: Footnote 1 of Table 3 cites the 16th edition , which may or may not be accurate. For waste water it is the 18th edition, for other analytical methods it may be other editions.

Requirements: **B4** **Analytical Methods Requirements** (DQO)

Identify the analytical methods and/or equipment required, including any extraction methods needed, laboratory decontamination procedures and materials needed (such as in the case of hazardous or radioactive samples), waste disposal requirements (if any), and any specific performance requirements for the method. The QAPP should also address what to do if there is a failure in the analytical system and who is responsible for corrective action.

Now that the DQOs are completed we can revise Section XI.

TASK 1. GROUP ASSIGNMENT: Revise Section XI:

XI Analytical Methods Requirements

XI Analytical Methods Requirements (Continued)

Original Section XII:

XII Quality Control Requirements

Table 4 contains precision/accuracy protocol for QC checks.

A comprehensive plan for the field has been prepared and is available from the QA officer.

Comments: Section XII/Element B5: Table 4 has no blanks cited for contamination detection. The "comprehensive" QC plan should be appended to this document.

Requirements: **B5** **Quality Control Requirements**

Discuss QC procedures that should be associated with each sampling, analysis, or measurement technique. Such specific procedures are performed routinely during the measurement process, and the results are required to be evaluated immediately by the technician upon completion of the test. Results must fall within certain acceptance criteria, or specific corrective action is required. For projects at or beyond the "proof-of-concept" stage, or for projects employing well-characterized methods, this section should list each required QC procedure, along with the associated acceptance criteria and corrective action. Because standard methods are often vague or incomplete in specifying QC requirements, simply relying on the cited method to provide this information is usually insufficient. In any case, QC procedures must frequently be modified on a project-specific basis in order to meet data specifications.

QC procedures must be compatible with the data specifications discussed above. This means, if a measurement must be precise within ± 20 percent, the stability of calibration checks must be somewhat better than ± 20 percent. For some research-oriented projects, the analytical technique may not be available until well into the project. In such instances, detailed QC requirements may not need to be specified in the initial QAPP. More appropriately, the initial document might specify general requirements for precision, bias, and detection limits, and the means of achieving these goals would be developed by the principal investigator during the course of the project.

List the required QC checks, such as matrix spikes, duplicates, blanks, laboratory control samples, surrogates, or second column confirmation. State the frequency of analysis for each type of QC check, and the spike compounds and levels. State or reference the required control limits for each QC check and corrective action required when control limits are exceeded.

Describe the procedures to be used to calculate each of the QC statistics, including the QC checks described in the preceding paragraph as well as precision

and bias. Copies of the formulas are acceptable as long as the accompanying narrative or explanation specifies clearly how the calculations will address difficult situations such as missing data values and "less than" or "greater than" values.

Now that the DQOs are completed we can revise Section XII.

TASK 1. GROUP ASSIGNMENT: Revise Section XII:

Original Section XIII:

XIII Instrument/Equipment Testing, Inspecting, and Maintenance Requirements

All field and analytical instruments and equipment will be inspected and tested daily, prior to operation. Any instruments and equipment not passing the daily inspection and test will not be used unless there are no alternates available. Operation and preventative maintenance for field equipment can be found in the manufacturer's instructions of each piece of equipment. Laboratory preventative maintenance procedures are provided in the laboratory QA Project Plan.

Comments: Section XIII/Element B6: No equipment can be used that is not operating correctly, regardless of availability of replacement equipment. Precision checks must be at least as precise as precision requirements for data. If Statistical Process Control Charts are maintained and evaluated this must be defined here.

Requirements: **B6** **Instrument/Equipment Testing, Inspection, and Maintenance Requirements**

Discuss how inspections and acceptance testing, including the use of QC standards and reference materials, of environmental sampling and measurement systems and their components must be performed and documented to assure their intended use as specified by the design. Identify and discuss how final acceptance shall be performed by independent personnel (e.g., personnel other than those performing the work). Discuss how deficiencies are to be resolved when acceptance criteria are not met, and how and when re-inspection will be performed as necessary.

