QUALITY MANAGEMENT PLAN

QMP

for

WED

Western Ecology Division (WED)
National Health and Environmental Effects Research Laboratory (NHEERL)
United States Environmental Protection Agency (EPA)
Corvallis, OR 97333

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Quality Management Plan

Western Ecology Division (WED)
National Health and Environmental Effects Research Laboratory (NHEERL)
United States Environmental Protection Agency
Corvallis, OR 97333

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FOREWORD

The Environmental Protection Agency deals with some of the most important yet divisive issues confronting the U.S. Government. As a highly visible regulatory agency it is absolutely essential that EPA's environmental regulations and policies are based on concepts and data that are accurate, reliable, and representative of the true situation. To help assure that research quality meets agency needs, the National Health and Environmental Effects Research Laboratory, Western Ecology Division (WED) operates a comprehensive Quality Assurance and Quality Control Program. The Quality Assurance Manager is responsible to assure that the quality of all research conducted by or for this division is commensurate with its intended use.

This program has three key components: The first is *planning*. It is the responsibility of the research managers (Branch Chiefs, Program Leader and Project Leaders) to develop and implement comprehensive plans for all research conducted or funded within their area of responsibility. All Research Plans are subjected to scientific peer review, and Quality Assurance Plans are reviewed for specific measures of quality by the WED Quality Assurance Manager.

The second is *implementation*. The functional responsibility for implementing the approved plans, assuring the quality of data, and reporting the results is assigned to a Project Leader.

The third is *independent review* provided by the Quality Assurance Manager (QAM). The QAM's role is very different from that of the Branch Chiefs. The QAM is responsible for certifying that all research is conducted according to the procedures described in an approved Quality Assurance Project Plan. Because independence, both real and perceived, is fundamental to Quality Assurance, the QAM reports to the Associate Division Director for Science.

The division's QA program is a prime element in assuring that the quality of WED research is commensurate with Agency needs. Please join me in providing your complete support for the division's quality assurance program.

Anne Fairbrother, Ph.D., D.V.M. Anne Fairbrother 9/6/06
Associate Director for Science, WED *Date*

NOTE:
This document can be viewed on-line or downloaded from WED's intranet website.
The blue highlighted areas are hyperlinks to the document indicated. For those reading this from paper, a list of all web links is included at the end.

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INTRODUCTION

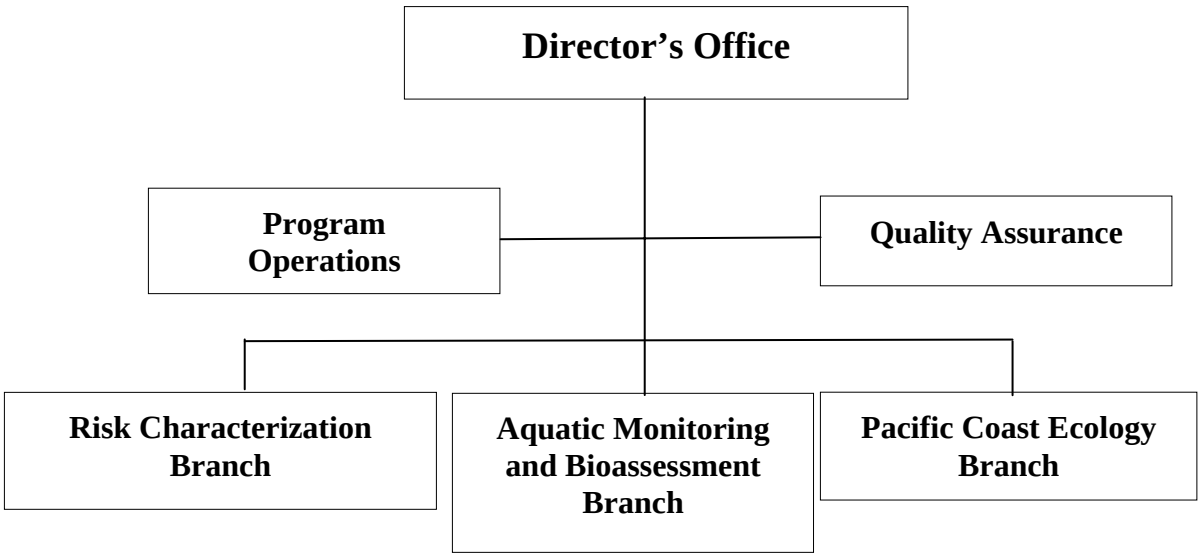
The U.S. Environmental Protection Agency (EPA) requires that all data collected or used by or for the Agency comply with a series of steps to assure the quality of the research. The basic policy is contained in EPA ORDER 5360.1 A2 May 5, 2000 *POLICY AND PROGRAM REQUIREMENTS FOR THE MANDATORY AGENCY-WIDE QUALITY SYSTEM* that follows the standards described in the ANSI/ASQC E4-1994: *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*. The EPA Quality Manual for Environmental Programs provides program requirements for implementing the order.

This Quality Management Plan (QMP) provides guidance to all persons associated with or funded by WED. It defines Quality Assurance Program goals, methods for attaining those goals, and explains basic and general responsibilities.

1. ORGANIZATION and MANAGEMENT

1.1 Organization

Western Ecology Division, NHEERL



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1.2 Responsibilities for Quality Assurance

Division Director has ultimate responsibility for all research conducted, funded, or managed within the division. He/she approves the division QMP, Research Plans and the Quality Assurance Annual Report and Work Plan.

Associate Director for Science oversees the division-wide quality assurance program to assure that all research supported or conducted by the division meets Agency quality assurance requirements.

Performance Agreements for senior managers and applicable staff contain critical elements commensurate with the QA responsibilities assigned them in this QMP and EPA Order 5360.1 A 2.

Branch Chiefs are responsible for the quality of research conducted, funded, or managed within their branches**.** They annually review and report to management the consistency of their projects with the Research Plans. They also approve Quality Assurance Project Plans (QAPPs) and manuscripts. They may delegate approval authority for approving Standard Operating Procedures (SOPs) to the program or project leaders.

Project Leaders (PLs) manage and monitor all the work, including QA, within the project. They approve QAPPs, and all SOPs that pertain to their projects. Any of the following items can be delegated to PIs or others for implementation, but the PL remains responsible for their establishment and execution.

Key QA/QC responsibilities of Project Leaders:

- Establish data quality objectives, specifications, and acceptance criteria for the project.
- Establish procedures to periodically verify and document the acceptability of data generated by EPA and/or contract support staff. These procedures would include review of project notebooks and prompt verification of contractor data reports and deliverables.
- Prepare (in consultation with the QAM and PO) a QA Review Form for solicitation packages for contracts, COOPs and IAGs in support of their project.
- Ensure that an approved QAPP exists prior to start up of any research activity.
- Annually review and document implementation of their project's QAPP.
- Identify the need for, and initiate, appropriate corrective actions.
- Interact with the PIs regarding QA/QC.
- Verify that adequate supportive QA/QC documentation is available for each research product and that EPA reports contain identifiable QA/QC and data usability sections.
- Ensure that all outputs comply with the technical output clearance process.

Institution Project Manager is the person at an extramural institution who is assigned to manage the project that is being done for or in cooperation with WED.

Principal Investigator (**PI**) is the person charged with conducting or leading a research project or a part of a project (task). Depending on the project there may be one or several principal investigators and they may be either EPA employees or cooperators in extramural institutions. The PI is the person who generally conceives experiments, analyzes data, and writes research reports, and thus generally appears as the primary author. A PI may or may not be one of the following:

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the Project Leader, Institution Project Manager, Program Leader, Branch Chief, etc. Duties of the PI are negotiated with the PL and are detailed in the QAPP.

Scientific Support Staff (intramural or extramural) are responsible for conducting technical tasks and for ensuring the quality of the results generated.

Key QA/QC responsibilities designated by the PI:

- Participate in preparing the QAPP.
- Document QC output(s).
- Follow established procedures, such as SOPs, and document any deviations.
- Perform and document preventive maintenance, as necessary.
- Maintain up-to-date laboratory notebooks and/or other appropriate record-keeping systems.
- Report to the PI all QA problems encountered and corrective actions taken.

Quality Assurance Manager is a member of the Office of the Division Director. This administrative arrangement avoids potential conflicts with operational programs and provides **independent review** of QA matters. WED's QAM is also the Records Liaison Officer (RLO).

The QAM/RLO is responsible for ensuring that all QA and records related activities are in compliance with agency policy and guidance. He reports to the Associate Division Director for Science.

Key responsibilities of the QAM/RLO:

- Certify that QAPPs and SOPs meet QA agency standards.
- Review funding actions for extramural projects and certify compliance with quality policy.
- Review all scientific outputs for compliance with Agency/WED research quality policies.
- Prepare the QMP.
- Review the QMP annually, and propose revisions as appropriate.
- Prepare an annual status report describing activities that demonstrate compliance with policies for all research conducted or funded by the division. This is the Quality Assurance Annual Report and Work Plan that is submitted to the NHEERL Director of Quality Assurance.
- Track the QA/QC status of WED projects.
- Conduct assessments of QA procedures in WED projects.
- Participate on WED's Science Council as a standing member.
- Provide records management training for WED managers and staff.
- Verify appropriate scheduling of records submitted for onsite archiving.

Delegation of Authority: In the absence of the QAM, a senior member of the IO or the Associate Division Director for Science may sign in the QAM's stead.

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2. QUALITY SYSTEM and DESCRIPTION

2.1 Quality Management Plan

The QMP sets forth the basis for the division's quality assurance program. It identifies roles and responsibilities of managers and scientists regarding research quality.

The first page carries the signatures of those who have approved and committed to follow the procedures that have been outlined. It provides the basis for assessing the effectiveness of the WED Quality Assurance Program. It provides the benchmark for periodic quality systems assessments (QSA) conducted by NHEERL and EPA Quality Staff, and Laboratory Competency audits These reviews are to assist WED in complying with current EPA policy and procedures and assure the NHEERL director that WED is in compliance with those policies. The QMP will be reviewed annually by the QAM, and if needed, minor changes (approved by the Division Director and Branch Chiefs) will be made by amendment. The QMP is re-approved by the NHEERL Director of Quality Assurance (DQA) every five years or sooner, if major revisions are needed.

2.2 Systematic Planning

WED's Science Council provides the forum for discussion and development of solutions for matters relating to planning and implementing the division's research program. This council provides the leadership for WED's scientific endeavors. Potential research projects are developed and evaluated through interactions with the Science Council. Research Plans are developed and peer reviewed for those that address high priority issues identified through the EPA and ORD planning process and that can be completed with available resources. The steps outlined in WED's Research Plans are similar to those in the Data Quality Objective process that identifies the clients and their needs, clarifies study objectives, selects appropriate hypotheses, defines the appropriate type of data, and specifies tolerable levels of potential errors.

