United States
Environmental Protection
Agency

Quality Management Plan (QMP)

Office of Research and Development (ORD)
National Homeland Security Research Center (NHSRC), 26 W. Martin Luther King Drive, Cincinnati, OH 45268

Quality Management Plan (QMP)

Office of Research and Development (ORD)
National Homeland Security Research Center (NHSRC), 26 W. Martin Luther King Drive, Cincinnati, OH 45268

Quality Management Plan Contact Information

Title: Quality Management Plan for the National Homeland Security Research Center

Organization: Office of Research and Development
National Homeland Security Research Center
Immediate Office

Address: U.S. Environmental Protection Agency
National Homeland Security Research Center (NHSRC)
26 W. Martin Luther King Drive (NG16)
Cincinnati, OH 45268

FAX: 513 487-2555
Phone: 513 569-7662

APPROVALS

_____ Signature	_____ Date	**Reggie Cheatham,** Director of Quality Staff Office of Environmental Information (OEI)
_____ Signature	_____ Date	**Jonathan G. Herrmann, Director** National Homeland Security Research Center
_____ Signature	_____ Date	**Angela L. Hadley,** Acting Deputy Director Immediate Office of the Director
_____ Signature	_____ Date	**Gregory Sayles** Associate to Director Immediate Office of the Director
_____ Signature	_____ Date	**Nancy H. Adams**, Division Director Decontamination Consequence Management
_____ Signature	_____ Date	**Kim R. Fox**, Division Director Water Infrastructure Protection
_____ Signature	_____ Date	**Deborah McKean**, Acting Director Threat and Consequence Assessment Division
_____ Signature	_____ Date	**Oba Vincent**, Team Leader Response Capability Enhancement
_____ Signature	_____ Date	**Eletha Brady-Roberts,** Director of Quality Assurance Immediate Office of the Director

This page left intentionally blank.

Contents

Abbreviations and Acronyms

ADP	Automated Data Processing
ADQ	Audit of Data Quality
ANSI	American National Standards Institute
ASQ	American Society for Quality
BOSC	Board of Scientific Counselors
CFR	Code of Federal Regulation
CIO	Chief Information Officer
CMD	Contracts Management Division
COMSEC	Communication Security
CRADA	Cooperative Research and Development Agreement
DCMD	Decontamination Consequences and Management Division
DD	Division Director
DQA	Director of Quality Assurance
DQI	Data Quality Indicator
DQO	Data Quality Objective
EPA	US Environmental Protection Agency
FTE	Full-Time Equivalent
FY	Fiscal Year
GALP	Good Automated Laboratory Practices
GPRA	Government Performance Results Act
GIAMD	Grants and Interagency Agreement Management Division
HSDN	Homeland Security Digital Network
H&S	Health and Safety
IA	Interagency Agreement
IO	Immediate Office
IQG	Information Quality Guidelines
LAN	Local Area Network
L/C/O	Laboratory/Center/Office
NAS	National Academy of Science
NDPD	National Data Processing Division
NHSRC	National Homeland Security Research Center
NRMP	National Records Management Plan
OEI	Office of Environmental Information
OGD	Office of Grants and Debarment
IRM	Information Resources Management
ORD	Office of Research & Development
PCSC	Personal Computer Site Coordinator

Abbreviations and Acronyms (Cont.)

PE	Performance Evaluation
PI	Principal Investigator
PTL	Programmatic Team Leaders
PM	Program Manager
PO	Project Officer
QA	Quality Assurance
QAARWP	Quality Assurance Annual Report and Work Plan
QAC	Quality Assurance Coordinator
QAM	Quality Assurance Manager
QAPP	Quality Assurance Project Plan
QATRAK	Quality Assurance Tracking System
QARF	Quality Assurance Review/Requirements Form
QC	Quality Control
QMP	Quality Management Plan
QS	Quality Staff
QSA	Quality System Audit
RCE	Response Capability Enhancement Team
RMO	Records Management Office
RTP	Research Triangle Park
SAB	Science Advisory Board
SOP	Standard Operating Procedure
STEs	Secure Terminal Equipment
STPs	Scientific Technical Products
TEP	Technical Evaluation Panel
TL	Team Leader
TCAD	Threat and Consequence Assessment Division
TSCA	Toxic Substances Control Act
TSA	Technical System Audit
TTEP	Technology Testing and Evaluation Program
WS	Water Security
WIPD	Water Infrastructure Protection Division

List of Tables

List of Figures

List of Text Boxes

This page left intentionally blank.

