QUALITY MANAGEMENT PLAN

for the

Mine Waste Technology Program (MWTP)

U.S. Environmental Protection Agency (EPA)
Office of Research and Development (ORD)
National Risk Management Research Laboratory (NRMRL)
Sustainable Technology Division (STD)

Revision 0
March 2003

Foreword

The Mine Waste Technology Program (MWTP) is housed in the Sustainable Technology Division (STD) of the National Risk Management Research Laboratory (NRMRL). As such, QA requirements specified in NRMRL's Quality Management Plan (QMP), revised March 2002, are applicable to this Program.

The Mine Waste Technology Program operates through an Inter-Agency Agreement (IAG) between EPA and the US Department of Energy (DOE). EPA is empowered to provide technical direction for the IAG and DOE provides administrative oversight to the program. As part of this agreement, EPA has assumed responsibility for QA oversight. MSE-Technology Applications (MSE-TA) is the DOE contractor who performs and documents the research activities in support of this Program. EPA MWTP personnel provide substantial oversight of MSE-TA activities through an active QA program as described in this document and provide technical direction to MSE-TA activities, through DOE.

EPA requires that MSE-TA prepare and implement a Quality Management Plan (QMP) which is consistent with the EPA QA requirements described in this document. The MSE-TA QMP is reviewed and approved by the EPA MWTP Program Manager and QA Manager and its implementation is assessed periodically.

The format of this MWTP QMP follows that of the NRMRL QMP. The purpose of this QMP is to document the specific procedures used by EPA in the implementation of the NRMRL QMP for the MWTP.

Mine Waste Technology Program (MWTP)
Quality Management Plan
March 2003

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Mine Waste Technology Program (MWTP)
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ABBREVIATIONS AND ACRONYMS

ADQ	Audit of Data Quality
ANSI	American National Standards Institute
DOE	Department of Energy
DQA	Data Quality Assessment
DQI	Data Quality Indicator
DQO	Data Quality Objective
EPA	US Environmental Protection Agency
IAG	Interagency Agreement
NRMRL	National Risk Management Research Laboratory
OEI	Office of Environmental Information
OIRM	Office of Information Resources Management
ORD	Office of Research & Development
PE	Performance Evaluation
QA	Quality Assurance
QAM	Quality Assurance Manager
QAPP	Quality Assurance Project Plan
QC	Quality Control
QMP	Quality Management Plan
QSA	Quality System Audit
RMO	Records Management Office
SOP	Standard Operating Procedure
STD	Sustainable Technology Division
TSA	Technical System Audit

1.0 Management and Organization

The Mine Waste Technology Program (MWTP) resides in the Industrial Multimedia Branch (IMB) of the Sustainable Technology Division (STD) of the National Risk Management Research Laboratory (NRMRL). Subhas Sikdar, the STD Division Director, is responsible for all MWTP activities. Roger Wilmoth, the IMB Branch Chief, serves as the EPA MWTP Program Manager. Lauren Drees, the STD QA Manager, serves as the EPA MWTP QA Manager. Several members of the IMB technical staff serve as EPA MWTP Project Managers. EPA MWTP Project Managers include Diana Bless, David Ferguson, George Huffman, Norma Lewis, and Ivars Licis.

1.1 MWTP Mission Statement

The mission of MWTP is to provide engineering solutions to national environmental issues resulting from the past practices of mining and smelting metallic ores. In accomplishing this mission, MWTP develops and conducts a program that emphasizes treatment technology development, testing and evaluation at bench- and pilot-scale, and an education program that emphasizes training and technology transfer. Evaluation of the treatment technologies focuses on reducing the mobility, toxicity, and volume of waste; implementability; short- and long-term effectiveness; protection of human health and the environment; community acceptance; and cost reduction.

1.2 MWTP Organizational Policy on Quality Assurance

The MWTP policy on quality assurance (QA) is:

- To ensure that MWTP meets NRMRL QA requirements as defined in the NRMRL QMP (March 2002);
- To implement a quality system that guides QA planning for individual projects and QA reviews of all activities in MWTP;
- To ensure that continuous improvement is practiced in the implementation of the MWTP quality system; and
- To ensure that adequate resources (including FTEs, contractor support, and travel funds) are provided to implement the MWTP QMP.

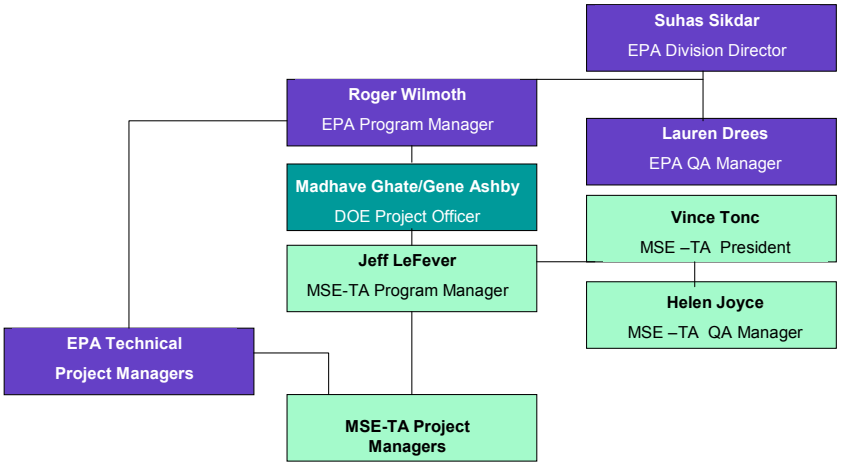

Figure 1. MWTP Organization Chart Including QA Personnel

1.3 QA Organization for MWTP

The QA organization for the MWTP is reflected in Figure 1. The EPA MWTP QA Manager (QAM) reports to the STD Division Director and is independent of MWTP activities. The EPA MWTP QA Manager works closely with the EPA MWTP Program Manager and Project Managers to ensure quality requirements are met.

1.4 MWTP QA Roles and Responsibilities

MWTP Program Manager is responsible for:

- Ensuring that EPA quality policy is implemented for the MWTP by including quality responsibilities as described in this QMP in the performance standards of all EPA MWTP Project Managers;
- Promoting (by words, actions, and involvement) the establishment of a quality culture for the MWTP;
- Promoting (by words, actions, and involvement) continuous quality improvement for the MWTP;
- Providing adequate resources (including full-time equivalents [FTE], contractor support, and travel) for the operation of the MWTP quality system;
- Reviewing and approving the MWTP QMP;
- Serving as the ultimate decision maker on unresolved quality issues;
- Preparing responses to findings of QSAs of the Program and submitting responses to the EPA MWTP QA Manager to ensure that all unresolved QA issues are adequately addressed.

STD Division Director is responsible for:

- Ensuring that the MWTP QA system is implemented by including quality responsibilities as described in this QMP in the performance standards of the EPA MWTP Program Manager;
- Reviewing and approving the MWTP QMP;
- Assigning an EPA MWTP QA Manager who is independent of Program activities.

EPA MWTP Project Managers are responsible for:

- Ensuring the development of QAPPs consistent with NRMRL policy for all MWTP projects that involve the collection or generation of primary and/or secondary data (Secondary data are environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended.);

- Ensuring that all project participants agree to the project objectives and planned experimental approach before the QAPP is submitted for QA review;

- Ensuring that all environmental data collection, evaluation, and use do not proceed until there is an approved QAPP;

- Ensuring that the approved QAPP is implemented and that significant changes (those that may or do affect the quality of data, the scope of the project, or the successful completion of the project) to the approved QAPP are documented and approved before the change is implemented;

- Ensuring that MWTP final reports are reviewed by the EPA MWTP QA Manager and approved prior to publication;

- Requesting or cooperating with any project-specific audits as required in Section 9.1; and

- Ensuring that responses are prepared to audit or review (QAPP, final report) findings;

- Ensuring that corrective action procedures are initiated in a timely manner and issuing documentation to QA Manager of all corrective actions;.

EPA MWTP QA Manager is responsible for:

- Reviewing and approving QAPPs, SOPs, and final reports;

- Entering quality document tracking information into the QA tracking system;

- Managing QA support contracts;
- Performing assessments as listed in Section 9.1 and preparing reports for submission to the EPA MWTP Project Managers and EPA MWTP Program Manager;

- Reporting issues regarding MWTP quality system noncompliance to the EPA MWTP Program Manager for further action when resolution cannot be made at the project level;

- Negotiating whenever there is disagreement to the proposed resolution to an audit or review (QAPP, final report) finding.

1.5 Activities, Programs and Legislative Acts Supported by the MWTP Quality System

The MWTP quality system supports a wide variety of technical activities and programs. These include:

- Implementation of the Mine Waste Technology Program as mandated by Congress
- The conduct of appropriate research, both basic and applied, to perform the mission of the program
- Conformance with the requirements of the Clean Water Act
- Conformance with the Hazardous Waste Act
- Conformance and assistance under the Superfund Act
- Technical transfer and outreach to disseminate research results
- Technical support to EPA Regions and to State and other Federal Agencies.

2.0 Quality System and Description

2.1 Graded Approach to Research Projects

Quality Assurance Project Plans (QAPPs) must be prepared to document QA/QC requirements for all MWTP research projects as for all NRMRL projects.

The NRMRL quality system "graded approach" is used for MWTP projects. Under the graded approach, the intended use of the data dictates the required level (or category) of quality. The graded approach utilizes four (4) QA categories for research projects. The four QA categories are:

Category I establishes QAPP requirements for projects involving enforcement activities, litigation, or research projects involving human subjects;

Category II establishes QAPP requirements for projects supporting the development of environmental regulations or standards;

Category III establishes QAPP requirements for projects involving

applied research or technology evaluations; and

Category IV establishes QAPP requirements for projects involving basic research or preliminary data gathering activities.

For both Category I and Category II projects, EPA MWTP follows, in its entirety, the R-5 document for QAPP preparation developed by EPA's Quality Staff (QS) (http://www.epa.gov/quality/qs-docs/r5-final.pdf). For Category III and IV projects, a subset of applicable R-5 requirements is utilized. The requirements used for Category III (applied research) and Category IV projects (basic research) are presented in Attachment A. QAPP requirements are also presented in Attachment A for projects involving the use of secondary data, sampling and analysis, and modeling and software development. (In some cases, these types of projects may be designated Category I or II; additional requirements in R-5 would then be applicable.) As guidance, the requirements in Attachment A include short descriptions of the applicable types of research.