2.3 Graded Approach

Since different research projects are associated with different levels of public awareness and have different immediate applications, a graded approach to project oversight is needed. Each project will be assigned a category according to the criteria in Appendix D of the NHEERL QMP:

> **Category 1:** Research that directly and/or immediately supports specific Agency rule-making, enforcement, regulatory, or policy decisions. This category may also include research of significant national interest, such as tasks that might be monitored by the Administrator. It may also include research conducted under a Cooperative Research and Development Agreement, more commonly known by the acronym CRADA, or other technology transfer project for which the data and/or the research conduct by which the data were obtained may be critical to the award of a patent or other important commercial or legal decision. Category I research tasks require the most detailed and rigorous QA and QC activities to ensure both legal and scientific defensibility.
>
> **Category 2:** Research of high programmatic relevance that, in conjunction with other ongoing or planned studies, is expected to provide complementary support of Agency rule-making, regulatory, or policy decisions.
>
> **Category 3:** Demonstration or proof of concept projects; method validation studies.

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> **Category 4:** Basic, exploratory, conceptual research to study basic phenomena or issues. Includes the characterization of health or ecological mechanisms and/or endpoints in order to improve the understanding of the interaction of environmental compounds, conditions, or processes with human and other life forms; and also includes development of assays or methods for detecting or estimating the influence of a particular environmental agent on a specified health or ecological endpoint.

The selection and justification of a research category is done in the Research Plan for each project. All supporting extramural agreements that are identified in project Research Plans assume the category of the project. The choice of category has implications for review and approval of project products, as well as, the retention of project records. At WED, categories 1-2, would be scheduled as 501 or 507 (permanent retention), while categories 3-4 would be scheduled as 503 with a 20 year retention. Through periodic review of project progress, exploratory projects could be categorically elevated if preliminary results show unexpected relevancy to the Agency or the public.

2.4 Quality Assurance Project Plan (QAPP)

All research is performed in compliance with an **approved QAPP** (see EPA order 5360.1 A2 section 5.b.). The types of research subject to this requirement include

1. Characterization of environmental or ecological systems and the health of human populations;
2. Direct measurement of environmental conditions or releases, including sample collection, analysis, evaluation, and reporting of environmental data;
3. Development or evaluation of methods for use in the collection, analysis, and use of environmental data;
4. Use of environmental data collected for other purposes or from other sources (also termed "secondary data"), including literature, industry surveys, compilations from computerized data bases and information systems, results from computerized or mathematical models of environmental processes and conditions;
5. Mapping of environmental processes and conditions.

Any document that is supplemental (principally, SOPs) to the QAPP and that defines or prescribes procedures that contribute to the quality of data, is considered an integral part of the QAPP and therefore also requires approval.

Since the implementation of the quality system is a management responsibility, the appropriate research manager approves QA planning documents. QAPPs are approved by branch chiefs and SOPs may be approved by any manager designated by the branch chief. The QAM certifies that the plans presented in the QAPP or SOP meet Agency standards.

Many good and useful ideas regarding research are not envisioned prior to experimentation and are therefore not included initially in QAPPs or SOPs. When such creative ideas are conceived, authority to implement them is given by the Project Leader and if the new activity alters the QA procedures, a written note will be forwarded to the QAM. This note will constitute an amendment to the applicable QAPP or SOP and will be reviewed and then added to the appropriate document.

Exceptions from having a QAPP may be authorized by the Branch Chief with the concurrence of the QAM for preliminary work. Exceptions are authorized for a designated time (normally less than 6 months) and are typically authorized to evaluate a procedure or concept prior to writing a QAPP. Request for exemption is submitted in a memo from the Project Leader, thru the Branch Chief, to the QAM. It contains an explanation of the intended work, reasons for wanting an exemption, requested period, and appropriate signatures. If needed, in a timely manner the QAM will remind the PL of an impending, exception expiration.

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Conditional approval may be granted for research to begin on a limited basis while non-critical deficiencies in the QAPP are being resolved.

Projects involving measurement of environmental parameters are organized according to Agency policy. The requirements are contained in EPA Requirements for QA Project Plans (QA/R-5) and guidance for writing in Guidance on Quality Assurance Project Plans (G-5). Abbreviated guidance and some examples are contained in Appendix 3 of this QMP for writing QAPPs at WED. Format is less important than the utility of a QAPP. If the suggested format compromises the usefulness, each author can feel constrained by the latter as long as all elements needed to specify quality are included.

Projects not involving measurement of environmental parameters follow the same general format with modifications specific to the type of activity. These, generally, modeling projects may be the basis for important decisions and, although they do not generate new data, attention to the origin and quality of data used in environmental evaluation is vital. The QAPP directs the attention of scientists towards explaining the limits or constraints of assumptions and the inherent error associated with data transformations. Some models allow error propagation while others may suggest sensitivity analysis as a method of evaluating error. There is included a discussion of whether the results are expected to be quantitative, comparative, or heuristic. QAPP guidelines for model development can be found in Guidance for Quality Assurance Project Plans for Modeling (EPA QA/G-5M) and an outline of modeling project QAPP components are found in Appendix 4.

2.5 Standard Operating Procedures

These documents may be prepared at any time for any routine activity. Branch management approval (may be delegated by the branch chief to the project leader) and QAM certification is required for all procedures that define activities that contribute to the quality of data. When approved, the SOP can be referenced by any QAPP and thus functionally becomes a part of that plan. Active SOPs are certified as being implemented as written through the use of the Biennial SOP Review Form by PLs/PIs/WACORs at the beginning of new projects or work assignments. This form is also used for the biennial review of SOPs used in ongoing projects.

The format for organizing a SOP includes the 12 section topics found in Appendix 5. SOPs are written in sufficient detail to be used as a method by the persons performing the procedure.

2.5.1 ORD-wide QA/QC Policies and Procedures

As these policies and procedures are developed, WED will adopt them to ensure consistency across ORD in the implementation of best practices to facilitate cross-organization cooperation. These may address topics such as standardized procedures for the use of notebooks, qualification of secondary data, minimum standards for measurement laboratory operations, or others.

2.6 Assessments

Technical systems assessments (TSAs) are the principle assessment tool used at WED. TSAs document the degree to which the procedures and processes specified in an approved QAPP are being followed. Quality systems assessments (QSAs) are performed by the Quality Staff of the Office of Environmental Information (OEI) to document the adherence of WED personnel to this Quality Management Plan. QSAs and that prescribed by the Agency Policy Directive, *Assuring the*

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Competency of EPA Laboratories are done triennially by individuals not associated with NHEERL or WED. These and other assessments are more fully addressed in Section 9, Assessment and Response.

2.7 Quality Assurance Annual Report and Work Plan (QAARWP)

This report to WED management from the QAM in October is about QA activities for the current fiscal year, setting goals for the following year and recommending revisions to the QMP that reflect current practices. This management approved Division QAARWP is forwarded to the NHEERL DQA for incorporation in the NHEERL QAARWP which is approved by the NHEERL Deputy Director for Management before submission to the Office of Environmental Information.

2.8 Review of Products

All products resulting from research at WED receive peer reviews following the Agency's Standard Operations Procedures for Technical Information Management and ORD Clearance Procedures (and Form). In addition to the responsibility to review EPA reports, the WED QAM, because of his scientific background, provides a technical review of all other products. Most manuscripts result from research described in an approved QAPP. The relationship of the subject matter to the appropriate QAPP is specified on the ORD Clearance form. If the manuscript is unrelated to a QAPP or is disassociated from data (i.e., position paper, editorial, etc.), an explanation is provided on the Clearance form. Completed clearance forms accompany manuscripts when submitted to the QAM for review.

Each WED Agency report (i.e., non-journal article) containing environmental data contain a readily-identifiable section that discusses data quality and any limitations on the use of the data with respect to the original intent. The purpose of this section is to minimize the possible misuse of data for other purposes. This requirement follows from section 2.5.1 of the EPA Quality Manual for Environmental Programs.

2.9 Requirements for Extramural Research

Contracts, cooperative agreements (COOPs) and interagency agreements (IAGs) are exercised by WED to directly support or complement its research goals. As with intramural research, COOPs and IAGs can only commence sampling or working with environmental data with approved QAPPs in place. Requirements for the documentation of extramural quality systems can be found in the Higher-level Contract Quality Requirements section of the Contracts Management Manual (Chapter 46) and various Federal Acquisition Regulations. Specific quality system requirements are identified in the Quality Assurance Review Form that is filled out by each project officer (PO), work assignment contracting officer representative (WACOR), or Task Order Project Officer (TOPO) during the solicitation phase of these procurements. This form is completed in consultation with the QAM. POs, WACORs and TOPOs receive training specific to their QA responsibilities in managing these extramural activities. Since one Federal agency can not impose its requirements on another, the QA/QC controls for IAGs are negotiated among the QA staff and PIs and POs of the agencies.

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3. PERSONNEL QUALIFICATIONS and TRAINING

Branch Chiefs are responsible for assuring that each employee has the necessary qualifications and job proficiency for assigned work. This typically includes formal education in a scientific discipline, on-the-job experience and off-site training by instrument vendors.

To assure that all division scientific management and staff have a uniform knowledge of QA policies and procedures all newly hired scientists will attend a presentation covering QA orientation, recordkeeping, planning documents, operating procedures, and audits. Every 3 years all scientific staff will attend a QA refresher session.

In addition to the training required to administer extramural projects, POs, WACORs and TOPOS will be trained in the QA requirements of these contracting roles and the use of the Quality Assurance Review form (QARF) WED-26. This form is used for contract, cooperative agreements and interagency agreement solicitations, as well as contract amendments and incremental funding actions.

The QAM at WED is required to be an experienced scientist who is trained in subjects relating to environmental science. All scientists and technical support staff are expected to be familiar with WED and Agency QA policies in facilitating the research effort. Training at the project and division levels is vigorously pursued as time and funds are available.

4. PROCUREMENT of ITEMS and SERVICES

4.1 Cooperative Agreements, Interagency Agreements, Contracts

Since **all** research is performed in compliance with an approved QAPP, prospective applicants for WED assistance are sent a copy of the WED QMP so they understand the extent of planning expected. A special condition of any funding vehicle for research, analysis, or sample collection includes a statement stipulating that no research can begin until a QAPP has been approved.

At the discretion of the EPA PL/PO, a QAPP may be required as part of the proposal or be required only from successful applicants. However, as a minimum, all proposals will include a QA capability statement or institutional QMP following the *Respondent Requirements* outline (page 3 of the QARF). In general, the QA capability statement is a qualitative statement of the offeror's QA/QC capabilities, whereas the QAPP provides a quantitative discussion. The Project Leaders specify the timing and level of QA documentation in the QARF that is included in solicitation and funding packages.

Following the Higher-Level contracting requirements for all solicitations (contracts and COOPs) for which greater that 15% of the expenditure is involved in the collection/use of environmental data (i.e., most all of WED's extramural activities), WED requires that QA/QC will be included among the technical evaluation criteria. These criteria are listed in the RFP. The responding organizations' QAPPs and/or QA capability statements/QMPs submitted with their proposals will be the basis for the QA part of the evaluation.

Agency guidelines recommend that at least five (5) percent, and not more than thirty (30) percent, of the total possible score be based on QA criteria. The PLs/POs specify in the QARF the percent of evaluation points applicable to QA.

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The PO, WACOR, or TOPO completes and submits a QARF with the request for funding. Each Contract, COOP or IAG funding action package is reviewed by the QAM to determine conformance with Division and Agency policy. For continuation or incremental funding of ongoing projects, the QAM evaluates evidence of compliance with an approved QAPP. The evidence includes QA and assessments reports, notes from the project leaders or project officers, manuscripts, performance evaluations, etc.