Discuss how periodic preventive and corrective maintenance of measurement or test equipment shall be performed to ensure availability and satisfactory performance of the systems. Identify the equipment and/or systems requiring periodic maintenance. Discuss how the availability of critical spare parts, identified in the operating guidance and/or design specifications of the systems, will be assured and maintained.

Now that the DQOs are completed we can revise Section XIII.

TASK 1. GROUP ASSIGNMENT: Revise Section XIII:

XIII Instrument/Equipment Testing, Inspecting, and Maintenance Requirements

Original Section XIV:

XIV Instrument Calibration and Frequency

All thermometers are precalibrated by the National Institute of Science and Technology. The organic vapor analyzer will be calibrated according to the manufacturer's instructions prior to each sampling event.

Laboratory calibration procedures are defined in the laboratory QA Project Plan.

Comments: Section XIV/Element B7: Laboratory calibration procedures are defined in the laboratory QAPP. What laboratory? QAPP from the laboratory should be provided.

Requirements: **B7** **Instrument Calibration and Frequency**

> Identify all tools, gauges, instruments, and other sampling, measuring, and test equipment used for data collection activities affecting quality that must be controlled and, at specified periods, calibrated to maintain bias within specified limits. Discuss how calibration shall be conducted using certified equipment and/or standards with known valid relationships to nationally recognized performance standards. If no such nationally recognized standards exist, document the basis for the calibration. Identify the certified equipment and/or standards used for calibration. Indicate how documentation of calibration shall be maintained and be traceable to the instrument.

Now that the DQOs are completed we can revise Section XIV.

TASK 1. GROUP ASSIGNMENT: Revise Section XIV:

XIV Instrument Calibration and Frequency

TASK 1. **GROUP ASSIGNMENT:** **Revise Section XIV:**

XIV Instrument Calibration and Frequency (Continued)

Original Section XV:

XV Inspection/Acceptance Requirements for Supplies and Consumables

All supplies and consumables, upon receipt, will be verified with shipping/receiving documents, and purchase order to verify quantity ordered equals quantity received. Incorrect quantity shipments will be reported to purchasing agent for resolution with the supplier. Incorrect items will be evaluated by receiving clerk for suitability of use.

Comments: Section XV/Element B8: Section is too vague and non-specific. No inspection criteria for specific items, no list of what the items will be. In this instance quantity ordered equals quantity received is the sole inspection criteria for all items. Receiving clerk making evaluation of suitability of non-conforming items is not acceptable.

Requirements: **B8** **Inspection/Acceptance Requirements for Supplies and Consumables**

Discuss how and by whom supplies and consumables shall be inspected and accepted for use in the project. Supplies and consumables are those items necessary to support the sampling and analytical operation. They include, but are not limited to: sample bottles, calibration gases, reagents, hoses, materials for decontamination of sampling equipment, deionized water, and potable water. Identify acceptance criteria for such supplies and consumables in order to satisfy the technical and quality objectives of the project or task.

Now that the DQOs are completed we can revise Section XV.

TASK 1. GROUP ASSIGNMENT: Revise Section XV:

XV Inspection/Acceptance Requirements for Supplies and Consumables

XV Inspection/Acceptance Requirements for Supplies and Consumables (Continued)

Original Section XVI:

XVI Data Acquisition Requirements (Non-direct Measurements)

Existing data from the limited study performed for Total Suspended Solids (TSS), by the AAA-Ace Environmental Sampling and Analytical Laboratory, funded by the Cedar Bay Homebuilders Association has been evaluated and results are not considered valid due to Laboratory not being able to show traceability of results to sampling events or locations. If reconstruction of samplers logs is accomplished that provides traceability of sample location to analytical results, those individual data are considered acceptable for use as background material.

Comments: Section XVI/Element B9: Acceptable section.

Requirements: **B9** **Data Acquisition Requirements (Non-direct Measurements)**

Identify the type of data acquired from non-measurement sources such as computer data bases, spreadsheets, and programs, and literature files. Define acceptance criteria for the use of the data in this project. Discuss any limitations on the use of the data based on uncertainty in the quality of the data and discuss the nature of that uncertainty.