The required quality level (or category) and associated QAPP requirements are determined by the EPA MWTP Project Manager at the beginning of a project. The EPA MWTP QA Manager should be consulted, if needed.

2.2 Quality-Affecting Activities

NRMRL's data generating research and testing activities always require QA oversight. However, for the MWTP, NRMRL's responsibilities involve the oversight of the activities performed by or for MSE-TA. It is important that EPA ensure that quality requirements are met during the planning, implementation, and reporting of MWTP research. Additionally, MSE-TA activities include other functions that may not always be attributed to project-specific efforts, such as the use of in-house data and software systems and the procurement of quality items and services. EPA ensures that these quality-affecting activities are addressed in the MSE-TA MWTP Quality Management Plan (QMP).

2.3 Principal Components of the EPA MWTP Quality System

The following are the principal components of the EPA MWTP quality system.

2.3.1 EPA MWTP Quality Management Plan

This EPA MWTP Quality Management Plan documents the EPA MWTP quality system and encompasses the management and technical activities necessary to plan, implement, and assess the effectiveness of QA and QC operations applied to all MWTP research projects. The EPA MWTP Program Manager is responsible for the development of the EPA MWTP QMP, although its preparation is normally delegated to the EPA MWTP

QA Manager. The QMP must be approved and signed by the STD Division Director, the EPA MWTP Program Manager, and the EPA MWTP QA Manager. In order to ensure that EPA MWTP Project Managers understand MWTP requirements, their concurrence signatures are required. The EPA MWTP QMP is reviewed annually by the EPA MWTP QA Manager and updated as needed. The approved QMP is valid for five years unless there is a significant change in the organization or in the procedures used. After five years or a significant change, the QMP is reviewed and revised as needed and subjected to the same approval processes described above.

2.3.2 QAPPs

QAPPs are prepared by MSE-TA/Montana Tech as described in Section 2.1. The QAPPs are reviewed and approved by the EPA MWTP Project Manager and QA Manager. Data collection activities should not begin until these approvals are obtained.

2.3.3 Assessments

Assessments are scheduled based on required periodic review, the importance of or public interest in the project or Program, problems in the measurement system (noted by the Project Manager or QA Manager), requests by the Project Manager or Program Manager, or selection by the QA Manager. The assessments planned by the Project Manager at the beginning of a project are specified in the QAPP. Specific requirements regarding assessments are presented in Section 9.0.

2.3.4 QA Review of Research Products

Final product reviews are conducted to evaluate the credibility of data, realization of project goals, comparability of data, validity of conclusions, and quality of data. MWTP reports should be subjected to a technical review by the EPA MWTP Project Manager and a quality review by the QA Manager prior to publication.

2.3.5 Computer Tracking System

A computer tracking system for the various elements of the quality system is in place in STD and is maintained by the QA Manager. This system tracks funding packages, QAPPs, QMPs, SOPs, audits, and project reports.

3.0 Personnel Qualifications and Training

The training requirements specified in the NRMRL QMP are applicable to MWTP activities. It is the policy of NRMRL that all persons managing or directing NRMRL projects have appropriate training for their assigned work. Training needs may be identified by EPA regulation (*e.g.*, requirements for project officer training), by those persons planning a technical activity (*e.g.*, TLP), or by those managing persons performing a technical activity (*e.g.*, branch chiefs or team leaders). Training programs are generally designed by the persons providing the training.

The process for specifying and documenting intramural training varies with the type of training:

- Technical Training - Documentation of technical training may be an appropriate degree in an area of study. Other documentation of technical training may include professional certifications (*e.g.*, Professional Engineer or PE) or certification of specialized training (*e.g.*, classes in computer applications or instrument operation as provided by technology vendors). Other specialized training requirements established by the project officer/principal investigator/TLP for a given NRMRL project may be described in the QAPP document or facilities manual. General technical training needs for branch, facility, or team members may also be identified by NRMRL managers. Each employee is responsible for submitting his/her training records to the Division's Human Resources Management representative who keeps a record of each NRMRL employee's formal technical training.

- Project Management Training - For extramural project management, NRMRL adheres to the Agency's requirements regarding initial and ongoing training, including requirements for training as Project Officer, Work Assignment Manager, and/or Contract Administrator. The Human Resources Management Division keeps records of project management training for NRMRL personnel. A certification that the designated EPA extramural project manager or work assignment manager has the appropriate management training is also required as part of each funding package.

- Quality System Training - Training in NRMRL's Quality System policies and procedures is planned and performed by NRMRL's QA staff. NRMRL has a Policy requiring mandatory training in NRMRL's quality system for all NRMRL management and technical personnel. The QAMs will retain copies of the training certificates. Additional training needs are usually identified by the QA staff through interactions with NRMRL technical and managerial staff. Quality training is generally designed to: (1) inform NRMRL staff of new QA policies

and procedures, (2) refresh and remind NRMRL staff of current QA policies and procedures, or (3) describe services provided by the NRMRL QA staff (metrology, document review, technical assistance).

- Safety Training - EPA specifies that personnel involved in laboratory or field activities receive appropriate safety training. The type and amount (hours) of training depend on the specific assignment and the nature of the potential hazards. Training requirements are specified by line managers and compliance with training requirements is monitored by Division/locality Safety Officers and other health and safety office personnel.

- Records Management Training - Every EPA employee has responsibility for records management. Each employee is responsible for creating records necessary to document their activities and actions, filing records for safe and efficient retrieval, and disposing of records only in accordance with agency directives and Federal regulations.

  To assist employees and contractors with their records management responsibilities, each location has a Records Management Officer (RMO) who will assist personnel with the implementation of the agency's National Records Management Program (NRMP). Further training and assistance are available online at intranet.epa.gov/records/training/index.htm.

4.0 Procurement of Services

NRMRL and EPA policies require that parties to assistance agreements shall have in place a quality system consistent with EPA requirements. Assistance agreements include grants, cooperative agreements, and interagency agreements (IAGs). Other extramural agreements covered by this policy include Cooperative Research and Development Agreements (CRADAs). Compliance with this policy is achieved by including appropriate written requirements into agreement documents.

4.1 Scope and Application

The EPA MWTP Program utilizes an interagency agreement (IAG) with the U.S. DOE. For IAGs, funding actions include the initial award funding and any modifications that add additional funds. For each funding action, the EPA MWTP Program Manager (or designee) must incorporate a completed Quality Assurance Planning Requirement (QAPR) form into the funding package (see Attachment B). The completed package is reviewed by the EPA MWTP QA Manager to ensure that appropriate requirements are included.

Typically, the QAPR form will include the requirement for a QMP, as well as

QAPPs for each project. All QAPP types will be marked as possibly being required during the course of the IAG. The requirements for QAPPs (see Attachment A) are included in the IAG package.

4.2 QA Responsibilities on IAGs

If work on a project will be performed by EPA and one or more other organizations, the responsibility for QA must be negotiated within the agreement. The Program Manager, in consultation with the QA Managers in the various organizations must agree on and document (in the agreement and on a QAPR Form for Initial Extramural Actions) which organization will take the lead for QA, the specific person from the organization who will be responsible, and the QA requirements that will be adhered to during the agreement. For the MWTP, EPA assumes the lead for quality and establishes the quality requirements.

4.3 Evaluation of Quality Deliverables

In order to ensure that MSE-TA provides quality services that satisfy MWTP QA/QC requirements, the MWTP QA Manager and Project Managers review QAPPs, SOPs, and final products, and audit projects and programs. Review/audit comments generated by the QA Manager (or designee) are provided to the Project Manager who is ultimately responsible for the quality of services provided.

5.0 Documentation and Records

The following is a discussion of MWTP procedures for documents and records, including computer-resident records. Records shall be maintained by the Project Manager so that all MWTP activities can be reconstructed. MWTP shall comply with EPA Records Management Policy.

5.1 EPA Records Management Policy

EPA records management policy is established by Office of Information and Resources Management and documented in the EPA Records Management Manual 2160. This procedure applies to all records, as defined under the Federal Records Act (44 U.S.C. 3101), regardless of media (including paper, microform, electronic, audiovisual, and record copies of Agency publications). All locations of NRMRL comply with EPA records management policy.

The management process that ensures that records accurately reflect completed work and/or fulfill statutory and contractual requirements, including any specific record keeping requirements is defined in EPA Order 2160 and EPA Directive 2100, Chapter 10. This document defines requirements and responsibilities for

record transmittal, distribution, retention, protection, preservation, traceability, disposition, and retrievability and includes the roles and responsibilities for management and staff. Following this EPA Order 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 the organization. NRMRL has a designated Records Management Officer and each Division has a person designated as the Records Liaison.

5.2 MWTP Program Documentation and Records

The EPA MWTP Program Manager is responsible for maintaining the following records:

- IAG documents
- Technical proposals (including peer review comments)
- Program quality assessment reports and responses
- Program correspondence documentation
- Budget issues and documentation

5.3 MWTP Project Documentation and Records

Documentation developed on a project-specific basis is the responsibility of the EPA MWTP Technical Project Monitors and is subject to EPA records management policy. The EPA MWTP Technical Project Monitors are responsible for maintaining the following records:

- QAPPs
- Final Reports (including peer review comments)
- Project quality assessment reports and responses
- Project correspondence documentation

When a project is completed as determined by the Project Manager, the project file is archived. This is accomplished by the Project Manager in conjunction with the Division's Records Liaison.

5.4 Research Laboratory-Specific Documentation and Records

NRMRL requires that documentation and records that may not be directly applicable to individual projects, (*e.g.*, refrigerator temperature logbooks, instrument logbooks, standard preparation logbooks, SOPs, balance calibration logbooks) also be maintained to support project results. EPA MWTP ensures that MSE-TA MWTP documentation (QMP, QAPPs) includes requirements for the generation and maintenance of this documentation.