4.2 Work Assignments and Task Orders

Technical support for WED research conducted by non-Student Services, onsite contracts is directed by work assignments (WA), or task orders (TO). Although the contracting organization must have a QMP that describes their corporate commitment and policy regarding quality (EPA ORDER 5360.1 A2 May 5, 2000), authorization to conduct technical support activities is based on the approved QAPPs. A WA or TO may assign work on one or many projects. The QARF is used to identify the projects involved and includes the WACOR or TOPO's signature indicating that all QA/QC requirements are being met on all projects involved. The QAM reviews the status of project approval, required reports, manuscripts, and correction of any findings from assessments and, if complete, certifies that the projects are in compliance with QA requirements and work may begin.

5. DOCUMENTATION and RECORDS

5.1 Records Management

Records management policy is established by the Office of Environmental Information and documented in the U.S. EPA Directive 2160 — Records Management Manual. This policy applies to all records regardless of media (including paper, microform, electronic, audiovisual, and record copies of Agency publications). Following this and other EPA Directives ensures compliance with all statutory, contractual and assistance agreement requirements for records from environmental programs and provides adequate preservation of key records necessary to support the mission of WED. The designated Records Liaison Officer at WED is the QAM.

To facilitate the minimum 20-year retention of these key records, WED scientists will use uniquely numbered, case-bound notebooks with tables of contents and pre-numbered archival quality pages to document their project-specific research/laboratory activities. GSA "Green" record books will continue to be used for various instrument logbooks, as will, three-ring binders for pre-printed routine field and laboratory forms, and instrument print outs. Periodically the project leaders will review the content of project notebooks for legibility, accuracy and completeness, and will document the review in each notebook's table of contents. A list of the owners of numbered notebooks will be maintained by the QAM/RLO and will be available to PLs for cross referencing.

It is WED's policy that all research projects conducted or sponsored by WED will have adequate and proper documentation in a manner that is consistent with the project file contents specified in EPA Records Disposition Schedules 501 and 503. Project files contain documentation related to the formulation and approval of the research plan, the selection of the research methodology, questionnaires, quality assurance project plans, raw data, laboratory notebooks, project-related correspondence, copies of interim reports showing data tabulation results and interpretations, copies of

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final reports/manuscripts, peer reviews, and quality assessments. This documentation is intended to ensure the defensibility of project results and facilitate the reconstruction or reanalysis of underlying data. Complete project files from COOPs and IAGs are to be transferred to EPA at their close.

WED maintains an on-site storage area for boxes of archived records that are awaiting disposition. The content of these boxes is listed in a Lotus Notes based database, "WED Archived Records" and is submitted to the database by the record creator using form WED-24.

5.2 Document Control

QAPPs and SOPs are prepared and maintained under a document control system that uniquely identifies documents and their versions. Following NHEERL's identification convention the following sequence of codes will be incorporated into all new QAPPs and SOPs:

SOP-NHEERL/WED/RCB/PI/05-02-001 3/20/2006

where:

SOP indicates the type of document
NHEERL/WED/RCB identifies the laboratory, division and branch
PI would be the initials of the principal author, generally a PI
05 indicates the year of the origin of this SOP
02 indicates that this was the second SOP authored by this individual in 2005
001 indicates that this is the first revision (the original would be 000)
March 20, 2006 is the date of this version

Record copies of QAPPs and SOPs, along with assessment reports, progress reports, and communications regarding QA are kept by the Project Leaders. These project records are to be in a project file that contains documentation related to the formulation and approval of the Research Plan, the QAPP, raw data (or lists of full paths to electronic data files), correspondences, final reports, etc. These folders are identified by the appropriate Records Schedules that correspond to the type of research in them. For example, regulation supporting (501 , permanent retention), basic exploratory (503 , 20 years retention) and air and water criterion supporting (507 , permanent retention)

Electronic copies of WED's QA records are organized using a Microsoft ACCESS database. Copies of approved Project Plans, QAPPs and SOPs, assessment reports, manuscript reviews, and the approval of funding packages are maintained in the database. The database provides for creating and maintaining a record of receipt, assignment, decisions, and return of each of the documents received. Database features provide flagging various documents for follow-up such as the biennial review of SOPs, or reminder to PI of a promised document review. Read-only access to the database system is available to anyone on the local area network. Access is provided to current and previously used SOPs in the database through WED's intranet site.

The database and the documents that it links to are located on a network server. Both are backed-up daily to tapes that are kept off-site for 6 months. Monthly, the database and the linked documents are copied to DVD. These procedures ensure WED's QA database and documents are protected from permanent corruption and that if any computer problem occurs, only work from the preceding day may be lost.

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Copies of finalized QA documents (QAPPs, SOPs) are requested in a computer format, and signed approval pages are scanned and pasted into the electronic versions maintained through the database.

WED quality management plans are kept as PDF files in the QA database for 10 years following the approval of a more recent version (Records Schedule 185). The current version will be available from WED's intranet site.

6. COMPUTER HARDWARE and SOFTWARE

The Information Technology (IT) Coordinator is responsible for ensuring that WED's computer practices are in compliance with Federal Government security protocols as well as Agency-wide IT policies, procedures, and guidelines. This individual is the TOPO for the on-site IT contract. Contractor performance is evaluated semi-annually on its adherence to these Agency and Government procedures.

6.1 Hardware and Software

The division computing environment is comprised of over 300 Windows based personal computers as well as Linux and UNIX workstations. These computers are connected to various centralized file servers and telecommunications devices to make up the division Local Area Network (LAN) that is part of the EPA Enterprise Wide Area Network (WAN).

The Enterprise Operations Center (EOC) is responsible for ensuring strict adherence to agency standards for hardware and software. Agency security protocols are also monitored by the EOC.

The following web sites provide more detailed information regarding computer architecture, IT policy and security.

http://intranet.epa.gov/architec/index.html
http://cfint.rtpnc.epa.gov/otop/policies/directives.cfm
http://intranet.epa.gov/itsecurity/

While these policies do not address computers that operate in conjunction with scientific instrumentation, some of WED's scientific instruments are on the LAN and the data from those that are not are routinely copied and archived to optical disks.

6.2 Software Development

Software (including SAS, VisualBasic, Access, and other procedures) that is developed on-site by EPA staff and the IT contractor follow best practices in quality control, such as IEEE standards and IBM Rational Unified Process®, respectively. Implementation quality is ensured by the procedures used during code development, such as using a version control system, establishing procedures for bug tracking and resolution, verifying the lab-wide file backup procedures, and by testing the models. Geospatial databases developed at WED follow Federal Geographic Data Committee standards when applicable.

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7. PLANNING

WED develops research projects that are aligned with the results of EPA and ORD planning processes such as the multi-year plan. Two planning documents are required for all projects before the collection of data or research activity can begin. These are

A peer reviewed **Research Plan** that documents the research activities to be performed and the resources needed to implement the plan. The form of this Research Plan can vary substantially depending on the type of research being conducted. (WED policy 5300.2)

A **Quality Assurance Project Plan** that documents the processes that assure data quality. (see Appendix 3 for content and format).

Research plans and QAPPs may be developed intramurally or by extramural cooperators or contractors.

Scientific progress is regularly monitored by division management and peer review.
When data are being used to select between two alternative conditions (e.g., compliance or non-compliance with a standard), the Agency's recommended systematic planning tool is the Data Quality Objectives (DQO) Process. This system consists of the following steps and is detailed in: Guidance for the Data Quality objectives Process E PA QA/G-4

1) State the problem
2) Identify the decision
3) Identify the inputs to the decision
4) Define the boundaries of the study
5) Develop a decision rule
6) Specify tolerable limits on decision errors
7) Optimize the design for obtaining data

Most environmental research conducted at WED is associated with identifying ecological concepts and patterns and describing ecosystem relationships. Although the results of this research are critical to the development of standards, regulations, and remediation policies, they are rarely used to resolve a problem or define a level of action as may be required at a hazardous waste or Superfund site. The steps outline in the DQO process (G-4) are therefore not specifically required, however the concepts discussed and the steps suggested to identify and clarify goals and needed data quality are useful and are followed to the extent applicable. The PI decides the data quality needed to adequately test the proposed hypothesis. Consideration of available measurement technology and costs often dictate the possibilities of data quality.

8. IMPLEMENTATION of WORK PROCESSES

The Project Leader is responsible for ensuring adherence to all project planning and procedural documents including the QAPP and supporting SOPs. The QAPP includes a distribution list that identifies all who are required to have a copy and who are expected to follow the procedures. Copies of all SOPs identified in the QAPP are provided to those implementing them. The Project Leader identifies new procedures that are needed for the project and initiates the writing of new SOPs. The

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PL also initiates biennial reviews of SOPs to verify that they are currently being applied as they are written. The PL also reviews the QAPP annually to assess whether it reflects the current practices and intent. If substantial differences are uncovered through this process, revisions are submitted to the QAM for approval concomitant with an incremental change in the version number and effective date of the documents. The PL provides updated versions of these revised documents to project personnel.

Through Performance Evaluations and other assessment tools, the PL can obtain real-time feed back from project critical procedures through data and assessment reports. These reports can identify short comings that can be corrected early in the project, bringing the procedures into compliance with the expectations delineated in the QAPP.

It is the Branch Chiefs' responsibility to ensure that all personnel involved in the project are appropriately qualified, trained and supervised. It is the PLs' responsibility to ensure that all project personnel fully understand the project objectives, the technical and QA/QC requirements of their part(s) of the project, and their roles and responsibilities in the overall conduct of the project.

9. ASSESSMENT and RESPONSE

There are two principal means (Quality Assurance Assessments and the Performance Evaluations) to determine compliance with a WED approved QA program. These procedures are used to verify that measurement systems are operating properly, to determine that data quality is adequately documented, and to evaluate management of the QA program.

9.1 Project-level Quality Assurance Assessments

These QA activities consist of a thorough on-site evaluation of a research activity. Assessments can be used to evaluate the existence and adequacy of all equipment, facilities, supplies, personnel, and procedures that are either used directly for, or in support of, the collection and interpretation of data. In addition, assessments are used to evaluate the documentation associated with data quality indicators. Assessments will be planned by the QAM with assistance from the Project Leader. The QAM has the lead responsibility for carrying out assessments. Assessments are designed to complement the peer review process by assuring that any QA issues that may affect the scientific credibility of the data are brought to the investigator's attention. The QAM may delegate this responsibility to project-independent EPA staff with specialized expertise not held by the QAM.

Assessment scheduling depends on the size of the project, the project duration, and the specified quality of the data. Projects in QA Categories I and II will be assessed at least every two years and other projects every three years. A Project Leader may request an assessment based on information presented in project progress reports, results of prior assessments, performance evaluations or other situations where there is concern for the quality of data.

The following assessment tools are used at WED:

Readiness reviews are conducted before specific technical activities (e.g., sample collection, field work, and laboratory analysis) are initiated to assess whether procedures, personnel, equipment, and facilities are ready for environmental data to be collected according to the QAPP and identified SOPs.