Now that the DQOs are completed we may need to revise Section XVI.

TASK 1. GROUP ASSIGNMENT: Revise Section XVI:

XVI Data Acquisition Requirements (Non-direct Measurements)

Original Section XVII:

XVII Data Management

The data management system used by the laboratory performing the analytical work shall be described in the laboratory QA Project Plan.

Comments: Section XVII/Element B10: Laboratory data management procedures are defined in the laboratory QAPP. What laboratory? QAPP from the laboratory should be provided. No mention of data management by project staff, regardless of source, no mention of procedures for data generated by project personnel.

Requirements: **B10** **Data Management**

Outline the project data management scheme, tracing the path of the data, beginning from receipt from the field or laboratory, to the use or storage of the final reported form. Describe the standard record-keeping procedures, document control system, and the approach used for data storage and retrieval on electronic media. Discuss the control mechanism for detecting and correcting paperwork errors and for preventing loss of data during data reduction (i.e., calculations), data reporting, and data entry to forms, reports, and databases. Provide examples of any forms or checklists to be used.

Identify and describe all data handling equipment and procedures that will be used to process, compile, and analyze the data. This includes procedures for addressing data generated as part of this project as well as data from other sources. The specifications should include any required computer hardware and software and should address any specific performance requirements for the hardware/software configuration used. Describe the procedures that will be followed to demonstrate acceptability of the hardware/software configuration required.

Now that the DQOs are completed we can revise Section XVII.

TASK 1. GROUP ASSIGNMENT: Revise Section XVII:

XVII Data Management

TASK 1. GROUP ASSIGNMENT: Revise Section XVII:

XVII Data Management

Original Section XVIII:

XVIII Assessments and Response Actions

Performance and systems audits will occur in the field and the laboratory. Field audits will consist of the staff overseeing all sampling procedures. Laboratory audits will include double blind performance evaluation samples to assess the efficiency of laboratory staff. The results will be given to Rebecca Quince for review.

Comments: Section XVIII/Element C1: Section is to vague and non-specific to be of value. Revise section thoroughly, addressing all criteria required for this section.

Requirements: **C1** **Assessments and Response Actions**

Identify the number, frequency, and type of assessment activities needed for this project. Assessments include, but are not limited to, the following:

- surveillance,
- peer review,
- management systems review,
- readiness review,
- technical systems audit,
- performance evaluation,
- audit of data quality, and
- data quality assessment.

Discuss the information expected from the assessment and success criteria (i.e., goals, performance objectives, acceptance criteria specifications, etc.) for each assessment proposed. For each proposed assessment, list the approximate schedule of activities, and discuss the information expected from the assessment and the criteria for success. For any planned self-assessments (utilizing personnel from within the project groups), identify the participants and their exact relationship within the project organization. For independent assessments, identify the organization and person(s) that will perform the assessments. Discuss how and to whom the results of the assessments will be reported. Define the authorities of the assessors. For example, if the assessors should order a work suspension upon finding a significant condition, this section delineates clearly their authority to do so. Define explicitly the unsatisfactory conditions under which the assessors are authorized to act. Recognizing that assessments may be needed at any time during the project, provide a schedule for the assessments to be performed.

Discuss how response actions to non-conforming conditions will be addressed and by whom. Identify who is responsible for implementing the response action. Describe how response actions will be verified, validated, and documented.

Now that the DQOs are completed we may need to revise Section XVIII.

TASK 1. GROUP ASSIGNMENT: Revise Section XVIII:

XVIII Assessments and Response Actions

Original Section XIX:

XIX Reports to Management

Interim QA reports will be issued bi-weekly during the course of the study. A final report will be issued at the termination of the project, and is the responsibility of the Project Director.

Comments: Section XIX/Element C2: No criteria is cited for what must be addressed in either the bi-weekly reports or the final report. Responsibility for preparation of the bi-weekly reports is not assigned. Distribution is not stated for bi-weekly or final reports.