5.5 Software Documentation and Records

NRMRL is required to maintain software quality documentation and records. EPA MWTP ensures that MSE-TA MWTP documentation (QMP, QAPPs) includes requirements for the generation and maintenance of this documentation.

5.6 NRMRL Quality Documentation and Records

The EPA MWTP QMP shall be controlled by the STD QA Office. Although the QA Manager may keep copies, records of reviews of QAPPs, SOPs, and final reports are the responsibility of the Project Manager.

6.0 Computer Hardware and Software

NRMRL, including MWTP, follows guidance published by the Office of Information Resources Management (OIRM) to ensure that computer hardware and software used in environmental programs meets technical requirements and quality expectations. Specific guidance includes:

EPA Directive 2100, Information Resources Management Policy Manual (http://www.epa.gov/irmpoli8/polman/), and

EPA Directive 2182, System Design and Development Guidance (http://www.epa.gov/irmpoli8/sysdesn/).

These comprehensive guidance documents address many issues regarding the use of computer systems, including development of software, design of databases, records management, security, and data standards.

EPA MWTP ensures that the MSE-TA QMP adequately addresses technical and quality requirements for computer hardware and software.

Project-specific requirements for hardware configurations and for configuration control are specified in specific project QAPPs. Project-specific requirements and plans for software testing, validation, and documentation are also described in the QAPPs for those projects.

7.0 Planning

It is the policy of NRMRL that systematic planning shall occur for all NRMRL research projects, including MWTP projects. Planning documents (including QAPPs) appropriate to the scope are developed.

NRMRL has established minimum requirements for various categories of QAPPs (see Attachment A). These requirements are also applicable to MWTP research. For projects that require original environmental data collection and/or sampling and analysis or use of secondary data, a graded approach (See Section 2) is in place. The overall intent is to allow flexibility, while still meeting NRMRL's interpretation of Agency policy for QA.

Effective quality planning requires clear identification of project goals and intended use of data. The EPA MWTP Project Manager, in consultation with project participants, determines the appropriate QAPP requirements to be used. The EPA MWTP Program Manager and/or QA Manager can be consulted if necessary.

It is the EPA MWTP Project Manager's responsibility to ensure that MSE-TA identifies and involves any and all appropriate sponsoring organizations, responsible official(s), project personnel, stakeholders, scientific experts, *etc.* (*e.g.*, all customers and suppliers) in the planning of the project. This includes research performed by Montana Tech under contract to MSE-TA. Once the planning is complete, project documentation should include (at a minimum) a complete description of the following:

- The project's goals, objectives, questions, and issues to be addressed;
- The project's schedule, resources (including budget), milestones, and any applicable requirements (*e.g.*, regulatory requirements, contractual requirements);
- The type of data needed and how the data will be used to support the project's objectives;
- The quantity of data needed and the specification of performance criteria for measuring data quality;
- How, when, and where the data will be obtained (including existing data) and identification of any constraints on data collection;
- Specifications of needed QA/QC activities to assess the quality performance criteria (*e.g.*, QC samples for both the field and laboratory, audits, technical assessments, performance evaluations, *etc.*);
- How the acquired data will be analyzed (either in the field or the laboratory), evaluated (*i.e.*, QA review, validation, verification), and assessed against the quality performance criteria and for its intended use.

Once all project planning is complete and documented, it is the EPA MWTP Project Manager's responsibility to submit the QAPP to the EPA MWTP QA Manager. The QA Manager performs a review against QAPP requirements and issues documentation to indicate whether planning requirements have been met and an assessment of whether

project goals can be met. (If deemed necessary by the QA Manager, a statistical review of the experimental design may also be requested. The QA Manager typically arranges for this review.) The documentation from the QA Manager shall include either an approval or a nonapproval. In the case of non-approval, detailed review comments shall be provided to the Project Manager. Resolution of all findings shall be accomplished and documented before any research is started.

8.0 Implementation of Work Processes

Once proper planning has been performed (as described in Section 7), it is important that the implementation of the required procedures be done. It is the responsibility of the EPA MWTP Project Manager to ensure that the required procedures are properly implemented by MSE-TA/Montana Tech and that the necessary reviews are performed.

8.1 QAPP Development, Review, and Approval

MSE-TA/Montana Tech develops a QAPP based on NRMRL guidance (see Section 2). The QAPP must be reviewed and approved by the EPA MWTP Project Manager and QA Manager before the project begins. QA comments are documented in a memo to the EPA MWTP Project Manager, with copies to the EPA MWTP Program Manager, and the MSE-TA/Montana Tech Project Manager and QA Manager, as applicable. The EPA MWTP Project Manager has final approval of the QAPP, once he/she determines that all technical and QA comments are adequately addressed.

8.2 SOP Development

In some instances, procedures for sampling, analysis, or other quality activity (*e.g.*, standards preparation) are routine and are used for more than one project. Oftentimes, it is necessary that more than one person perform a procedure. In these cases, an SOP should be written. SOPs are also recommended for special or critical operations. SOPs can make the development of QAPPs more efficient, since they can be attached or referenced. The need for the development of an SOP is determined by the EPA MWTP Project Manager. Project-specific SOPs are reviewed by the EPA MWTP Project Manager and QA Manager during QAPP review. EPA MWTP ensures that SOP preparation procedures are adequately described in the MSE-TA QMP.

8.3 QAPP/SOP Implementation

It is the responsibility of the EPA MWTP Project Manager to ensure that the required procedures specified during the planning process for a specific project are implemented during data collection activities. This is done through regular

discussions with MSE-TA/Montana Tech personnel, as applicable, by personally observing the procedures being performed, or by requesting that the EPA MWTP QA Manager perform an audit of the project activities outlined in a QAPP and/or SOP. In any case, deviations from project requirements must be documented, along with the corrective action performed. Corrective action must be performed as soon as possible to minimize any effect on data quality. If data quality is affected by any deviations, this must be discussed in any project report/paper.

8.4 QAPP/SOP Revisions

During the course of a project, it may be necessary that QAPPs and/or SOPs be revised. Revisions are required whenever a significant change in the plan or procedure occurs. Over time, it may also be necessary to revise QAPPs and/or SOPs to ensure they are still applicable for the work being performed. For long-term projects, QAPPs and project-related SOPs need to be reviewed on a yearly basis for long term projects. Revisions (as necessary) in the form of an addendum or fully revised document must be made as soon as a significant change is identified. The EPA MWTP Project Manager is responsible for ensuring that the required revisions are performed.

Significant revisions to a QAPP/SOP must be reviewed and approved by the EPA MWTP QA Manager. Copies of the most current document must be made available to the appropriate project/Program personnel. All previous document versions must be archived.

9.0 Assessment and Response

NRMRL conducts a variety of assessments at the NRMRL-wide, Division, and project-specific level to provide an increased understanding of the program or system being examined, and to provide a basis for improving such programs or systems. The following discussion identifies the assessments which are performed by or for EPA in support of the MWTP. The required frequencies, the assessor capabilities, and the procedures for documenting and responding to assessments is also presented.

9.1 Types of Assessments

The following assessments are performed in support of the MWTP.

9.1.1 Quality Systems Audits

A quality systems audit (QSA) is an on-site review of the implementation of an organization's quality system as documented in the organization's approved QMP. This review is used to verify the existence of, and

evaluate the adequacy of, the internal quality system.

The EPA MWTP QA Manager will perform an internal QSA of the MWTP Program every three years to assess the implementation of this QMP. The EPA MWTP QA Manager will perform an independent QSA of the MSE-TA quality system every three years to assess the implementation of the MSE-TA QMP.

9.1.2 Technical Systems Audits

A technical systems audit (TSA) is a qualitative on-site evaluation of sampling and/or measurement systems. The objective of the TSA is to assess and document acceptability of all facilities, maintenance, calibration procedures, reporting requirements, sampling and analytical activities, and quality control procedures. Normally, an approved QAPP provides the basis for the TSA. TSAs are most often scheduled by the Project Manager and conducted by the QA Manager (or designee). Assistance for TSAs is available from QA support contractors. TSAs are most useful when conducted early in the life cycle of a project when corrective actions (if necessary) can be performed that will minimize any loss of data. However, a TSA can be performed any time during a project's life cycle.

For MWTP, TSAs are required for all Category I & II projects. For Category III & IV projects, at a minimum, the EPA MWTP QA Manager will perform two TSAs each year. The identification of the projects which will be audited will be made by the EPA MWTP Program Manager.

9.1.3 Audits of Data Quality

An audit of data quality (ADQ) is an examination of data after they have been collected and verified by project personnel. Assessing whether the Data Quality Indicator (DQI) goals specified in the QAPP were met requires a detailed review of the recording, transferring, calculating, summarizing, and reporting of the data. ADQs will be performed by the EPA MWTP QA Manager, or designee, if requested by the EPA Project Manager or Program Manager.

9.1.4 Performance Evaluations

A performance evaluation (PE) is a quantitative evaluation of a measurement system. Although each measurement in a test program could be subjected to a performance evaluation, the critical measurements (designated in the QAPP) are more commonly evaluated. An evaluation

of a measurement system usually involves the measurement or analysis of a reference material of known value or composition. The value or composition of reference materials must be certified or verified prior to use, and the certification or verification must be adequately documented. Ideally, the identity of the reference material is disguised so that the operator or analyst will treat the material no differently than a test program sample. PEs will be submitted to MSE-TA by the EPA MWTP QA Manager, or designee, if requested by the EPA Project Manager or Program Manager.

9.1.5 Data Quality Assessments

A Data Quality Assessment (DQA) is a scientific and statistical evaluation to determine if validated data obtained from environmental data operations are of the right type, quality, and quantity to support their intended use. The DQA process is described in Guidance for Data Quality Assessment, Practical Methods for Data Analysis, EPA QA/G-9, QA97 Update, EPA/600/R-96/084, July 2000, available at http://www.epa.gov/quality/qa_docs.html. For MWTP projects, these assessments are normally conducted by the MSE-TA Project Manager, and they should be performed routinely on all projects. The EPA MWTP Project Manager should verify that these data quality assessments are performed.