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Surveillance is used to continuously or periodically assess the implementation of an activity or activities to determine conformance to established protocols or SOPs.

Technical systems assessments (TSAs) qualitatively document the degree to which the procedures and processes specified in the approved QAPP are being implemented.

Assessments of data quality are conducted on previously verified data to determine how well the measurement system performed with respect to the data quality indicators and acceptance criteria specified in the QAPP.

9.1.1 Performance Evaluations (PEs)

This assessment tool is used by WED Project Leaders to test the ability of a measurement system to obtain acceptable results. These are often used for specific chemical analyses and use certified reference materials, or may be interlaboratory proficiency testing studies. They may be part of a pre-award evaluation or used throughout the course of a project with results included in data reports. Implementation and assessment of Performance Evaluations are the responsibilities of the Project Leader. This assessment is based on the comparison of PE sample results with control limits established in the QAPP DQO statements to identify compliance or out-of-control conditions.

9.2 Division-wide Quality Assurance Assessments

Implementation of the WED Quality Management Plan is evaluated every 3-4 years by OEI Quality Staff and every 3 years through Laboratory Competency assessments performed by non-EPA personnel. Yearly, the NHEERL DQA assesses adherence to the QMP through review of WED's QAAWRP, Laboratory Competency and Quality Staff audit reports, and periodic QSAs.

9.3 Assessment Reports

9.3.1 Project-level

These reports are submitted by the QAM to the EPA Project Leader, through a Branch Chief. Written assessment reports will contain a summary of the areas evaluated during the assessment, statement on novel or good QA practices followed, and identification of problem areas.

When significant concerns are identified in the assessment report, the Project Leader develop an action plan to correct any significant deficiencies including a time frame in which to accomplish these actions. A copy of the plan will be forwarded to the QAM, who will monitor the corrective actions.

Performance evaluation reports by the Project Leaders summarize results with a list of conclusions and recommended corrective actions. These ongoing reports are kept by the Project Leader who follows up with the analyst to address the identified corrections. Copies of these reports are sent to the QAM.

9.3.2 Division-wide

Upon completion of these assessments, written reports are prepared and submitted to the Associate Director for Science of WED. Corrective actions and recommendations are identified and the QAM oversees their implementation.

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10. QUALITY IMPORVEMENT

Even the most thoroughly thought out and reviewed projects are not static, and the most well intentioned scientists and support staff may be implementing their parts of a project incorrectly. It is through periodic review of project plans and their QAPPs that Project Leaders are able to redirect their research activities to respond to unexpected findings and changes in priorities. Similarly, QSAs and the annual review of WED's quality system and QMP through the QAARWP provide mechanisms for identifying areas for improvement.

It is through the timely use of the various assessment tools that WED Project Leaders and Principal Investigators are able to detect procedural, implementation, and training deficiencies. Through prompt responses to the reported findings of these assessments the projects can be brought back on track.

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REFERENCES

List of web addresses appearing in QMP:

EPA ORDER 5360.1 A2 May 5, 2000 Policy and Program Requirements for the Mandatory Agency-wide Quality System http://www.epa.gov/quality1/qs-docs/5360-1.pdf

ANSI/ASQC E4-1994 ..... http://qualitypress.asq.org/perl/catalog.cgi?item=T55

EPA Quality Manual for Environmental Programs http://www.epa.gov/quality1/qs-docs/5360.pdf

ORD Policies and Procedures Manual, Chapter 13.....
http://dcordhqapps1.epa.gov:9876/orma/policies.nsf/f536fba05d681a598525702600653e9c/bbe0316b92a235b38525710f0070e73f/$FILE/13.1%20QA%20SOP.doc

EPA Guidance for the Data Quality Objectives Process E PA (QA/G4)..... http://www.epa.gov/quality1/qs-docs/g4-final.pdf

EPA Requirements for QA Project Plans (QA/R-5)..... http://www.epa.gov/quality/qs-docs/r5-final.pdf

EPA Guidance on Quality Assurance Project Plans (QA/G-5) http://www.epa.gov/quality1/qs-docs/g5-final.pdf

NHEERL Quality Management Plan (QMP)..... http://www.nheerl.epa.gov/administration/qa/files/qmp05.pdf

ORD Clearance form (EPA 362)..... http://p2626xoray001/pages/forms/Publications/ORD-362.doc

Publication Review and Clearance Procedures..... http://www.nheerl.epa.gov/administration/tim/tim_sop.pdf

Quality Assurance Review Quality form (WED-26).....
http://wedcor.cor.epa.gov/pages/forms/qa/QARF_for_NHEERL.doc

Institute of Electrical and Electronics Engineers ..... http://standards.ieee.org/software/

IBM Rational Unified Process for programming projects http://www-306.ibm.com/software/awdtools/rup/

Federal Geographic Data Committee ..... http://www.fgdc.gov/

Requirements for Extramural Research in sections of the Federal Acquisition Regulations:

(http://www.epa.gov/quality/exmural.html#fed-regs)

Universities, hospitals and other non-profit organizations..... 40 CFR Part 30
(http://www.epa.gov/quality/qa_cfrs.html#40PART30

Admin. Reqirem'ts for Grants and COOPs to State and Local Gov'ts.....40 CFR Part 31
(http://www.epa.gov/quality/qa_cfrs.html#40PART31)

State and Local Assistance.....40 CFR Part 35

(http://www.epa.gov/quality/qa_cfrs.html#40PART35)

Higher-level contract quality requirements.....FAR 48 CFR part 46.202-4
(http://acquisition.gov/far/current/html/Subpart%2046_2.html#wp1069847)

Contracts Management Manual.....Chapter 46-QA

http://epawww.epa.gov/oamintra/policy/cmm.pdf

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Appendix 1

QA POLICY

EPA Quality System Documents Requirements for EPA Organizations:
(http://www.epa.gov/quality1/qa_docs.html#EPArqts)
This web address provides a list and current status of EPA requirement and guidance documents. It also provides links to the current versions.

EPA Order 5360.1 A2 (May 5, 2000)
(http://www.epa.gov/quality1/qs-docs/5360-1.pdf)
Policy and Program Requirements for the Mandatory Agency-Wide Quality System. This is the primary instruction upon which all EPA QA programs are based.

EPA Manual 5360 A1 (May 2000)
(http://www.epa.gov/quality1/qs-docs/5360.pdf)
EPA Quality Manual for Environmental Programs defines program requirements for EPA organizations in implementing the mandatory Quality System defined in 5360.1 A2. Equivalent specifications are defined in Requirements Documents for organizations receiving financial assistance from EPA through extramural agreements.

Requirements for non-EPA Organizations: (follow this link to all requirement documents listed below)
(http://www.epa.gov/quality1/qa_docs.html#noneparqt)
Quality requirements for non-EPA organizations are defined in the Code of Federal Regulations and the Quality Staff in OEI have issued documents to provide information on satisfying the Federal Regulations. These documents contain policy statements that identify and discuss mandatory elements of the Agency's Quality System for organizations receiving financial assistance from EPA through extramural agreements (e.g., contracts, grants, cooperative agreements, and interagency agreements). These documents may be used by EPA organizations as well.

EPA Requirements for Quality Management Plans (QA/R-2)

EPA Requirements for QA Project Plans (QA/R-5

Guidance for Implementing Requirements: (follow this link to all guidance documents listed below)

(http://www.epa.gov/quality1/qa_docs.html#guidance)

The Quality Staff also issues documents to assist in the development and implementation of a suitable Quality System for both EPA and non-EPA organizations.

Guidance for the Data Quality Objectives Process (G-4)

Decision Error Feasibility Trials (DEFT) Software (G-4D)

Guidance for the Data Quality Objectives Process for Hazardous Waste Sites (G-4HW)

Guidance on Quality Assurance Project Plans (G-5)

Guidance on Sampling Designs to Support QA Project Plans (G-5S)

Geospatial Data Quality Assurance Projects (G-5g)

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Guidance on QA Project Plans for Modeling (G-5m)

Guidance for the Preparation of Standard Operating Procedures (G-6)

Guidance on Technical and Related Assessments (G-7)

Guidance for Data Quality Assessment: Practical Methods for Data Analysis (G-9)

Data Quality Assessment Statistical Toolbox - DataQUEST (G-9D)

Guidance for Developing a Quality Assurance Training Program (G-10)

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Appendix 2

GLOSSARY

The definitions listed below represent standard language to the extent it is applicable. Exceptions are for the terms accuracy, completeness and precision. Definitions found in other sources are generally identical, but suggest that a mathematical presentation for the reverse concept. In example consider the definition for precision that is typically unambiguous and described by words similar to those presented below. However, as a final sentence in the definition there is often a statement requiring that the values of precision reflect standard deviation expressed as the coefficient of variation (CV). Clearly the CV describes the imprecision, not precision. We prefer to express the words and values with similar connotations. The terms of accuracy and completeness follow similar arguments.

Accuracy - An indication of how close measured values are to the true value. One manner of expressing this is as 100% minus the % deviation (absolute value) from the true value.

$$\text{Accuracy } (\%) = (1.0 - (\sum (|V_t - V_m|)/n)/V_t) * 100$$

where:

V_t is the true or standard value
V_m is the measured value
n is the number of measured values

Other mathematical expressions are also valid and are acceptable. Use of the above absolute (based on %) scale hides the aspect of bias that may be important information. Removal of the absolute signs will yield + or - values that reveals bias as well as accuracy. If this practice is used, interpretation of values greater than 100% is understood to be less than accurate since, by definition, no value can be more than perfectly accurate (i.e. 100%).

Bias - the systematic or persistent distortion of a measurement process that causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value).

Calibration - To make adjustment (as in adjusting an instrument to present the correct response to some measurement). A calibration curve is often created by measuring different known concentrations and plotting the known values against the machine response. By applying the slope of such a curve to machine outputs, the measurements are adjusted to yield calibrated values. Note the difference between calibrating (making an adjustment) and making a measurement and comparing the value with the know quantity of the standard.

Comparability - The degree of confidence with which two or more sets of data may be compared. 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 the previous projects with which these results will be compared. All these factors are qualitative and hard to measure. Comparability of data is generally best described in a narrative statement that references the items listed above.

Completeness - During experimentation or monitoring, some samples may be impossible to secure, some measurements may become lost, or be inaccurate because of malfunctioning equipment, among

other reasons. Completeness is the % of values available for evaluation. The number of missing values influences the usefulness of the statistical evaluation of the information and too many missing values will, at some point, become unacceptable for the desired goals.

$$\text{Completeness (\%)} = 1.0 - (N_e - N_o)/N_e) * 100$$

where:

N_e is the expected number of measurements for the study.

N_o is the number of measurements obtained.

Precision - an indication of the similarity of repeated analyses or sampling. A useful method of expression is as 100% minus the coefficient of variation of repeated measurements.

$$\text{Precision (\%)} = (1.0 - SD/\overline{X}) * 100\,(\%)$$

where:

SD is the standard deviation

$\overline{X}$ is the mean

Alternately, the coefficient of variation, CV, ($SD / \overline{X}$) may be used.

The exact nature of the precision index is specified to eliminate possible confusion. For example, when the CV is used, smaller values are associated with greater precision and the index is therefore intuitively reversed.