Requirements: **C2** **Reports to Management**

Identify the frequency, content, and distribution of reports issued to inform management of the following:

- status of the project;
- results of performance evaluations and system audits;
- results of periodic data quality assessments; and
- significant quality assurance problems and recommended solutions.

Identify the responsible organization(s) that will prepare the reports, and the recipients of the reports. Identify any other status reports to management as well as their content and frequency.

Now that the DQOs are completed we may need to revise Section XIX.

TASK 1. GROUP ASSIGNMENT: Revise Section XIX:

XIX Reports to Management

Original Section XX:

XX Data Review, Validation, and Verification Requirements

All data reduction procedures will follow the method specifications for performing calculations, found in Bloch et al (1986). All data will be reviewed 100%. Data validation processes will include verification that all QA criteria have been met. Data reporting procedures will ensure that all data outlined have been evaluated to determine if data quality is adequate.

Comments: Section XX/Element D1: Section is to vague and non-specific to be of value. Revise section thoroughly, addressing all criteria required for this section.

Requirements: **D1** **Data Review, Validation, and Verification Requirements**

State the criteria used to review and validate - that is, accept, reject, or qualify - data, in an objective and consistent manner. Provide examples of any forms or checklists to be used.

Project-specific calculations or algorithms should be discussed. Some projects may require special calculation during or after data generation:

Example: Indoor Air Pollution. Consider a project that is meant to estimate the number of residences within the greater Washington, D. C., area exhibiting NO_2 concentrations greater than 100 $\mu g/m^3$ at a frequency of 30 of more days per year. Once NO_2 measurements are available, one would attempt to extrapolate the limited information to the greater metropolitan area. The QAPP should explain the statistical techniques that will be employed, including how uncertainties will be assessed.

For other projects, one may only need to calculate a mass balance of a destruction/removal efficiency. While these are much simpler requirements, the specific formulas and data inputs should be listed. This approach helps assure that at least the minimum necessary data are collected for the intended interpretation (even if additional interpretation schemes are eventually employed).

Now that the DQOs are completed we may need to revise Section XX.

TASK 1. GROUP ASSIGNMENT: Revise Section XX:

XX Data Review, Validation, and Verification Requirements

XX Data Review, Validation, and Verification Requirements (Cont.)

Comments: Element D2: Not Addressed.

Requirements: **D2** **Validation and Verification Methods**

Describe the process to be used for validating and verifying data, including the chain of custody for data throughout the life cycle of the project or task. Discuss how issues shall be resolved and the authorities for resolving such issues. Describe how the results are conveyed to data users. The review of data can include checks of the following: transmittal errors, field and laboratory QC data, detection limits, instrument calibration, special sampling or analysis conditions, performance evaluations, technical systems audits, contract compliance issues (e.g., holding times), and statistical data treatments, such as tests for identification of potential outliers.

TASK 1. GROUP ASSIGNMENT: Write Section XXI:

XXI Validation and Verification Methods

Comments: Element D3: Not Addressed.

Requirements: **D3** **Reconciliation with Data Quality Objectives**

Describe how the results obtained from the project or task will be reconciled with the results of the DQO Process. Describe how issues will be resolved. Discuss how limitations on the use of the data will be reported to decision makers. Identify the procedures used to assess precision, bias, and completeness for the project data.

A methodology has been developed to assist users in reconciling data results with the DQOs. The Data Quality Assessment (DQA) Process© is used to assess the scientific and statistical quality of data collected for a specific purpose. In the DQA Process, the data will be analyzed scientifically to inspect for technical anomalies and to judge that the context of the data is correct. At the same time, the data will be evaluated statistically to confirm that the statistical model was correct by selecting a statistical test and validating the test by verifying assumptions, such as for distribution and independence. The outcome of the DQA process will indicate whether a decision can be made using the existing data or additional data must be collected.

TASK 1. GROUP ASSIGNMENT: **Write Section XXII:**

XXII Reconciliation with Data Quality Objectives

REFERENCES

Bloch, S. Conducting Field Research in Agricultural Hydrology Agricultural Handbook No. 95. Washington, D.C.: U.S. Department of Agriculture, 1986.