9.2 Peer Review

In NRMRL, peer review is a separate function from QA. All MWTP final reports must be subjected to peer review during the EPA clearance process. Two independent reviews are required. Reviewers should not be involved in the specific project being reviewed, and should be technically knowledgeable in the subject matter. The EPA MWTP Project Manager is responsible for ensuring that these reviews are performed and that peer review comments are adequately addressed.

9.3 Assessor Capabilities and Authority

Assessors should be thoroughly familiar with QA practices, policies, and procedures. The optimal assessment team consists of a QA professional, a person with expertise in the technical area being evaluated, and, if there are complex issues regarding experimental design or data analysis, a statistician. In many cases, a QA staff member can fill more than one role.

Assessors evaluate MWTP projects under the authority of and with the permission of the EPA MWTP Project Manager and Program Manager. Assessors do not

have the direct authority to change project procedures or to alter project goals. Their role is to provide information to the Project Manager as to the best practices and to clearly point our errors observed in the implementation of the QAPP. These errors may be in technical procedures, in data archival or analysis, in project management or reporting, or in any aspect of a project that impacts the data quality.

9.4 MWTP Assessment and Response Procedures

The EPA MWTP QA Manager is responsible for planning, scheduling, and conducting assessments, as required by this QMP or requested by MWTP management. The EPA MWTP QA Manager may be assisted in the performance of assessments by QA support contractors. At the conclusion of each assessment, the assessment report shall include a description of the type of corrective actions required to resolve any findings of nonconformance to MWTP quality policy as specified in this QMP and project-specific documents.

9.5 "Stop Work" Order

QA staff members are often on-site and able to interact directly with project personnel. If a QA staff member observes work practices which could have serious adverse impacts on data quality, the QA staff member should promptly notify the EPA MWTP Project Manager.

9.6 Assessment Reports and Corrective Action

For QSAs and TSAs, on-site assessments are followed up by a debriefing to the auditee and EPA MWTP Project Manager (if available) at the end of the on-site portion of the evaluation. If the EPA MWTP Project Manager is not present at the debriefing, then assessments are also followed up by a verbal or brief written summary to the EPA MWTP Project Manager on the first working day after the completion of the on-site portion of the audit.

The general format for assessment reports is:

- Cover page (assessment identification)
- Summary (brief discussion of findings, those issues that require corrective action)
- Assessment procedures
- Assessment results (detailed accounting of findings and other observations)
- Discussion (impact of findings)

- Appendices (checklists, protocols, other data)

Assessment reports are generated by the assessor within three business days after completion of the assessment. Reports are sent as drafts to the EPA MWTP Project Manager and EPA MWTP QA Manager (if not the assessor) for review. After finalization of the report by the EPA MWTP QA Manager, the final assessment report is submitted to the EPA MWTP Project Manager, the EPA MWTP Program Manager, and the auditee.

It is the responsibility of the EPA MWTP Project Manager to ensure that MSE-TA and/or Montana Tech adequately resolve audit findings. If findings cannot be resolved by the EPA MWTP Project Manager, the EPA MWTP Program Manager's assistance is requested. The file on a given audit is maintained in active status until all findings are resolved and documented. Audit reports are then archived in the EPA MWTP Project Manager's project files.

10.0 Quality Improvement

All of the policies and procedures described in this manual were developed to document QA planning for the MWTP. Two levels of quality improvement processes combine to evaluate the effectiveness of the NRMRL quality system and ensure continual quality improvement. At the QA Program level, QSAs discussed in Section 9.4 are performed by the EPA MWTP QA Manager. Any problems or areas where quality improvement can be made are identified and reported to the EPA MWTP Program Manager, who is responsible for implementing the necessary corrective action. At the Project QA level, the document reviews and audits discussed in Sections 8.0 and 9.0 are conducted to evaluate proposed procedures and their implementation. Any problems or areas where quality improvement can be made are identified and reported to the EPA MWTP Project Manager, who is responsible for implementing the necessary corrective action. In addition, all project personnel are responsible for quality improvement activities with respect to their particular roles.

Finally, it is the responsibility of the designated EPA MWTP QA Manager to monitor the quality procedures which are implemented on a day-to-day basis. This is done via audits, discussions with project managers, and involvement in the implementation of the quality system.

If possible, the cause of any identified problem will be determined before corrective action is determined. The corrective action shall be planned, documented, agreed upon, and implemented to minimize the effect on program/project quality.

11.0 References

NRMRL Quality Management Plan, March 2002.

EPA Requirements for Quality Management Plans, EPA QA/R-2, EPA /240/B-01/002, March 2001,OEI, Washington, D.C.

Guidance for the Data Assessment, Practical Methods for Data Analysis, EPA QA/G-9, QA00 Update, EPA /600/R-96/084, July 2000, OEI, Washington, D.C.

Attachment A

PLANNING DOCUMENT REQUIREMENTS AND GUIDANCE

PLANNING DOCUMENT REQUIREMENTS AND GUIDANCE

For Category I (enforcement, litigation, or projects involving human subjects) and Category II (development of environmental regulations or standards), NRMRL's requirements are those listed in *EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations, EPA QA/R-5*, EPA/240/B-01/003, March 2001. *Guidance for Quality Assurance Project Plans, EPA QA/G-5*, EPA/600/R-98/018, February 1998 may be used to help address these requirements. (These documents are available at http://www.epa.gov/quality/)

QAPP requirements for Category III (Applied Research) and Category IV (Basic Research) are presented in this appendix. *Guidance for Quality Assurance Project Plans, EPA QA/G-5*, EPA/600/R-98/018, February 1998 referenced above may be used to help address the requirements listed for Category III and IV QAPPs; however, only the requirements listed in this appendix need to be addressed.

QAPP requirements for Sampling and Analysis Projects, Secondary Data Research Projects, Methods Development Projects, and Software and Data Management Projects are also presented in this appendix. Requirements for modeling projects are currently under development. (See your QAM if you need these requirements.)

For projects involving design, construction, and/or operation of environmental technology, the requirements in Part C of "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology," ANSI/ASQC E4-1994, American Society for Quality Control, Milwaukee, WI, January 1995 will be followed.

The requirements for QMPs submitted to NRMRL in response to solicitations are also presented in this appendix.

QAPP REQUIREMENTS FOR SAMPLING AND ANALYSIS PROJECTS

A sampling and analysis activity or project is typically defined as a study performed to generate data to either monitor parameters on a routine basis or to characterize a particular population for later studies. The following requirements should be addressed as applicable.

SECTION 1.0, PROJECT DESCRIPTION AND ORGANIZATION

1.1 The purpose of the study shall be clearly stated in the sampling and analysis plan (SAP).

1.2 Responsibilities and points of contact for each organization shall be identified in the SAP. This should include identification of key personnel and/or organization(s) responsible for sample collection and custody, analytical and/or process measurements, data reduction, report preparation, and quality assurance.

SECTION 2.0, SAMPLING

2.1 Sampling points for all measurements (*i.e.*, analytical, physical, and process, including locations and access points) shall be identified in the SAP whenever possible. If the specific locations cannot be identified at the time of plan generation, discuss the documentation and/or communication mechanism(s) for ensuring adequate information is captured to later identify sampling points.

2.2 The anticipated sampling frequency (*e.g.*, how many sampling events and how often events occur), the number of sample types (*e.g.*, metals, VOCs, SVOCs, *etc.*), and the minimum number of samples of each type taken at each event shall be provided.

2.3 The expected measurements (*i.e.*, specific analytes) planned for each sample type shall be summarized.

2.4 If applicable, known site-specific factors that may affect sampling procedures shall be described.

2.5 If applicable, any site preparation (*e.g.*, sampling device installation, sampling port modifications) needed prior to sampling shall be described.

2.6 Each sampling procedure (including a list of equipment needed and the calibration of this equipment as appropriate) to be used shall be discussed or referenced. Maintenance requirements/procedures (as appropriate) must also be addressed in this section.

2.7 If compositing or splitting of samples is planned, the applicable procedures shall be described.

2.8 A list of sample quantities to be collected, and the sample amount required for each analysis, including QC sample analysis, shall be specified.

2.9 Containers used for sample collection, transport, and storage for each sample type shall be described.

2.10 Sample preservation methods (*e.g.*, refrigeration, acidification, *etc.*) shall be described.

2.11 Requirements for shipping samples shall be described.

2.12 Holding times requirements shall be noted.

2.13 Procedures for tracking samples in the laboratory and for maintaining chain-of-custody when samples are shipped shall be described. COC procedures shall be described to ensure that sample integrity is maintained (labeling, seals, records).

2.14 Information to be recorded and maintained by field personnel shall be discussed.

SECTION 3.0, TESTING AND MEASUREMENT PROTOCOLS

3.1 Each analytical method to be used shall be referenced. This includes EPA-approved and other validated nonstandard methods.

3.2 If applicable, modifications to EPA-approved or other validated nonstandard methods shall also be described.

SECTION 4.0, QA/QC CHECKS

4.1 The SAP shall list and define all calibrations and QC checks and/or procedures used for the project, both field and laboratory as needed..

4.2 For each specified calibration, QC check, or procedure, required frequencies and acceptance criteria shall be included.

SECTION 5.0, DATA REDUCTION AND REPORTING

5.1 Data reduction procedures specific to the project, and also specific to each organization, shall be summarized.

5.2 The reporting requirements (*e.g.*, units, reporting method [*e.g.*, wet or dry]) for each measurement and matrix shall be identified.

SECTION 6.0, REPORTING REQUIREMENTS

The deliverables expected from each organization responsible for field and/or analytical activities shall be described.

QAPP REQUIREMENTS FOR BASIC RESEARCH PROJECTS

A basic research project is a study performed to generate data used to evaluate unproven theories, processes, or technologies.

SECTION 1.0, PROJECT OBJECTIVES AND ORGANIZATION

- State the project objectives.

1.2 Identify the responsibilities of all project participants (e.g., QAPP preparation, sample collection and analyses, data reduction/validation/analysis, report preparation, QA).