When duplicate determinations are made, the relative percent difference (RPD) may be calculated as:

$$\text{RPD} = |V_1 - V_2| / ((V_1 + V_2)/2) * 100$$

were:

V_1 and V_2 are the two values of a measurement.

Quality Assurance (QA) - 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 client.

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 client.

Representativeness - a measure of the degree to which the data accurately and precisely represent a characteristic of a population parameter, variation of a property, a process characteristic, or an operational condition.

Validation - confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled. In environmental studies, validation might include checking to determine if the samples within the expected range of

concentrations or behaviors. In design and development, validation concerns the process of examining a product or result to determine conformance to user needs.

Verification - confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. In analytical processes this would include results from various QC operations, such as, blanks, sample replicates, certified reference materials, etc. 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.

For more definitions see:

EPA Quality Manual for Environmental Programs. May 2000. Appendix A, Terms and Definitions.

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Appendix 3

PREPARING QUALITY ASSURANCE PROJECT PLANS

Agency policy regarding QAPP development will be followed at WED as contained in: EPA Requirements for QA Project Plans (QA/R-5) and guidance for writing is in: Guidance on Quality Assurance Project Plans (G-5). An abbreviated guidance with suggested outline is contained below:

Graded Approach: WED recognizes that a "one size fits all" approach to quality requirements for research does not work. The level of detail in the QAPP will vary according to the nature of the work being performed and the intended use of the data.

Each project will be assigned a category according to the criteria listed in Section 2.3.

Exemptions: It is recognized that under some circumstances it is necessary to conduct preliminary experiments or range finding tests to facilitate appropriate experimental design that will form the basis of a QAPP. It is also obvious that for some low cost purchase orders or COOPs, the cost of developing a QAPP is disproportionate to the task. Other projects that consist entirely of developing a policy or reviewing an area of science may make writing a QAPP useless. Request for exemption are submitted in a memo from the project leader, thru the branch chief, to the QAM. It contains:

- explanation of the intended work
- reasons for wanting an exemption
- requested period
- appropriate signatures.

Inclusions: Any document that is supplemental to the QAPP and that defines or prescribes procedures that contribute to the quality of data, is considered an integral part of the QAPP and therefore requires the same management and QA approval as for the QAPP. This typically includes SOPs, and amendments and alterations to the QAPP.

Format: The same format is used for all (in-house, extramural, experimental, analytical, modeling, data manipulation, etc.) projects sponsored by WED. It is obvious that not all sections apply equally to all types of projects. Thus, when a section is irrelevant, a simple note is included that indicates that it is not applicable with a simple explanation.

The recommended format presented in this Appendix allows different approaches to the development of QAPPs. For a simple project, the QAPP may contain the entire set of instructions needed to complete a project. For a complicated, extensive project, the QAPP may be composed of a summary of goals, management, organization, and any other portion that lends itself to a general treatment, with reference to associated SOPs in Appendix 5 that detail the procedures for various tasks. The advantage of the latter approach is that the QAPP is conveniently divided into manageable portions, that can be added or amended as different tasks are added.

The development or application of **mathematical models** and the use of **pre-existing data** garnered from the literature, databases, or archived files, presents unusual problems in describing the procedures for quality assurance. Appendix 4 shows an outline of the types of modeling activities that are appropriate for the generic QAPP elements that must be

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addressed. Again, if a particular activity is not used, don't include it, but do consider them all, as this list comes from the Agency's guidance document for modeling project QAPPs: Guidance on QA Project Plans for Modeling (EPA/QA G-5m) (EPA, 2002e) and Guidance on Geospatial Data Quality Assurance Projects (EPA/QA G-5g) (EPA, 2002d).

QAPP Format and Content

The QAPP must be composed of the following four standardized, recognizable elements covering the entire project from planning, through implementation, to assessment. **Sub-element s may be combined, or not addressed by stating: "Not Applicable because…."**.

A. Project Management
B. Measurement/Data Acquisition
C. Assessment/Oversight
D. Data Validation and Usability

Document control:
Each page will have a footer containing:

Short Title **Page 1 of xx**
QAPP-NHEERL/WED/RCB/LW/05-02-001 3/20/06

This is the first revision (original=000) as of March 20, 2006 of the second (02) QAPP written in 2005 by Lidia Watrud in the Risk Characterization Branch.

A. PROJECT MANAGEMENT

This group of QAPP elements covers the basic area of project management, including:

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 for Measurement Data
A8 Special Training Requirements/Certification
A9 Documentation and Records

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A4. PROJECT ORGANIZATION: Present a brief introduction describing the need for the research, how this work relates to previous work, and the context of the project in relation to accepted knowledge and practice (literature review). An extensive introduction presumably already exists in the proposal or Research Plan that was intended to convince the reader of the need and worthiness of this project. Please don't copy that introduction, but rather make this brief, but sufficient for the reader to understand why the work is important.

Goals: List the goals of the project. This section is also not intended to be a treatise of the research, nor a justification for work, but a simple statement of goals so that the reader can understand how the methods match the intended results. Project deliverables and a schedule for their completion should be agreed upon between the Principal Pnvestigator and the Project Leader and stated in this section.

Organization: Explain the QA organization of the project. Identify all project participants (especially the PI(s)) and their roles and responsibilities for all planned tasks. Identify lines of project responsibility for each task or group of measures. Subcontractors are included in the description. A flow chart may be a useful way of presenting the lines of responsibility.

A7. DATA QUALITY OBJECTIVES: DQOs establish the data user's requirements for precision, accuracy, completeness, representativeness, and comparability. There are two forms for developing DQOs: the first is primarily for research and the second is a more formal process for monitoring or research done specifically to support an EPA regulatory decision. WED research falls mainly within the first type and this outline presents only the short form for research. The formal DQO process is presented in the EPA guidance document (Guidance for the Data Quality Objectives Process (G-4) and includes a description of when it should be used.

One method to determine the required data quality objectives (DQOs) is to make a list of all measurements needed to answer the questions posed in the research. Determine the level of precision, accuracy, and completeness needed to accomplish your goals. This can often be presented in a table format (example Table 1). It is important to remember that the values presented as your data quality objectives will be the standards for evaluating the data collected. Make sure that the DQOs reflect the needs of the project and are not too restrictive or too lax. Remember that the DQOs may be changed if in the course of the project you have been too optimistic regarding your measurement ability or that your analysis requires greater precision, accuracy or completeness.

B. MEASUREMENT / DATA ACQUISITION

This group of QAPP elements covers all aspects of measurement systems design and implementation, including:

B1 Sampling Process Design (Experimental Design)
B2 Sampling Methods Requirements
B3 Sample Handling and Custody Requirements
B4 Analytical Methods Requirements

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B5 Quality Control Requirements
B6 Instrument/Equipment Testing, Inspection, and Maintenance Requirements
B7 Instrument Calibration and Frequency
B8 Inspection/Acceptance Requirements for Supplies and Consumables
B9 Data Acquisition Requirements (Non-direct Measurements)
B10 Data Management

B1. STATISTICAL RESEARCH DESIGN: The selection of an appropriate research design for specific objectives is a crucial step in optimizing available resources and in determining the success and applicability of a study, whether data are developed or existing data are used. The number and kind of factors controlled or observed, the pattern of randomization, and the extent of sample and analytical replication in a study determine what hypotheses are testable, whether relationships can be fit, the precision of estimates, and the range of conditions over which inferences may be made. A statistical research design focuses on specific objectives, but in so doing, may limit the application of the results. No research design has universal application.

Projects designated as "range finding" will follow the same tenets. However, range finding projects may require deviations that must be documented in writing and caveated appropriately during the planning phase.

B2. SAMPLING: For each sample type, describe sampling methods and analytical procedures. Many procedures lend themselves to description as standard operating procedures, a practice recommended when it will clarify and compartmentalize description of specific tasks. When an SOP is used, reference in this section should direct the reader to its location. Help in sampling design will be available in the near future as an EPA document: Guidance on Sampling Designs to Support QA Project Plans (G-5S).

Methods
Describe procedures for selecting, collecting and handling samples. Many of these items can be most effectively presented in tables (example table 2) or lists, other items need a more detailed presentation. Make certain that sufficient information is presented to clarify the procedure and allow judgment of appropriateness and completeness. Some of the items that should be considered are listed below:

- What rules are used to select sampling points and frequencies?
- What procedures are to be used in collecting samples? This may include decontamination of sampling implements, identification of temporal and spatial conditions of the sample, corollary information (weather conditions, slope, etc.) that identify the sample in a manner meaningful to the goal of the experiment.
- Preparation of sample containers
- Specification of sample volumes
- Preservation methods, maximum holding times.
- Record keeping procedures. Attach field sampling data sheets, sample inventory forms, shipping forms, and any other forms used in this process.
- Sample labeling
- Sample handling, transportation and custody. This instruction is particularly important for monitoring studies that may become the basis for litigation or if samples will be analyzed by

different subcontractors or shipped. Discuss an approach for verifying sample receipt and evaluation of sample condition upon receipt, security within sample storage areas, and sample archiving (location, labeling). Identify how long samples are required to be stored after analysis and if samples should be stored after holding times are exceeded.

B4. ANALYTICAL METHODS: Describe the analytical procedures used for each sample. If standard methods (i.e. methods described by American Society of Testing Materials (ASTM) or American Public Health Association (APHA), etc.) are used, provide a copy of the procedure as an appendix. Analysis often depends on an instrument that measures some parameter of the sample. A useful presentation can often be organized by instrument although in some systems other approaches may be easier to understand. When measurements don't depend on an instrument (i.e. bird census determined by identifying bird songs along a prescribed transect) use this heading to describe the process of measurement. Some of the items that should be considered are listed below:

Instruments: Make a list of the instruments, the parameters measured, and the inferences to be made. This list will clarify the measurement procedure and be useful for the person making the measurements and the person reviewing the plan. This may be presented in a table (example table 3), a list or in paragraph format.

B5. QUALITY CONTROL (QC): Describe the procedures used to evaluate the instrument and the quality (precision and accuracy) of data being collected. In most analytical systems, accuracy is determined by routine and periodic measurement of standards and blanks. Describe the procedures for introduction and evaluation of standards and blanks. These procedures will differ between instruments and will vary from the simple measurement of standard weights before and after each measurement session to the insertion of blanks, blind replicates of samples, and standard chemical preparations into a GC sample train. Describe how this process will be accomplished and how the data will be compared to DQOs and what rules will govern the acceptance, modification or rejection of data. This presentation can often be facilitated by displaying some information in tables (example table 5). These procedures should be completed as quality control (QC) samples are analyzed. QA/QC data should be stored in a format associated with the coincident data. An easy way to accomplish this is to create an additional column (in a spread sheet) or file (in a relational database) that will naturally accompany the data collected from the session covered by the standard measurements. Analytical precision is a considerably different thing than sampling precision. Both should be known to evaluate an environmental condition.