NOTES

APPENDIX A

TERMS AND DEFINITIONS FROM BOTH R-2 AND R-5

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.

calibration - comparison of a measurement standard, instrument, or item with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustments. (R-5 Only)

chain-of-custody - an unbroken trail of accountability that ensures the physical security of samples, data, and records.. (R-5 Only)

contractor - any organization or individual that contracts to furnish services or items or perform work; a supplier in a contractual situation.. (R-5 Only)

data quality assessment - 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.

data usability - the process of ensuring or determining whether the quality of the data produced meets the intended use of the data.. (R-5 Only)

design - specifications, drawings, design criteria, and performance requirements. Also the result of deliberate planning, analysis, mathematical manipulations, and design processes.

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

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 compiled from other sources such as data bases or the literature.

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

environmental processes - manufactured or natural processes that produce discharges to or that impact the ambient environment.. (R-5 Only)

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.

financial assistance - the process by which funds are provided by one organization (usually government) to another organization for the purpose of performing work or furnishing services or items. Financial assistance mechanisms include grants, cooperative agreements, performance partnership agreements, and government interagency agreements.. (R-5 Only)

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

information resources management - the planning, budgeting, organizing, directing, training and controls associated with information. The term encompasses both information itself and related resources such as personnel, equipment, funds and technology.. (R-5 Only)

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

management - those individuals directly responsible and accountable for planning, implementing, and assessing work.. (R-2 Only)

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 - the qualitative assessment of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained.. (R-2 Only)

method - a body of procedures and techniques for performing an activity (e.g., sampling, modeling, chemical analysis, quantification) systematically presented in the order in which they are to be executed.. (R-5 Only)

objective evidence - any documented statement of fact, other information or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests which can be verified... (R-2 Only)

organization - a company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration.. (R-2 Only)

participant - when used in the context of environmental programs, an organization, group, or individual that takes part in the planning and design process and provides special knowledge or skills to enable the planning and design process to meet its objective.. (R-5 Only)

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 assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them.. (R-5 Only)

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.. (R-2 Only)

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, assessment, 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 manager - the individual designated as the principal manager within the organization having management oversight and responsibilities for planning, documenting, coordinating, and assessing the effectiveness of the quality system for the organization.. (R-5 Only)

quality assurance project plan - 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.. (R-2 Only)

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 assessment) pertaining to the quality system.

quality management plan - 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.

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

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.

self-assessment - assessments of work conducted by individuals, groups, or organizations directly responsible for overseeing and/or performing the work.. (R-2 Only)

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.. (R-5 Only)

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

surveillance (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.. (R-2 Only)

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

validation - confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled. In design and development, validation concerns the process of examining a product or result to determine conformance to user needs.. (R-5 Only)

verification - confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. In design and development, verification concerns the process of examining a result of a given activity to determine conformance to the stated requirements for that activity.. (R-5 Only)

IMPORTANT INFORMATION

U.S. EPA Region 6 Quality Assurance Staff:

Regional Quality Assurance Manager, 6MD:

Don Johnson - (214) 665-8343, Fax (214) 665-7082, email: johnson.donald@epa.gov

Programmatic Divisional QA Officers:

Charles Ritchey, 6PD, (214) 665-8350, email: ritchey.charles@epa.gov

Dr. Randall Romig, 6WQ-D, (214) 665-8346, email: romig.randall@epa.gov

Walt Helmick, 6SF-D, (214) 665-8373, email: helmick.walt@epa.gov

Gerald Carney, 6EN-XP, (214) 665-6523, email: carney.gerald@epa.gov

Mailing Address:

Name (6__-_)
U.S. EPA Region 6
1445 Ross Avenue
Dallas, Texas 75202-2733

Call for any assistance we can give you on QA matters, such as finding out about the status of your QA Plans, advice on writing your QA Plans, or attending one of our QA Courses.

NOTES