SECTION 2.0, EXPERIMENTAL APPROACH

2.1 Describe the process, site, facility, apparatus, and/or environmental system to be tested.

2.2 Describe all known or pre-established test conditions and variables, including replicate experimental runs.

2.3 Describe the planned approach (statistical and/or non-statistical) for evaluating project objectives (i.e., data analysis).

SECTION 3.0, SAMPLING AND MEASUREMENT APPROACH AND PROCEDURES

3.1 Complete a table similar to the following to summarize the experimental sampling strategy to be used.

Sample/Measurement Location	Matrix	Measurement	Frequency	Experimental QC[1]	Total No. Samples

[1]QC samples generated during experiment, as applicable (e.g., blanks, replicate samples, spikes)

3.2 Complete a table similar to the following to summarize the experimental sampling and analytical procedures to be used.

Matrix	Measurement	Sampling/ Measurement Method[1]	Analysis Method[1]	Sample Container/ Quantity of Sample	Preservation/ Storage	Holding Time(s)[2]

[1]Provide details in text, as necessary, if standard method or SOP cannot be referenced
[2]Both to extraction and analysis, if applicable

SECTION 4.0, QA/QC CHECKS

Complete a table similar to the following to summarize QA/QC checks.

Matrix	Measurement	QA/QC Check[1]	Frequency	Acceptance Criteria	Corrective Action

[1]Include all QA/QC checks (experimental and analytical, as applicable) for accuracy, precision, detection limits, mass balance, etc. (e.g., matrix spikes, lab control samples, blanks, replicates, surrogates)

SECTION 5.0, DATA REPORTING

Describe data reduction procedures specific to the project.

SECTION 6.0, REFERENCES

Provide references to methods and germane prior publications.

IN ADDITION, WHEN APPLICABLE...

- If bulk sample(s) will be collected in the field for use in laboratory experiments, include applicable information from Section 2.0 of *QAPP Requirements for Sampling and Analysis Projects*.
- List all project-specific target analytes (i.e., when a class of compounds is specified in the table).
- Indicate if reporting is on a wet or dry weight basis (solid matrices only).
- Describe the method used to establish steady-state conditions.
- Describe how sampling equipment is calibrated.
- Describe how cross-contamination between samples is avoided.
- Describe the procedures used to collect representative samples.
- Describe sample packing and shipping procedures.
- Describe instrument calibration procedures and acceptance criteria if not included in a referenced method or SOP.

QAPP REQUIREMENTS FOR APPLIED RESEARCH PROJECTS

An applied research project is a study to demonstrate the performance of technologies under defined conditions. These studies are often pilot- or field-scale. The following requirements should be addressed as applicable.

SECTION 0.0, DISTRIBUTION LIST

A distribution list shall be provided to facilitate the distribution of the most recent current version of the QAPP to all the principal project participants.

SECTION 1.0, PROJECT DESCRIPTION AND OBJECTIVES

1.1 The purpose of study shall be clearly stated.

1.2 The process, site, facility, and/or environmental system to be tested shall be described.

1.3 Project objectives shall be clearly stated and identified as primary or non-primary.

SECTION 2.0, PROJECT ORGANIZATION

2.1 Key points of contact for each organization involved in the project shall be identified.

2.2 All QA Managers and their relationship in the organizations (*i.e.*, location within each organization) shall be identified with evidence that the QA Manager is independent of project management.

2.3 Responsibilities of all other project participants and their relationship to other project participants shall be identified, meaning that organizations responsible for planning, coordination, sample collection, sample custody, measurements (*i.e.*, analytical, physical, and process), data reduction, data validation, and report preparation shall be clearly identified.

SECTION 3.0, EXPERIMENTAL APPROACH

3.1 The general approach and the test conditions for each experimental phase shall be provided. The statistical methods that will be used to evaluate the data (*i.e.*, ANOVA, or summary statistics) should be identified.

(NOTE: As deemed appropriate to the project by the TLP, the information requested in

Sections 3.2, 3.3, and 3.4 may be presented here or in Section 4; the information requested in Sections 3.5 may be presented here or in Section 5; and the information requested in Sections 3.6 may be presented here or in Section 7.)

3.2 The sampling strategy shall be included and evidence must be presented to demonstrate that the strategy is appropriate for meeting primary project objectives, *i.e.*, a description of the statistical method or scientific rationale used to select sample sites and number of samples shall be provided.

3.3 Sampling/monitoring points for all measurements (*i.e.*, including locations and access points) shall be identified.

3.4 The frequency of sampling/monitoring events, as well as the numbers for each sample type and/or location shall be provided, including QC and reserve samples.

3.5 All measurements (*i.e.*, analytical [chemical, microbiological, assays], physical, and process) shall be identified for each sample type or process, and project-specific target analytes shall be listed and classified as critical or noncritical in the QAPP.

3.6 The planned approach (statistical and/or non-statistical) for evaluating project objectives shall be included.

SECTION 4.0, SAMPLING PROCEDURES

4.1 Whenever applicable, the method used to establish steady-state conditions shall be described.

4.2 Known site-specific factors that may affect sampling/monitoring procedures shall be described.

4.3 Any site preparation needed prior to sampling/monitoring shall be described.

4.4 Each sampling/monitoring procedure to be used shall be discussed or referenced. If compositing or splitting samples, those procedures shall be described.

4.5 For samples requiring a split sample for either QA/QC purposes or for shipment to a different laboratory, the QAPP shall identify who is responsible for splitting samples, and where the splitting is performed (*e.g.*, field versus lab).

4.6 If sampling/monitoring equipment is used to collect critical measurement data (*i.e.*, used to calculate the final concentration of a critical parameter), the QAPP shall describe how the sampling equipment is calibrated, the frequency at which it is calibrated, and the acceptance criteria for calibration or calibration verification, as appropriate.

4.7 If sampling/monitoring equipment is used to collect critical measurement data, the QAPP shall describe how cross-contamination between samples is avoided.

4.8 The QAPP shall include a discussion of the procedures to be used to assure that representative samples are collected.

4.9 A list of sample quantities to be collected, and the sample amount required for each analysis, including QC sample analysis, shall be specified.

4.10 Containers used for sample collection, transport, and storage for each sample type shall be described.

4.11 The method for uniquely identifying each samples shall be described.

4.12 Sample preservation methods (*e.g.*, refrigeration, acidification, *etc.*), including specific reagents, equipment, and supplies required for sample preservation shall be described.

4.13 Holding time requirements shall be noted.

4.14 Procedures for packing and shipping samples shall be described.

4.15 Procedures to maintain chain-of-custody (*e.g.*, custody seals, records) during transfer from the field to the laboratory, in the laboratory, and among contractors and subcontractors shall be described to ensure that sample integrity is maintained.

4.16 Sample archival requirements for each relevant organization shall be provided.

SECTION 5.0, TESTING AND MEASUREMENT PROTOCOLS

5.1 Each measurement method to be used shall be described in detail or referenced. Modifications to EPA-approved or similarly validated methods shall be specified.

5.2 For unproven methods, verification data applicable to expected matrices shall be included in the QAPP meaning the QAPP shall provide evidence that the proposed method is capable of achieving the desired performance.

5.3 For measurements which require a calibrated system, the QAPP shall include specific calibration procedures applicable to each project target analyte, and the procedures for verifying both initial and continuing calibrations (including frequency and acceptance criteria, and corrective actions to be performed if acceptance criteria are not met).

SECTION 6.0, QA/QC CHECKS

6.1 At a minimum, the QAPP shall include quantitative acceptance criteria for QA objectives associated with accuracy, precision, detection limits, and completeness for critical measurements (process, physical, and analytical, as applicable) for each matrix.

6.2 Any additional project-specific QA objectives shall be presented, including acceptance criteria. This includes items such as mass balance requirements.

6.3 The specific procedures used to assess all identified QA objectives shall be fully described.

6.4 The QAPP shall list and define all other QC checks and/or procedures (*e.g.*, blanks, surrogates, controls, *etc.*) used for the project, both field and laboratory.

6.5 For each specified QC check or procedure, required frequencies, associated acceptance criteria, and corrective actions to be performed if acceptance criteria are not met shall be included.

SECTION 7.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

7.1 The reporting requirements (*e.g.*, units, reporting method [wet or dry]) for each measurement and matrix shall be identified.

7.2 The deliverables expected from each organization responsible for field and laboratory activities shall be listed.

7.3 Data reduction procedures specific to the project, and also specific to each organization, shall be summarized.

7.4 Data validation procedures specific to each organization used to ensure the reporting of accurate project data to internal and external clients shall be summarized.

7.5 Data storage requirements for each organization shall be provided.

7.6 The product document that will be prepared for the project shall be specified (*e.g.*, journal article, final report, *etc.*). The contents of this document can be referenced to a NRMRL or program-specific QMP, if appropriate.

SECTION 8.0, ASSESSMENTS

8.1 The QAPP shall identify all scheduled audits (*i.e.*, both technical system audits [TSAs] and performance evaluations [PEs]) to be performed, who will perform these audits, and who will receive the audit reports.

8.2 The QAPP shall provide procedures that are to be followed that will ensure that necessary corrective actions will be performed.

8.3 The responsible party(-ies) for implementing corrective actions shall be identified.

SECTION 9.0, REFERENCES

References shall be provided either in the body of the text as footnotes or in a separate section.

QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

1.1 The purpose of study shall be clearly stated.

1.2 Project objectives shall be clearly stated.

1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.

1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical analysis, if applicable, shall be included.

1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

SECTION 2.0, SOURCES OF SECONDARY DATA

2.1 The source(s) of the secondary data must be specified.

2.2 The rationale for selecting the source(s) identified shall be discussed.

2.3 The sources of the secondary data will be identified in any project deliverable.

SECTION 3.0, QUALITY OF SECONDARY DATA

3.1 Quality requirements of the secondary data must be specified. These requirements must

be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)

3.2 The procedures for determining the quality of the secondary data shall be described.

3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

SECTION 4.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.

4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.

4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

QAPP REQUIREMENTS FOR METHOD DEVELOPMENT PROJECTS

A method development project is typically needed in situations for which there exists no standard or known method, or when an existing method needs to be modified to meet a project-specific need. The following requirements should be addressed as applicable.