B7. INSTRUMENT CALIBRATION: The intent of this section is to identify the needs and procedures for calibration. Describe how and when the instrument will be calibrated (example table 4). Describe the traceability of the calibration standard to some authenticated system and describe the procedure for maintaining standards. It is important to distinguish the difference between calibrating and checking accuracy. To calibrate an instrument is to adjust the output so that the reading is accurate. For a balance, this may be accomplished by adjusting the tension on a spring or adjusting a potentiometer. For a spectrophotometer this may be accomplished by making a standard curve of a dilution series and applying the mathematical fit (calibration curve) to the measurements of unknown samples. Some instruments need calibration frequently (i.e. a pH meter is calibrated each time it is used), while others need calibration rarely (i.e. a balance). Some instruments require calibration at several concentrations. Often instrument detection limits determine the accuracy of measurements at the extremes of instrument sensitivity. Although values may be recorded by some instruments, those

values may have no meaning if they fall outside detection limits. For those measurement systems with either high or low limitations a description of how to deal with values that fall outside acceptable limits must be described *a priori*..

B8. CONSUMABLES: Where consumable items, such as solvents, standard gasses, reagents, etc. are involved, discuss acceptability rules and procedures used to inspect and evaluate.

B10. DATA MANAGEMENT: Trace data from collection to the final report. This may include various steps such as: entry into field notebook, transcription into computer spread sheet or database, verification, proof reading, outlier identification, editing, analysis, report writing. Include identification of units, when they change and how such changes are accomplished, (i.e., original data may be captured as peak height from some detector, changed to quantity based on a standard, changed to concentration by dividing by amount injected into detector, changed into concentration of tissue by dividing by mass of tissue in the sample, changed to concentration on area basis by a regression of mass to area, and finally reported on the basis of amount per hectare by another regression). The issue for QA is to specifically identify each data transformation and justify the use of auxiliary information when it is used to alter the values or the form of presentation. Some modifications introduce additional error, such as the error in measuring a second variable like area or mass. It is important to propagate all errors associated with any data generated in the laboratory or obtained from the literature.

Provide information on your computer system, method and frequency of file back-up. Discuss how long sample data should be stored, by whom and where.

C. ASSESSMENT / OVERSIGHT

This group of QAPP elements addresses the activities for assessing the effectiveness of the implementation of the project and associated QA and QC activities, including:

C1 Assessments and Response Actions
C2 Reports to Management

C1. ASSESSMENTS AND RESPONSE ACTIONS: Identify the frequency, and type of assessment activities for this project. Assessments include, but are not limited to the following:

- surveillance
- peer review
- performance evaluation
- assessments

Describe the procedures that best serve this project and provide an outline to implement the assessment activity. Explain how the project will be internally reviewed and state how the results of your review will be acted upon and documented.

The QAM has the responsibility to perform assessments of all projects (except Performance Evaluations that are the Project Leader's). The goals are to: (1) evaluate the implementation of the QAPP, and (2) provide assistance regarding QA procedures. Assessments are often useful prior to or

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at the commencement of sampling or analysis. Regular assessments should be performed every two years or more frequently at the request of the Project Leader. Include a proposed assessment schedule with consideration of sampling and analytical periods and times when an assessment would be disruptive (i.e. test week or vacation times). The proposed schedule is intended only as a guide and assessment times will be arranged by the mutual consent of the Project Leader and the QAM.

C2. REPORTS TO MANAGEMENT: This section should specify the frequency of progress reports to EPA and define an approach to address project QA/QC in the final deliverables. The QA portion of the progress reports should address:

- A summary of precision, accuracy and completeness for all samples analyzed.
- Any problems that could affect the quality of the data collected, the project schedule or the completion of the project;
- A summary of any corrective actions implemented and the result;
- Changes in the project's experimental design, objectives, or staffing;
- The need for additional equipment to achieve project objectives.
- Identify any problems with equipment.
- A summary of data quality evaluation (especially for modeling or data review projects).

D. DATA VALIDATION AND USABILITY

This group of QAPP elements covers the QA activities that occur after the data collection phase of the project is completed, including:

D1 Data Review, Validation, and Verification Requirements
D2 Validation and Verification Methods
D3 Reconciliation with User Requirements

D1. DATA REVIEW, VALIDATION, AND VERIFICATION REQUIREMENTS: Describe procedures to periodically verify and document the acceptability of data generated by EPA and/or contract support staff. These procedures would include review of project notebooks and prompt verification of contractor data reports and deliverables. The frequency of these activities would be highest during the initial implementation of procedures and for those that produce project-critical data. State the criteria used to review and validate data.

Provide examples of any forms or checklists to be used.
Identify any project-specific calculations required.

UPDATES AND REVISIONS
Many good and useful ideas regarding research are not conceived prior to experimentation and are therefore not included in QAPPs or SOPs. Also, because research is complex, changes to original QAPPs are sometimes needed. The Project Leader is responsible to determine if an anticipated change will impact the quality of the project. If a change is desirable, the change should be submitted for approval through the same channel as the original.

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QAPP

FOR

PROJECT TITLE

Assistance agreement number (extramural projects)
Project Leader:
Principal Investigator:
Institution:

Project TITLE

Management Approvals:

Signature indicates that this QAPP is approved and will be implemented in conducting the research of this project.

Name_____
(Branch name) Branch Chief *Signature* *Date*

Name _____
Project Leader and/or Officer *Signature* *Date*

Extramural **Project Managers and/or Principal Investigators**:[1]

Signature indicates commitment to follow the procedures in this QAPP.

Name _____
Principal Investigator *Signature* *Date*

Quality Assurance:

Signature indicates that this QAPP meets the quality requirements of WED.

Bob Ozretich _____
Quality Assurance Manager *Signature* *Date*

1 A chain of responsible persons should be established where signatures are required for each independent PI or manager. Subordinates do not need to sign the approval page.

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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.

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The following tables are presented as examples of one way to organize and present some of the information in a QAPP. These tables should not be regarded as a prescribed format since the appropriate format necessarily varies with the type of research described.

Table 1. Data quality objectives

Parameter	Measurement units	Expected range (units[1])	Accuracy (%)	Precision (%)	Completeness (%)
Leaf mass (dry)	g	0.5 - 2.0	98	98	95
Benzene concentration	μg/ml	10 - 500	95	90	95
Soil Temperature	C	-20 to 40	95	95	100

1. Expressed in the same units as measured.

Table 2. Summary of sample collection, handling, and preservation activities

Sample Type[a]	Parameter(s) Measured	Sample Container	Minimum Sample Size	Preservation Method/Storage	Maximum Holding Time
Stream H_2O	pH	syringe	50 ml	Store on ice	4 hours
Soil	Pesticide concentration	plastic, 1-L HDPE[b] or glass	50 g	Store on ice	28 days
Leachate collected from	N, TKN[c]	1-L HDPE[b]	500 ml	H_2SO_4 < 2 pH Store on ice	28 days
Leaves	dry mass (g)	paper bag	25 g	dry at 100C for 24 hrs.	6 months
Audio recording	bird songs	audio cassette	3	NA	1 year

a For example - air, soil, through-fall, lysimeter, stream, lake, tissue, blood, plant tissue
b High density polyethylene
c Total Kjeldahl Nitrogen

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Table 3. Instrument Calibration

Instrument	Calibration procedure	Frequency
Mettler balance PM3000	Calibrated by factory service technician (if needed) during annual maintenance	yearly
Gas Chromatograph	Calibration curve determined by injecting concentration standards covering expected range injected.	each session
pH meter	Adjust meter using standard buffers.	each session
Lambda PAR sensor	Returned to manufacturer for spectrum verification and intensity calibration	yearly

Table 4. Quality control checks for instruments

Instruments	Q.C. Check	Frequency	Data summary	Acceptance criteria	Action if values are unacceptable
Mettler balance PM3000	Record readings for NIST traceable standard weights that cover the range of expected values	before and after each session	calculate accuracy	greater than DQO	Re-weigh all samples on another balance. Clean, adjust or send balance for repair.
Oxford and Eppendorf pipettes	determine mass of dispensed volume	before each session	Single measure-ment	Within ± 1% of expected volume	Clean, adjust, replace pipette. Send defective pipette to supplier for maintenance.
Gas Chromatograph	Concentration standards covering expected range injected.	before each session	Plot dose / response curve.	linear response, R^2 > .95	repeat standards injection until linear response. Clean detector, or otherwise repair instrument.
Trained observers (bird songs)	Test observers against experts using audio tapes or field trials.	yearly	Species count	accuracy > 80%	Retrain and re-test.

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Table 5. Preventive maintenance

Instrument	Frequency	Preventive Maintenance
Mettler balance PM3000	yearly	Contract service
Gas Chromatograph	yearly or when column is changed	detector cleaned, diagnostic self test
Oxford and Eppendorf pipettes	yearly or when QC checks are unsatisfactory	replace gaskets, lubricate, clean, use contract maintenance service.

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Appendix 4

QA PROJECT PLAN ELEMENTS FOR MODELING
http://www.epa.gov/quality1/qs-docs/g5m-final.pdf

Document control:
Each page will have a footer containing:

Short Title **1 of xx**

QAPP-NHEERL/WED/RCB/NS/05-02-001 3/20/06

This is the first revision (original=000) as of March 20, 2006 of the second (02) QAPP written in 2005 by Nathan Schumaker in the Risk Characterization Branch.

GROUP A: PROJECT MANAGEMENT

A1. Title and Approval Sheet
Contents this element will contain:
- Title of QA Project Plan
- Revision number of QA Project Plan
- Effective date of QA Project Plan revision
- Names of all organizations involved in modeling project
- Names of all key project officials responsible for the work, with space for dated signatures

A2. Table of Contents and Document Control Format
Contents this element will contain:
- Title of all sections, including subsections, tables, figures, references, appendices
- Page numbers for each section
- Section for each QA Project Plan element
- Document control box

A3. Distribution List
Contents this element will contain:
- List of all individuals (and their role on the project) who will be provided copies of the approved QA Project Plan, including all persons responsible for implementation, including project managers, QA Manager(s), and representatives of all groups involved.

A4. Project/Task Organization
Contents this element will contain:
- Concise organizational chart showing the relationships and lines of communication among all
- project participants, other data users, and any subcontractors relevant to environmental data operations

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- Project name and organizations involved, and a description of their respective responsibilities

A5. Problem Definition/Background

Contents this element may contain:

- Goals and objectives of this project that will address this problem
- Definition of the population the problem targets and what measures within this population the problem addresses
- Reason the project includes a modeling approach to address the problem (is it a new predictive tool?)
- Types of decisions that may be made as a result of this project
- Names of those responsible for making these decisions
- Any other types of problems that the project may address
- Background information on the problem
- Reasons the project is important, how it supports other existing research, programs, or regulations
- Conflicts or uncertainties that will be resolved by this project
- Reasons one model is determined to be better than another for this application

A6. Project/Task Description and Schedule

Contents this element may contain:

- Summary of all work to be performed, products to be produced, and the schedule for
- implementation
- List of products, deliverables, and milestones to be completed in the various stages of the project
- Schedule of anticipated start and completion dates for the milestones and deliverables, and persons responsible for each

A7. Quality Objectives and Criteria for Model Inputs/Outputs

Contents this element may contain:

- Project data quality objectives (DQOs), performance criteria, and acceptance criteria
- Description of task that needs to be addressed and the intended uses of the output of the modeling project to achieve the task
- List of requirements associated with the hardware/software configuration for those studies involving software evaluation

A8. Special Training Requirements/Certification

Contents this element may contain:

- Types of required training and certification needed by the project team
- Plan for obtaining training and/or certification
- Documentation of training and/or certification

A9. Documentation and Records

Contents this element may contain:

- Description of information to be included in reports
- Proper document control and distribution procedures

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- Details on document storage
- Backup plan for records stored electronically
- Description of the change control process (who approves changes, etc.)
- Length of retention periods for each record
- Data assessment reports, interim project progress reports
- Model science formulation report, peer review reports
- Model assessment reports, interim project progress reports
- Code standards, code auditing and testing reports, interim project progress reports
- Model calibration report
- Model evaluation records (How well does the model report variability and uncertainty in its output?)
- User's manual
- Configuration management (after production version) and code maintenance manuals (e.g., or software, internal documentation of logic and structure)

GROUP B: MEASUREMENT AND DATA ACQUISITION

B7. Calibration

Contents this element may contain:

- Objectives of model calibration activities, including acceptance criteria
- Frequency of model calibration activities
- Details on the model calibration procedure
- Method(s) of acquiring input data
- Types of output generated by the model calibration
- Approach to characterize uncertainty (e.g., sensitivity analysis)
- Corrective action to be taken if criteria are not met
- Resources and responsibilities for calibrating the model
- Analysis of model output relative to acceptance criteria

B9. Non-direct Measurements (Data Acquisition Requirements)

Contents this element may contain:

- Types of data needed for implementing a project that are obtained from non-measurement sources such as databases, literature files
- Need for non-direct measurements, intended use of data
- Method(s) of identifying and acquiring data
- Method of determining the underlying quality of the data
- SOPs and field or lab-specific deviations associated with these procedures
- Acceptance criteria for non-direct measurements: such as completeness, representativeness, bias, precision, qualifying data

B10. Data Management and Hardware/Software Configuration

- Contents this element may contain:
- Information on the project data management process (field, office, and lab)
- Record-keeping procedures, document control system, audit trails

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- Control mechanism for detecting and correcting errors, preventing loss of data
- Procedures for assuring applicable Agency resource management requirements are satisfied
- Required computer hardware/software and any specific performance requirements

Data Management

- Any data forms, checklists, on-line interactive screens used in the modeling process
- Any graphics developed to document the data management process (process flow diagrams, modeling flow charts, etc.)
- Documentation of internal checks used during data entry
- Data calculations and analyses that should to be highlighted in the QA Project Plan
- Plans for characterization of uncertainty and variability in the model results (e.g., summary
- statistics, frequency distributions, goodness-of-fit tests)

Hardware/Software Configuration

- List of equipment, hardware, and software that will be used on the project
- Description of performance requirements
- Decisions regarding security issues
- Decision regarding communication issues
- Decisions regarding software installation issues
- Decisions regarding response time issues
- Plans for requirements documentation
- Coding standards
- Testing plans
- Plans for data dictionary (may not need to be a separate document)
- Plans for a user's manual
- Plans for a maintenance manual (explaining software logic and organization)
- Plans for source code for the ultimate user of the model or model framework
- Configuration management plan (procedures to control software/hardware configuration during development of the original model version)

GROUP C: ASSESSMENTS AND OVERSIGHT

C1. Assessment and Response Actions

Contents this element may contain:

- Assessment/oversight strategies and schedule of assessment activities, order of events
- Organizations and individuals expected to participate in assessments, including peer reviews
- Information expected, success criteria
- Scope of authority of assessors to recommend or direct changes to the model (corrective actions)
- Qualitative and quantitative assessments

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- Internal assessments (internal QA officer's review of input data, code verification, calibration, benchmarking) and external assessments (peer review of model theory or mathematical structure)
- Surveillance activities (continued monitoring of status and progress of the project, tracking project milestones and budgets)
- Plans for model performance evaluations
- Plans for sensitivity analysis
- Plans for uncertainty analysis
- Plans for data quality assessment
- Plans for code testing

Hardware/Software Assessments

- Plans for hardware and software configuration testing, if appropriate
- Plans for code verification tests
- Plans for internal and external peer reviews
- Plans for checking for programming errors
- Plans for checking for correct insertion of model equations
- Plans for checking for code's linkage to analysis of uncertainty

Hardware/Software Configuration Tests

- Plans for software code development inspections
- Plans for software code performance testing
- Plans for a test of the model framework
- Plans for integration tests (check computational and transfer interfaces between modules)
- Plans for regression tests
- Plans for stress testing of complex models (to ensure that maximum load during peak usage does not exceed limits of the system)
- Plans for acceptance testing (contractually-required testing needed before a new model or model application is accepted by the customer and final payment is made)
- Plans for beta testing of pre-release hardware/software, recording of anomalies
- Plans for checking for programming errors

Plans for science and product peer review

- Theoretical basis for the model
- Mathematical model structure
- Model algorithms
- Model predictions
- Model calibration
- Plans for data quality assessment
- Plans for peer review of final technical product

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C2. Reports to Management

- Contents this element may contain: plans for documentation of:
- Project reporting schedule
- Frequency, content, and distribution of reports
- Deviations from approved QA Project Plan
- Need for response actions to correct deviations
- Potential uncertainties in decisions based on input data and model limitations
- Data Quality Assessment findings

GROUP D: DATA VALIDATION AND USABILITY

D1. Departures from Validation Criteria

Contents this element may contain:

- Criteria used to review and validate (accept, reject, or qualify) model components such as theory, mathematical procedures, code, and calibration (convergence criteria, etc.)
- Criteria used to review and validate input data
- Criteria used to test model performance
- Criteria used to review or validate model outputs

D2. Validation Methods

Contents this element may contain:

- Methods for review of model components such as theory, mathematical procedures, code, and calibration (peer review, etc.)
- Methods for review of input data
- Methods for review of model performance tests
- Methods for assessment of model output and usability

D3. Reconciliation with User Requirements

Contents this element may contain:

- Discussion of project or task results
- List of departures from assumptions set in the planning phase of the model
- Report on limitations on use of output data for decision makers or users

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Appendix 5

WED Standard Operating Procedure Format

Condensed from the document entitled: Guidance for the Preparation of Standard Operating Procedures (SOPs) for Qualtiy Related Documents, EPA QA/G-6
http://www.epa.gov/quality/qs-docs/g6-final.pdf

Document control:
Each page will have a footer containing:

Short Title/ID # 1 of xx
SOP-NHEERL/WED/PCEB/BB/05-02-001 3/20/06

This is the first revision (original=000) as of March 20, 2006 of the second (02) SOP authored in 2005 by Bruce Boese of the Pacific Coast Ecology Branch.

WED SOPs will consist of the following 12 sections:

(For activities such as field work, a separate SOP is not required for each procedure. All the procedures can be included under a single SOP title. If sections are not applicable or relevant, their entries should be NA with a brief explanation)

Title-Signature Page (outline same as QAPP, SOP author, first line management, QAM)

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1. **Scope & Applicability** (describing the purpose of the process or procedure and any organizational or regulatory requirements)

2. **Summary of Method** (briefly summarizing the procedure)

3. **Definitions** (identifying any acronyms, abbreviations, or specialized terms used)

4. **Health & Safety Warnings** (indicating operations that could result in personal injury or loss of life and explaining what will happen if the procedure is not followed or is followed incorrectly; listed here and at the critical steps in the procedure)

5. **Cautions** (indicating activities that could result in equipment damage, degradation of sample, or possible invalidation of results; listed here and at the critical steps in the procedure)

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6. **Interferences** (describing any component of the process that may interfere with the accuracy of the final product)

7. **Personnel Qualifications** (denoting the minimal experience the SOP follower should have to complete the task satisfactorily, and citing any applicable requirements, like certification or "inherently governmental function")

8. **Equipment and Supplies** (listing and specifying, where necessary, equipment, materials, reagents, chemical standards, and biological specimens)

9. **Procedure** (identifying all pertinent steps, in order, and materials need to accomplish the procedure such as:

- Instrument or Method Calibration and Standardization
- Sample Collection
- Sample Handling and Preservation
- Sample Preparation and Analysis (such as extraction, digestion, analysis, identification, and counting procedures)
- Troubleshooting
- Data Acquisition, Calculations & Data Reduction Requirements(such as listing any mathematical steps to be followed)
- Computer Hardware & Software (used to store field sampling records, manipulate analytical results, and/or report data)

10. **Data and Records Management** (e.g., transcription/verification/authentication documentation, identifying any forms to be used (attach as Appendices), storage location hard and electronic versions, and archiving information).

11. **Quality Control and Quality Assurance Section** - QC activities are designed to allow self-verification of the quality and consistency of the work. Describe here the preparation of appropriate QC procedures (self-checks, such as calibrations, recounting, re-identification, control charts) and QC material (such as trip, field, or method blanks; positive and negative controls; replicates; splits; spikes; performance evaluation samples, SRMs) that are required to demonstrate successful performance of the method. Specific criteria for each should be included. Describe the frequency of required calibration and QC checks and discuss the rationale for decisions. Describe the limits/criteria for QC data/results and actions required when QC data exceed QC limits or appear in the warning zone. Describe the procedures for reporting QC data and results.

12. **Reference Section** - Documents or procedures that interface with the SOP should be fully referenced (including version), such as related SOPs, published literature, or methods manuals. Citations cannot substitute for the description of the method being followed in the organization. Attach any that are not readily available.

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U.S. EPA / NHEERL
QUALITY ASSURANCE REVIEW FORM
FOR EXTRAMURAL ACTIONS

I. General Information

A. Select ***all*** that apply: **Initial Extramural Action**	**Existing Vehicle Action**	**B. Specific or Descriptive Title**:
☐ Contract ☐ Sole Source ☐ Assistance Agreement ☐ IAG* (funds out) ☐ IAG* (funds in) ☐ CRADA*	☐ Contract No.:_____ ☐ Work Assignment No.:_____ ☐ Delivery/Task Order No.:_____ ☐ Modification No.:_____ ☐ COOP, IAG No.:_____ ☐ Incremental Funding ☐ Other:	

If you are processing an **IAG or **CRADA**, the responsibility for QA must be negotiated within the agreement. The Project Officers (POs) in consultation with the QAMs in the various organizations must agree on, and document which organization will take the lead for QA, the names of the QAM and PO from each organization, and the QA requirements which will be adhered to during the agreement. Include this information in the IAG/CRADA package.*

C. Branch:	**D. QA Category:**
	☐ 1. Research directly and immediately supporting regulations or congressional or presidential mandates, etc. ☐ 2. Research of high programmatic relevance, etc. ☐ 3. Research demonstrating proof of concept; method validation studies ☐ 4. Basic exploratory research to study mechanisms, conditions, etc.