SECTION 1.0, BACKGROUND

A description of the situation that requires the generation of a new or modified method shall be clearly stated. *Why are we doing this?*

SECTION 2.0, SCOPE AND APPLICATION

The scope and application of the method shall be clearly stated. Specifically, to what matrices, conditions, *etc.*, will this method apply for this project? What detection limits and/or practical quantitation limits are needed? How is this method intended to be used in the future (*e.g.*, research only, potential regulatory usage, *etc.*)?

SECTION 3.0, PROJECT ORGANIZATION

Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, sample collection, measurements (*i.e.*, analytical, physical, and process), data reduction, data validation (independent of data generation), data analysis, report preparation, and quality assurance.

SECTION 4.0, EXPERIMENTAL APPROACH INCLUDING SAMPLING AND ANALYTICAL SPECIFICATIONS

4.1 A description of the test(s) to be conducted in order to support the development of the method shall be included. All known or preestablished test conditions and variables shall be provided.

4.2 All planned measurements (*i.e.*, analytical [chemical, microbiological, assays, *etc.*], physical, and process) shall be identified, and project-specific target analytes shall be listed.

4.3 Any known restrictions/specifications for sampling (*e.g.*, collecting soil samples from a site or water samples from a port, *etc.*) or subsampling (*e.g.*, mixing sample before taking subsample for analysis, *etc.*) shall be documented. Include specifications for: type and

size of sample containers; amount of sample needed for preparation and analysis; preservation; holding times; representativeness; compositing; QC samples; *etc*.

4.4 The type of instrumentation that will be used and any required instrument conditions shall be documented. Include a discussion of calibration and calibration verification including frequency, acceptance criteria, and corrective action to be taken if acceptance criteria are not met.

SECTION 5.0, QA/QC CHECKS

Any planned QC checks and criteria that must be met for the method to be considered successful shall be specified. QC checks may include spikes, replicates, blanks, controls, surrogates, *etc*.

Note: For chemical methods, quality control procedures to determine the precision, accuracy, and method detection limit should be described. For microbiological methods, positive and negative control procedures should be described.

SECTION 6.0, METHOD VERIFICATION

The tests that will be used to verify the method's performance once it's been developed shall be specified.

SECTION 7.0, REPORT

The report for a successful method development project will be a method written in a format appropriate for the application *e.g.*, SW-846 for RCRA applications, Standard Methods for bacteria in drinking water, a SOP for a specific application (with supporting method performance data appended), *etc.*

SECTION 8.0, REFERENCES

References shall be provided either in the body of the text as footnotes or in a separate section.

QAPP REQUIREMENTS FOR SOFTWARE AND DATA MANAGEMENT PROJECTS

Types of projects to which this guidance applies include the following: software development, software/hardware systems development, data base design and maintenance, and data validation and verification systems. The QAPP requirements for software development in this appendix do not mandate a particular method for software development. Project managers should choose software development and QA methods best suited to their individual projects within the parameters set forth here. Table D-1 provides a set of alternative QAPP elements for situations in which the elements applicable to measurement projects are not appropriate. The applicability of different elements is based on (1) the QA category and (2) the size or complexity of the task. Projects that involve both measurement and software/systems development should have plans addressing all applicable QA elements. Main issues to consider for inclusion in a QAPP for software and data management are listed in the following sections.
Additional guidance for software and data management projects is available from the QAMs.

SECTION 0.0, APPROVAL BY PROJECT PARTICIPANTS

The EPA Technical Lead Person (TLP) shall be responsible for obtaining signatures of appropriate project participants on the signature page of the QA plan, documenting agreement to project objectives and the approach for evaluating these objectives.

SECTION 1.0, PROJECT DESCRIPTION

This section should provide an overview of the project, its intended uses, quality objectives, schedules and appropriate milestones, information about the hardware and operating systems, and planning documents.

SECTION 2.0, PROJECT ORGANIZATION AND RESPONSIBILITIES

This section should discuss all important intramural and extramural project personnel and should show the relationship between the development team and the personnel responsible for QA and testing.

SECTION 3.0, FUNCTIONAL REQUIREMENTS

This section should provide a list of the most important functions that the software system must address. This section can also state any quantitative or qualitative data quality objectives (DQOs) that might apply to the software.

SECTION 4.0, SYSTEM DESIGN OVERVIEW (HIGH LEVEL DESIGN)

A brief description of the system design is all that is necessary in the QAPP, if additional design documentation is planned.

SECTION 5.0, DETAILED DESIGN

Complex projects and those with significant defensibility requirements should have a detailed design document.

SECTION 6.0, IMPLEMENTATION

Written standard operating procedures (SOPs) for software development should be provided for extremely large and complex software projects. The internal checks applied during development should also be described.

SECTION 7.0, TESTING

The QAPP should outline the testing strategy to be used.

SECTION 8.0, DATA VALIDATION AND VERIFICATION

The QAPP must describe the means for checking the correctness of outputs.

SECTION 9.0, CHANGE CONTROL AND CONFIGURATION MANAGEMENT

This section should describe the procedures for controlling and documenting all significant changes to software and hardware.

SECTION 10.0, AUDITS AND REVIEWS

This section should describe planned assessments, including performance evaluation audits (PEAs), technical systems audits (TSAs), quality systems audits (QSAs), and audits of data quality (ADQs). Additional types of reviews applicable to these projects include peer reviews and beta testing.

SECTION 11.0, MAINTENANCE AND USER SUPPORT

Where software or data generated by the project will be distributed outside NRMRL, maintenance and user support must be addressed.

SECTION 12.0, SYSTEM DOCUMENTATION AND ARCHIVING

Documentation is required for software projects in all QA categories. Table D-2 gives documentation requirements by QA Category.

SECTION 13.0, QA PROGRESS REPORTS TO MANAGEMENT

System development QA and QC results and plans should be reported regularly, particularly in projects in Categories I and II and where contractually required.

TABLE D-1
QA ELEMENTS FOR SOFTWARE AND DATA MANAGEMENT
QAPPS

	QAPP Element	Category Applicability
-	Title/Signature Page	I, II, III, IV
-	Table of Contents	I, II, III
1.	Project Description	
	a. Background	I, II, III, IV
	b. Intended Application for Software	I, II, III, IV
	c. Quality Objectives for Software	I, II, III, IV
	d. Scope of Work	I, II, III
	e. Schedule and Milestones	I, II, III, IV
	f. Facilities Description	I, II, III
	g. Experimental/Test Matrix Design	I, II*, III*
	h. Planning Documents	I, II*, III*
2.	Project Organization and Responsibilities	I, II, III
3.	Functional Requirements	I, II, III
4.	System Design Overview	I, II, III
5.	Detailed Design	I, II*
6.	Implementation	I, II*
	a. Development of SOPs	
	b. QC for Implementation	
7.	Testing	I, II, III, IV*
	a. Individual Module Tests	
	b. Integration Tests	
	c. System Tests	
	d. Retesting after Changes	
	e. Acceptance Testing (if applicable)	
	f. Beta Testing (if applicable)	
8.	Data Validation and Verification	I, II, III, IV*
9.	Change Control and Configuration Management	I, II, III, IV*
10.	Audits and Reviews	I, II*, III*
11.	Maintenance and User Support	I, II, III*
12.	System Documentation and Archiving	I, II, III, IV
13.	QA Progress Reports to Management	I

*These elements may not be applicable for all projects in the specific category.

TABLE D-2
RECOMMENDED DOCUMENTATION FOR ARCHIVING
BY QA CATEGORY

Document	QA Category
QA Project Plan	I, II, III, IV
Requirements Document	I, II, III*
Design Document	I, II, III*
Coding Standards or SOPs	I, II, III*
Source Code with In-line Comments (archived)	I, II, III, IV
User's Manual	I, II, III
Command Summary or Instructions for Use (in lieu of a formal user's manual)	IV
Maintenance Manual or Installation Instructions	
(if source code is distributed outside EPA)	I, II, III, IV
(if source code is not distributed)	I, II*, III*
Data Dictionary	I, II, III
Testing and Validation Procedures and Results	I, II, III*
Backup Source Code and Build Procedures on Computer-readable Media	I, II, III, IV

*Project Officer and QA Manager's option

REQUIREMENTS FOR QUALITY MANAGEMENT PLANS (QMPs)

This quality management plan (QMP) requirements list is applicable to multi-year, multi-project efforts and is based on EPA guidance (http://www.epa.gov/quality/qs-docs/r2-final.pdf). A QMP defines an organization's quality system and documents policies and procedures that will be used to meet customer's quality needs.

Note (1): If a requirement is not applicable, state "not applicable" and provide an explanation regarding why. Note (2): To eliminate redundancy, reference to other sections of the QMP is permissible. Note (3): Ensure that the QMP clearly designates the personnel responsible for performing each procedure described in the QMP.

SECTION 0.0, QMP APPROVAL

An approval page for the signatures of the senior accountable manager, senior line management (as appropriate) and the QA manager of the organization(s) that are part of this program level quality system needs to be provided. Signatures must be obtained prior to submitting the QMP for Agency review.

SECTION 1.0, QUALITY SYSTEM MANAGEMENT AND ORGANIZATION

1.1 **Program Quality Policy.** State the "quality policy," established and implemented by program management, which ensures that this environmental program produces the type and quality of results needed and expected.

1.2 **Program Organizational Structure and Communication**. Describe functional responsibilities (including QA personnel), levels of accountability, authority, and communication for each organization that is part of this program level quality system. Demonstrate that the QA Manager(s) is/are independent of groups generating, compiling, and evaluating environmental data. Include a discussion of how disputes regarding quality system requirements, QA/QC procedures, assessments, or corrective actions are resolved. Note: It may be helpful to include organizational charts in addition to a narrative discussion.

1.3 **Technical Activities.** Briefly describe all technical activities (*e.g.*, basic research, technology evaluation, modeling, technology construction, *etc*.) that are supported by the quality system.

1.4 **Communicating the Program's Quality System.** Describe how program management ensures that the quality management plan is communicated to and understood by those

who are required to follow it (*e.g.*, training, meetings, *etc.*).

1.5 **Resources.** Describe program management procedures for allocating resources (human and financial) to implement the quality system (including, but not limited to, personnel training, quality system audits).

1.6 **Authority to Stop Work for Safety and Quality Considerations.** Define who has the authority to stop unsafe work, or work of inadequate quality.

1.7 **Management Assessment of Quality System Adequacy.** Describe how program management assesses and documents quality system adequacy. Include frequency of assessment, description of assessment (purpose, types of activities reviewed), and possible response actions.

SECTION 2.0, QUALITY SYSTEM AND DESCRIPTION

2.1 **Quality System Elements.** Generally describe the principal components (or "tools") comprising the quality system and how they are used to implement the quality system. This includes (but is not limited to): QMPs; QA project plans, standard operating procedures; and audits/assessments. Include how and when each component is applied to individual projects and tasks.

2.2 **Quality Management Plan Reviews and Revisions.** Describe procedures for updating quality system documentation.

SECTION 3.0, PERSONNEL QUALIFICATION AND TRAINING

3.1 **Personnel Training and Qualification Procedures.** Describe how program management ensures that all personnel performing work (including subcontractors, if applicable) are trained and qualified to perform work prior to initiating work. In addition to formal education, include specific on-the-job training for technical and management personnel (*e.g.*, lab, field, health and safety, management, QA).

3.2 **Formal Qualifications and Certifications for Specialized Activities.** Identify when formal qualification or certification is required.

3.3 **Training Documentation.** Describe how program management ensures that required training is performed and documented.

3.4 **Evidence of Personnel Job Proficiency.** Describe how objective evidence of personnel job proficiency is documented and maintained.

3.5 **Re-Training.** Describe how the need for re-training is evaluated.

SECTION 4.0, PROCUREMENT OF ITEMS AND SERVICES RELATED TO TECHNICAL ACTIVITIES

4.1 **Procurement Planning and Control.** Describe procedures for planning and controlling the procurement of items and services (*e.g.*, subcontractor who provides analytical support, subcontractor who provides drilling support, calibrated sampling equipment, *etc.*).

4.2 **Procurement Technical and Quality Requirements.** Describe procedures for ensuring that procurement documents (*e.g.*, formal contract with subcontractor, purchase order for equipment, *etc.*) clearly describe the item or service needed and the associated technical and quality requirements (including a quality system consistent with EPA requirements when applicable). Include a discussion of when procurement documents will require the supplier to furnish a demonstrated capability to furnish items and services that meet all requirements and specifications.

4.3 **Procurement Document Specification of Verifying Supplier's Conformance.** Describe procedures for ensuring that procurement documents specify how the supplier's conformance to customer's requirements will be verified.

4.4 **Procurement Document Review.** Describe procedures for the internal review of procurement documents to ensure accuracy and completeness.

4.5 **Review of Changed Procurement Documents.** Describe procedures for ensuring that changed procurement documents receive the same level of internal review and approval as the original documents.

4.6 **Review of Procured Items and Services.** Describe how procured items and services are reviewed to ensure compliance with requirements and specifications.

SECTION 5.0, DOCUMENTS AND RECORDS

5.1 **Records Management Procedures.** Describe records management procedures from preparation to disposal, including maintenance (protection from damage and deterioration), storage (including accessibility), and retention (including disposition in accordance with statutory or contractual requirements). Describe how these records management procedures are controlled and maintained. Include printed and electronic records. Identify which documents/electronic records are included under these record management procedures (*e.g.*, QAPP, data package, electronic data, laboratory

notebooks, chain-of-custody forms, *etc.*).

5.2 **Document Control.** Identify which documents require control (*e.g.*, technical manuals, operating procedures, QAPPs, SOPs, final reports, *etc.*). Describe procedures for document review and approval (internal to the organization and external, *e.g.*, client), and revision (before and after submission to client). Include procedures for distribution, replacement of previous document versions, and for ensuring that obsolete documents are no longer used.

SECTION 6.0, COMPUTER HARDWARE AND SOFTWARE

This section applies to computer hardware and software operations that directly impact the quality of the results of environmental programs (both developed and purchased) including: design, design analysis, data handling, data analysis, modeling of environmental processes and conditions, operations or process control, and data bases.

6.1 **Conformance to User and EPA Requirements.** Describe procedures for ensuring computer software and computer hardware/software configurations meet user's requirements and conform to applicable EPA requirements (*e.g.*, Y2K compliance, security [protection from physical loss of data], and privacy [protection from unauthorized use of data]).

6.2 **Configuration Testing.** Describe procedures for testing computer hardware/software configurations prior to use to ensure technical requirements and quality expectations are met; include how the results of configuration tests are documented and maintained.

6.3 **Configuration Change Assessment.** Describe procedures for assessing changes to hardware/software configurations; include how changes are evaluated based on the impact on technical and quality objectives of the program.

6.4 **Re-Testing and Re-Documentation.** Describe procedures for re-testing and re-documentation when components are changed (creating a new configuration) or when program requirements change (bringing capability of the configuration into question).

In addition to environmental data collection activities, Sections 7-10 must also be addressed for the design, construction, and operation of environmental technologies; use of secondary data (*i.e.*, use of environmental data); and development/modification of mathematical models (*i.e.*, use and/or generation of environmental data), when applicable.

SECTION 7.0, PROJECT PLANNING

7.1 **Planning and Documenting the Generation, Acquisition, and Use of Environmental Data.** Describe procedures for planning and documenting all work involving the generation, acquisition, and use of environmental data (and the design, construction, and operation of environmental technologies as applicable). Identify types of planning documents generated (*e.g.*, work plans, QAPPs, *etc.*) and summarize their purpose.

7.2 **Identifying and Documenting Type and Quality of Environmental Data Needed.** Describe how the type and quality of environmental data needed (including secondary data, mathematical models, and the quality of technology design) are identified. Describe how this information is documented (*e.g.*, DQO Process, QAPP, *etc.*)

7.3 **Including Key Users, Customers, and Technical Staff in Planning.** For each applicable technical activity, describe procedures for involving the key users and customers of the data (and technology or model), in addition to the technical staff, during project-specific planning.

7.4 **Reviewing and Approving Planning Documents.** Describe procedures used for review and approval (internal to organization and external, *e.g.*, client) of planning documents prior to initiation of work. Reference to Section 5.0 may be applicable.

SECTION 8.0, IMPLEMENTATION OF WORK PROCESSES

8.1 **Implementation of Work According to Planning Documents.** Describe procedures (*e.g.*, meetings, documentation) for ensuring that all work is performed according to approved planning and technical documents.

8.2 **Standard Operating Procedures Documentation.** Describe the process for documenting standard operating procedures. Describe how standard operating procedures should be written so that they are easily understood by the user and contain sufficient detail and clarity.

SECTION 9.0, PROJECT ASSESSMENT AND RESPONSE

For the purposes of this section, audits and assessments are synonymous.

9.1 **Planning Project Assessments.** Describe how, in the planning stage, management determines the appropriate type of assessment activity (*e.g.*, technical systems audit, performance evaluation audit, *etc.*) for a particular project.

9.2 **Assessment Planning and Procedures.** Describe the process used to ensure assessments

are performed according to approved written procedures.

9.3 ***Assessment Personnel Qualifications.*** Describe procedures for ensuring that assessments are performed by qualified personnel. Assessors shall be capable of assessing technical requirements and other procedures specified in the planning document.

9.4 **Assessor Responsibility and Authority to Stop Work.** Describe the assessor's responsibility and authority to stop work. Describe conditions under which a stop work order may be needed.

9.5 **Assessment Documentation, Reporting, and Review.** Describe assessment documentation, reporting, and review procedures. Include procedures for documenting and reporting assessment results to management. Include a discussion of how the assessor reports the impact of a negative assessment result on planned operations. For each procedure, include a time line for completion.

9.6 **Assessment Responses and Follow-up Action.** Describe procedures for documenting assessment responses and how corrective action occurs. Include how follow-up is performed to ensure action was taken. For each procedure, include a time line for completion.

SECTION 10.0, ASSESSMENT AND VERIFICATION OF DATA USABILITY

10.1 **Assessing, Verifying, and Qualifying Data.** Describe procedures for assessing, verifying/validating, and qualifying data obtained from environmental data operations according to their planned intended use, including secondary data and mathematical modeling. (Describe procedures for assessing and verifying the performance of environmental technology for its intended use.)

10.2 **Expressing and Documenting Limitations on Data.** Describe procedures for expressing and documenting (in print, or electronically) any limitations on this intended data use (and/or technology performance).

10.3 **Providing Independent Review of Data-Containing Project Reports.** Describe procedures for the independent review of project reports containing data, or reports containing the results of environmental data operations (and/or technology performance), to confirm that the data or results are presented correctly. Reference to Section 5.0 may be applicable.

10.4 **Management Approval of Reports.** Describe procedures for obtaining management approval of these reports prior to release, publication, or distribution. Reference to

Section 5.0 may be applicable.

SECTION 11.0, QUALITY SYSTEM IMPROVEMENT

11.1 **Quality Improvement Process.** Describe the quality improvement process used to continuously develop and improve the quality system. Include procedures such as communication with and among customers and suppliers; staff identification of problems and solutions, *etc*.

11.2 **Preventing, Detecting and Correcting Quality System Problems.** Describe procedures used to prevent, detect and correct quality system problems.

11.3 **Response Actions.** Describe procedures for planning, documenting, and implementing response actions to quality system problems.

Attachment B

QA PLANNING REQUIREMENTS (QAPR) FORM FOR

INITIAL EXTRAMURAL ACTIONS

AND

NRMRL QA REQUIREMENTS/DEFINITIONS LIST

QUALITY ASSURANCE PLANNING REQUIREMENTS (QAPR) FORM
INITIAL EXTRAMURAL ACTIONS

1. Choose one: ○ Contract ○ IAG* ○ Simplified Acquisition
   ○ Assistance Agreement ○ CRADA*

- QA ID Number: (To be entered by QA Manager)
- Title:
- Does this extramural action involve the collection and/or use of environmental data; the design, construction, and operation of environmental technologies; or development of software, models, or methods? Check one.
  ☐ Yes - proceed with Step 5 ☐ No - proceed to Step 10
- **IMPORTANT**. In order to contractually bind the awardee to the requirements delineated on this form and on the corresponding guidance documents included with this form, incorporate the following statement (verbatim) into the statement of work or special conditions:

  The awardee shall comply with all requirements as delineated on the "Quality Assurance Planning Requirements Form" included with this extramural action.
- Include the "NRMRL QA Requirements/Definitions List" in the extramural documentation.
- Check **one** of the following as applicable from Chapter 4 of the NRMRL QMP. Appropriate language must be incorporated into the solicitation and/or award/agreement documentation by CMD. If the option chosen contains "QMP," include "Requirements for Quality Management Plans" in the extramural documentation.