II. Scope of Work

A. Does this extramural action involve the collection, generation, use, and/or reporting of environmental data; or development of software and/or models, or methods? ***(If "No", skip to Section IV, and sign the form.)***	☐ Yes ☐ No
B. For solicitations, will the activities in Section IIA account for greater than 15% of the cost or effort? If so, the QA documentation specified in the RFP or SOW and/or provided for in Section III1or III2 shall be included in the technical evaluation at a weight of 10-20%, or pass/fail. ***(*check N/A for existing vehicle actions)***	☐ Yes ☐ No ☐ *N/A
C. Will the SOW or any subsequent work assignments or task orders, or COOP, or IAG involve any cross-federal organizational efforts? If so, which organization will take the lead for QA?	☐ Yes ☐ No
D. Has a QAPP already been approved for the activities specified in the SOW or RFP?	☐ Yes ☐ No
1. Provide the title, date or revision number, and date of QA approval:	
2. Does the QAPP require *any* revision by the contractor or cooperator? ***(*If IID is "No", check N/A)***	☐ Yes ☐ No ☐ *N/A
E. Is an applicable QAPP in the process of being prepared or revised by EPA, the contractor, or grantee/cooperator? (*QAPP must be approved by EPA before the collection or use of environmental data.*) ***(*If IID is "No", check N/A)***	☐ Yes ☐ No ☐ *N/A
1. Provide the expected title and approximate date for submission to QA staff for approval:	

III. Quality-Related Requirements

A. Quality System Documents (Specifications): In Section III.B., "R-2" refers to EPA Requirements for Quality Management Plans (QA/R-2) (EPA/240/B-01/002, 03/20/01) and "R-5" refers to EPA Requirements for Quality Assurance Project Plans (QA/R-5) (EPA/240/B-01/003, 03/20/01). Copies of these documents are available at http://www.epa.gov/quality/.

B. QA Documentation Options: *[For solicitations, complete items 1-4; for all actions other than solicitations, complete items 3-4. All documentation specified under "Other" must be defined in the NHEERL Quality Management Plan or individual Division QMPs and be consistent with requirements defined in EPA Order 5360 A1. For all items checked below, there must be adequate information in the SOW (or its appendices) for the offeror to develop this documentation. Where applicable, reference a specific section of the SOW.]*

Before Award Documentation

1.a. ☐ Documentation of an organization's Quality System: Either	☐ QMP developed in accordance with R2 or ☐ Other: "Respondent Requirements Demonstrating Their Organization's Quality Assurance and Quality Control System" attached to, and referenced from within the SOW or RFP (found on page 3 of this document)
b. ☐ Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by contract: Either developed in accordance with	☐ R-2 and R-5 or ☐ Other:
2. a. ☐ Programmatic QA Project Plan: Either developed in accordance with	☐ R-5 or ☐ Other:
b. ☐ Application of QA and QC activities to the single project covered by contract: Either	☐ QA Project Plan developed in accordance with R-5 or ☐ Other:
c. ☐ Not applicable.	

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After Award Documentation

3. a. ☐ Documentation of an organization's Quality System: Either	☐ QMP developed in accordance with R-2 or ☐ Other: "Respondent Requirements Demonstrating Their Organization's Quality Assurance and Quality Control System" attached to, and referenced from within the SOW or RFP (found on page 3 of this document)
b. ☐ Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by the contract: Developed in accordance with	☐ R-2 and R-5 or ☐ Other:
c. ☐ Not applicable.	
4. a. ☐ Documentation of the application of QA and QC activities to applicable project(s): Either developed in accordance with	☐ R-5; ☐ A supplement to the following Programmatic QA Project Plan _____ ; or ☐ Other:
b. ☐ Programmatic QA Project Plan with supplements for each specific project: Developed in accordance with:	
c. ☐ Existing documentation of the application of QA and QC activities will be used: Either	☐ Documentation developed pre-award; ☐ Documentation will be identified in individual SOW or RFP, or ☐ Documentation identified in Section _____ of the SOW or RFP
C. Reports: Are quality reports or reports containing quality assurance information (for example, status of quality system implementation, review of a quality system, quality control data, etc.) required? ☐ **Yes** ☐ **No** If yes, identify the required reports and the time frame for submission:	

D. Assessments: Select all quality assessments that will be performed post-award by EPA staff:	☐ Readiness reviews; ☐ PE samples; ☐ Technical systems audits;	☐ Surveillance audits; ☐ These and/or others are specified in the SOW/QAPP at some frequency.

IV. Signatures**

The signatures below verify that the Statement of Work or Request for Proposal has been reviewed to ascertain the necessary QA and QC activities required to comply with EPA Order 5360.1 A2, that the Contracting Officer's Representative (COR), Technical Lead (TL) and/or Project Officer (PO) understands these requirements, and that the COR/TL/PO will ensure that the quality requirements indicated on the pages of this form are incorporated into all necessary sections of the SOW or RFP. *(Sign/date below, obtain a concurrence signature from the QA Staff, and submit the form along with the other extramural action documentation.)*

NHEERL COR, TL / PO	Date	NHEERL QA Staff Member	Date
NHEERL TL (when needed, if COR or PO is not the TL)	Date		

**If this form accompanies an incremental funding action, the signature of the Project Officer acknowledges that the assistance recipient has fulfilled any QA requirements identified in the initial funding decision memo and is current with any periodic QA/QC reports that are identified in the project's QAPP as specified in Section IIIC, above.

Respondent Requirements
Demonstrating Their Organization's
Quality Assurance and Quality Control System

In accordance with EPA Order 5360.1 A2, conformance to ANSI/ASQC E4 must be demonstrated by each solicitation respondent. Providing responses to the list of topics provided below are sufficient to demonstrate this conformance. Responding to the topics listed below provides a description of each respondent's Quality System that sets forth its capabilities in providing products (such as those described in the Statement of Work or Request for Proposals) of known and verifiable quality. Each respondent, as a separate and identifiable part of its technical proposal, shall submit its responses to these topics. The Quality System documentation of the respondent will become part of the evaluation. For more information on these requirements visit: http://www.epa.gov/QUALITY/faq4.html

For the successful respondent, the Quality System documentation will be reviewed by the EPA Quality Assurance Manager and approved following an acceptable response to his requested revisions. In addition, a project-specific Quality Assurance Project Plan (QAPP) (following directions in the Quality Management Plan of the originating NHEERL Division) shall be submitted to the Government at least thirty (30) days prior to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the successful respondent shall also implement it as written and approved by the Government.

Topics to be addressed in demonstrating an organization's Quality System

(a) A statement of policy concerning the organization's commitment to implement a Quality Control/Quality Assurance program to assure generation of data of adequate quality to meet the requirements of the Request for Proposals (RFP) or Statement of Work (SOW).

(b) An organizational chart showing the position of a QA function or person within the organization. It is highly desirable that the QA function or person be independent of the functional groups which generate measurement data.

(c) A delineation of the authority and responsibilities of the QA function or person.

(d) The type and degree of experience in developing and applying Quality Control/Quality Assurance procedures to the proposed methods needed for performance of the SOW or RFP.

(e) The background and experience of the proposed personnel who will be assigned to the project.

(f) The responder's general approach for accomplishing the QA specifications within the scope of the SOW or RFP, or their specific approach that would provide results of known and verifiable quality.

The respondents shall be aware of the following nonexclusive list of words and phrases that may indicate the need for a discussion of QA activities as they describe the various (a thru f) features of the particular application of their organization's Quality System to this SOW or RFP.

validation	**verification**	**hardware/software evaluation**
audit procedures	**positive/negative controls**	**matrix spikes**
system evaluation	**configuration management**	**change control**
Standard Reference Materials		**acceptance or QA/QC testing**
Standard Operating Procedures	**surrogates**	**documenting software code**

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ORD CLEARANCE FORM

1. **EPA Pub. No.** (if applicable)	2. **Laboratory/Center/Office Tracking Number** WED-	3. **Copyright Permission** ☐ Yes (attached) ☐ No (not applicable)

4. Title

5. Author(s), Affiliation, and Address: Include either Telephone Number or Email Address (required) to provide unique identifiers for non-EPA authors.

6. Internet Address (If the product is posted on a website, provide the URL for linking to the publication.)

A PDF file of the final publication and a WordPerfect or Word file of the product abstract (approximately 200 words) must be submitted with the final package for uploading to the Technical Information Management (TIMS) Database.

7. Enter these numbers:	**8. Project Officer/Principal Investigator Name and Telephone Number**
OMIS Task #	
APG FY & #	
APM FY & #	**9. Cooperative Agreement, Contract, Grant, Interagency Agreement Number**
Multi-Year Plan (MYP)	
Past Research	

10 . Product Type			
☐ Assessment Document	☐ EPA Published Proceedings	☐ Newsletter	☐ IRIS Assessment
☐ Book	☐ Paper in EPA Proceedings	☐ Newsletter Article	☐ ETV Document
☐ Book Chapter		☐ Risk Assessment Guidelines	
☐ Criteria Document	☐ Non-EPA Published Proceedings	☐ Summary	
☐ Internal Report	☐ Paper in Non-EPA Proceedings	☐ Unpublished Report	

10a. Product Types having Subtypes	**10b. Product Subtypes**
☐ Communication Product	☐ Announcement ☐ Brochure ☐ External Fact Sheet ☐ Flyer ☐ General Public ☐ Videotape
☐ Data	☐ Database ☐ Map ☐ Model ☐ Scientific Data ☐ Software ☐ Spreadsheet
☐ Extramural Document	☐ Contract ☐ Cooperative Agreement ☐ Grant ☐ Interagency Agreement
☐ Journal	☐ Non-Peer Reviewed ☐ Peer Reviewed
☐ Presentation	☐ Abstract ☐ Exhibit ☐ Extended Abstract ☐ Paper ☐ Poster ☐ Slide
☐ Published Report	☐ Guidance Document ☐ Handbook ☐ Issue Paper ☐ Manual ☐ Methodology ☐ Report (default) ☐ Technology Transfer ☐ User's Guide
☐ SITE Document	☐ Bulletin ☐ Capstone Doc ☐ Capsule ☐ Report ☐ Summary

11. Bibliographic Citation (For presentations, give name, place and date)

12. Technical Information Manager Signature and Date

Signature Date

13. Laboratory/Center/Office Recommending Approval

Signatures Dates

14. Comments	**15a. Peer Review Categories**
	☐ 1 Major Agency Scientific or Technical Work Product
	☐ 2 Important, Highly Visible Scientific
	☐ 3 General Scientific or Technical Work Product
	☐ 4 Non-major Scientific or Technical Work Product

16a. Hierarchical Keywords			**15b. Contact/location for peer review comments**
1			
2			**17. This Product enunciates new policy or affects existing policy:** ☐ Yes ☐ No
3			

16b. Free Form Keywords

18. Approving Official Signature and Date

Signature Date

ORD-362 (Rev. 06/10/05)

19. Impact Statement Attached (Required for most products other than abstracts)
☐ **Yes** ☐ **No**

20. This manuscript reports research performed under the following:

Research Plan Title:

QAPP Title (if different):

If not applicable, explain:

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Biennial Review Form

SOP Title:

Originating Branch, project, or group and number: **Version**:
(*e.g.TERA 1.1, WRS 14A, SOP-WED/RCB/BB/06-01-000*)

Original Preparer:

QA certification date of this version:

BIENNIAL REVIEWS [a]

Date	EPA Reviewer (signature/title: PI, or project leader, or WACOR w/ WA#)

[a] **Signature documents the biennial review when no revisions are deemed necessary.**

If a modified version of this SOP is being followed these revisions should be submitted for review and approval.