  The external organization shall submit:

For **Competitive** Extramural Actions (e.g., contract, some simplified acquisitions, some assistance agreements).	For **Non-Competitive** Extramural Actions (e.g., CRADAs, IAGs, some simplified acquisitions, some assistance agreements).
☐ Before Award: NRMRL's Quality System Specifications After Award: QMP and QAPP for the entire effort	(No corresponding choice)
☐ Before Award: NRMRL's Quality System Specifications After Award: Joint QMP/QAPP** for the entire effort	☐ Joint QMP/QAPP** for entire effort
☐ Before Award: NRMRL's Quality System Specifications After Award: QMP for the entire effort and a QAPP for each applicable project	☐ NRMRL's Quality System Specifications; QAPP for each applicable project
☐ Before Award: QMP for entire effort After Award: QAPP for the entire effort	☐ QMP for entire effort; QAPP for entire effort
☐ Before Award: QMP for the entire effort After Award: QAPP for each applicable project	☐ QMP for entire effort; QAPP for each applicable project
☐ Other (non-contracts):	☐ Other (non-contracts):

- Indicate in the table below all potentially applicable QAPP types that may be required at any stage of the project. Print the requirements document, and include it in the extramural action documentation.

Project Type (Choose all that apply)	Category No. (Choose from the corresponding options)
☐ Enforcement (Cat I)	Category: I
☐ Regulatory Support (Cat II)	Category: II
☐ Applied Research (Cat III)	Category: III
☐ Basic Research (Cat IV)	Category: IV
☐ Secondary Data (Cat I-IV)	Category: ☐ I ☐ II ☐ III ☐ IV
☐ Design/Construction/Operation of Environ. Technology (Cat I-IV)	Category: ☐ I ☐ II ☐ III ☐ IV
☐ Model Development (Cat I-IV)	Category: ☐ I ☐ II ☐ III ☐ IV
☐ Sampling & Analysis (Cat I-IV)	Category: ☐ I ☐ II ☐ III ☐ IV
☐ Method Development (Cat I-IV)	Category: ☐ I ☐ II ☐ III ☐ IV
☐ Software Development & Data Management (Cat I-IV)	Category: ☐ I ☐ II ☐ III ☐ IV

- **The awardee shall comply with the following:**

Quality Assurance Audits. The awardee and any subcontractor shall anticipate that one or more quality assurance audits may be performed during the project duration. These external quality assurance audits will be performed by EPA or an EPA support contractor. Selection of the specific areas of focus for audits will be commensurate with the scope and needs of the program. These external audits are intended to complement, not replace, the internal audits performed by the awardee.

Quality Assurance Reporting. Each published interim or final report produced as a result of an activity that required quality documentation shall include, as an integral section of the project report or as an Appendix, a readily identifiable discussion of the data quality of research results. Published final reports shall include the following items as a minimum:

- Discussions of the quality of data produced in terms of precision, accuracy, completeness, method detection limit, and representativeness, or semi-quantitative assessments of data quality, as applicable.
- Limitations or constraints on the use of the data, if any.

Ethics and Data Integrity. The awardee and any subcontractor shall adhere to an ethics and data integrity code. No person shall participate in:

- the intentional selective reporting of data,
- the intentional reporting of data values that are not the actual values obtained,
- the intentional reporting of dates and times of data analyses that are not the actual dates and times of data analyses, or
- the intentional representation of another's work as one's own.

Substantive Changes to EPA-Approved Quality Documentation. Any substantive changes to the specifications in the EPA-approved quality documentation shall be submitted as a revision to the quality documentation by the awardee. The awardee shall identify the change and explain the rationale for the change. The EPA TLP, in concert with the awardee, is responsible for ensuring that quality documentation is kept current. Any revisions to EPA-approved quality documentation must be submitted to the EPA TLP and the QA representative for review. Implementation of the revision(s) commence(s) only after the awardee receives written EPA approval.

10. Sign/date below, obtain QA signature, and submit with extramural action documentation.

The signatures below verify that the appropriate QA requirements have been discussed and documented on this form.

NRMRL Technical Lead Person (TLP)	Date	NRMRL QA Staff Member	Date

*If you are processing an **IAG or CRADA**, the responsibility for QA must be negotiated within the agreement. The TLPs 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 TLP from each organization, and the QA requirements that will be adhered to during the agreement. Include documentation in **IAG/CRADA** package. (Note: Documentation may partially consist of this form with the following statement in the agreement "The organizations have negotiated and agree to the requirements as delineated in the Quality Assurance Planning Requirements Form included with this IAG/CRADA package.")
**A joint QMP/QAPP, for NRMRL purposes, is the NRMRL's Quality System Specifications combined with a QAPP.

NRMRL QA Requirements/Definitions List

EPA's Quality System Website: http://www.epa.gov/quality/qs-docs/r5-final.pdf

Category Level Designations (determines the level of QA required):

Category I Project - applicable to studies performed to generate data used for enforcement activities, litigation, or research project involving human subjects. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5, March 2001": http://www.epa.gov/quality/qs-docs/r5-final.pdf

Category II Project - applicable to studies performed to generate data used in support of the development of environmental regulations or standards. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5, March 2001": http://www.epa.gov/quality/qs-docs/r5-final.pdf

Category III Project - applicable to projects involving applied research or technology evaluations. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5, March 2001": http://www.epa.gov/quality/qs-docs/r5-final.pdf as outlined in the NRMRL QAPP requirements for the specific project type (see below).

Category IV Project - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5, March 2001": http://www.epa.gov/quality/qs-docs/r5-final.pdf as outlined in the NRMRL QAPP requirements for the specific project type (see below).

Project Types:

Applied Research Project - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Applied Research Projects" from Appendix B of the NRMRL QMP.

Basic Research Project - pertains to a study performed to generate data used to evaluate unproven theories, processes, or technologies. These studies are often bench-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Basic Research Projects" from Appendix B of the NRMRL QMP.

Design, Construction, and/or Operation of Environmental Technology Project - pertains to environmental technology designed, constructed and/or operated by and/or for EPA. The QAPP shall address requirements in Part C of "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology," ANSI/ASQC E4-1994, American Society for Quality Control, Milwaukee, WI, January 1995. (Please contact a member of the QA Staff for further information.)

Method Development Project - pertains to situations where there is no existing standard method, or a standard method needs to be significantly modified for a specific application. The QAPP shall address all requirements listed in "QAPP Requirements for Method Development Projects" from Appendix B of the NRMRL QMP.

Model Development Project - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. The QAPP shall address all requirements listed in "QAPP Requirements for Modeling Projects" (Requirements still in development. Please contact a member of the QA Staff for further information.)

Sampling and Analysis Project - pertains to the collection and analysis of samples with no objectives other than to provide characterization or monitoring information. The QAPP shall address all requirements listed in "QAPP Requirements for Sampling and Analysis Projects" from Appendix B of the NRMRL QMP.

Secondary Data Project - pertains to environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended. Sources may include: literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. The QAPP shall address all requirements listed in "QAPP Requirements for Secondary Data Projects" from Appendix B of the NRMRL QMP.

Software Development and Data Management Project - pertains to software development, software/hardware systems development, database design and maintenance, data validation and verification systems. The QAPP shall address all requirements listed in "QAPP Requirements for Software Development Projects" from Appendix B of the NRMRL QMP.

Definitions:

Environmental Data - For EPA, environmental data include information collected directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature.

Incremental Funding - Incremental funding is partial funding, no new work.

NRMRL's Quality System Specifications for Extramural Actions - These requirements typically pertain to single project efforts. The five specifications are:

(1) a description of the organization's Quality System (QS) and information regarding how this QS is documented, communicated and implemented;

(2) an organizational chart showing the position of the QA function;

(3) delineation of the authority and responsibilities of the QA function;

(4) the background and experience of the QA personnel who will be assigned to the project; and

(5) the organization's general approach for accomplishing the QA specifications in the SOW.

Quality Assurance (QA) - Quality assurance is a system of management activities to ensure that a process, item, or service is of the type and quality needed by the customer. It deals with setting policy and running an administrative system of management controls that cover planning, implementation, and review of data collection activities and the use of data in decision making. Quality assurance is just one part of a quality system.

Quality Assurance Project Plan (QAPP) - A QAPP is a document that describes the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP documents project-specific information.

Quality Control (QC) - Quality control is a technical function that includes all the scientific precautions, such as calibrations and duplications, that are needed to acquire data of known and adequate quality.

Quality Management Plan (QMP) - A QMP is a document that describes an organization's/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. A QMP documents the overall organization/program, and is primarily applicable to multi-year, multi-project efforts. An organization's/program's QMP shall address all elements listed in the "Requirements for Quality Management Plans" in Appendix B of the NRMRL QMP.

Quality System - A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner and provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance and quality control activities.

Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

Supplemental Funding - Supplemental funding is additional funding of new work.

Technical Lead Person (TLP) - This person is technically responsible for the project. For extramural contract work, the TLP is typically the contracting officer's representative (COR). For intramural work, the TLP is typically the Principal Investigator.

Abbreviations:

COR	Contracting Officer's Representative	IAG	Interagency Agreement
NRMRL	National Risk Management Research Laboratory	QA	Quality Assurance
QA ID	Quality Assurance Identification	QAM	Quality Assurance Manager
QAPP	Quality Assurance Project Plan	QMP	Quality Management Plan
QS	Quality System	SOW	Statement of Work
TLP	Technical Lead Person	CRADA	Cooperative Research & Development Agreement