1.0 Background

The Environmental Protection Agency (EPA) Order CIO 2105.0 (formerly Order 5360.1 A2) *Policy and Program Requirements for the Mandatory Agency-Wide Quality System*[1], May 2000, establishes policy and program requirements for the preparation and implementation of quality management systems. The intent of the Order is to develop a consistent approach to environmental decisions that ensures the collection of supporting data that are scientifically sound, legally defensible, and of known and documented quality. The Office of Environmental Information (OEI) Quality Staff is responsible for developing quality assurance (QA) and quality control (QC) requirements and for overseeing implementation of the Agency wide Quality System.

The Office of Research and Development's National Homeland Security Research Center (NHSRC) has adopted the policy described in the *EPA Quality Manual for Environmental Programs*, CIO 2105-P-01-0[2] (formerly order 5360 A1), which articulates that EPA organizations shall provide for the following: (1) a Quality Assurance Manager, or equivalent position, who functions independently of direct environmental data generation and reports on quality issues to the senior manager having executive leadership authority for the organization, and (2) a Quality Management Plan (QMP). This QMP document defines the quality system that is established and implemented at the National Homeland Security Research Center. Moreover, it provides the authority and guidance for how quality assurance activities are planned, documented, implemented, and assessed.

Quality System functions pertaining to the NHSRC are covered by this QMP regardless of where the work is performed – Cincinnati, Ohio; Research Triangle Park, North Carolina; Washington D.C.; Las Vegas, Nevada; and contractor work sites.

1.1 Purpose of NHSRC's QMP

The purpose of this QMP is to describe the NHSRC quality system**.** The NHSRC quality system is designed to be useful to project personnel, managers, and QA staff. This QMP is a comprehensive document that incorporates quality policies, and lines of authority and responsibility for all Center personnel. NHSRC's management and QA staff work to ensure that (1) standard policies and procedures are in place for the quality system elements described in the NHSRC quality system; (2) all environmental data collection, evaluation, and use are performed in accordance with an approved planning document; and (3) all NHSRC projects (both intramural and extramural) produce defensible data of defined quality.

1 *Policy and Program Requirements for the Mandatory Agency-Wide Quality System*, CIO 2105.0, 2000, OEI, USEPA, Washington, D.C. http://www.epa.gov/irmpoli8/ciopolicy/2105-0.pdf

2 *EPA Quality Manual for Environmental Programs*, CIO 2105-P-01-0, 2000, OEI, USEPA, Washington, D.C. http://www.epa.gov/irmpoli8/ciopolicy/2105-P-01-0.pdf

This page left intentionally blank.

2.0
Structure And QA Management

The National Homeland Security Research Center (NHSRC) is a principal entity with EPA's Office of Research and Development responsible for homeland security related research. The Center develops the scientific foundations that provide decision makers with the tools they need to prevent and manage a range of potential threats.

This section discusses NHSRC's organizational structure, and the Center-wide management and implementation of the quality system.

2.1 Organizational Structure

The National Homeland Security Research Center's research focuses on the mitigation of environmental contamination associated with terrorist threat scenarios that involve chemical, biological or radiological contaminants, including measuring and modeling environmental exposures, studying human health, quantifying human health risks, and developing risk assessment methodologies.

The program areas for which NHSRC is responsible involve numerous scientific and engineering disciplines; therefore, the Center may engage experts from other EPA organizations to serve as a Principal Investigator (PI). The Quality Assurance Manager (QAM) from the respective organization or Laboratory/Center/Office (L/C/O) is responsible for the QA of the research project. Moreover, the lead PI who is responsible for a project being funded by NHSRC will be supported by their assigned L/C/O QAM. In the case where the lead PI is not a member of NHSRC, the NHSRC quality staff will concur and sign their initial next to the signature of the partner QAM.

2.1.1 Mission

NHSRC develops and delivers reliable, responsive expertise and products based on scientific research and evaluations of technology. Our expertise and products are widely used to prevent, prepare for, and recover from public health and environmental emergencies arising from terrorist threats and incidents.

2.1.1.1 Directives

The Public Health Security and Bioterrorism Preparedness and Response Act (Bioterrorism Act, 2002), together with Homeland Security Presidential Directives 7, 9, 10 and 22, charge EPA with protecting our nation's critical water infrastructure; monitoring for chemical, biological, and radiological terrorism threats to public health and the environment; and supporting decontamination approaches to be used during a terrorist attack.

2.1.2 Quality Policy Statement

The quality policy of NHSRC is that environmental data generated, processed or used will be of adequate and sufficient quality for their intended use. The purpose of the NHSRC Quality Assurance policy is to:

- Ensure that NHSRC meets EPA QA requirements as defined in EPA CIO 2105[3] (http://www.epa.gov/irmpoli8/ciopolicy/2105-0.pdf) and the guidance provided in the EPA's Overview for *EPA's Quality System for Environmental Data and Technology*[4]*;*
- Implement a quality system that guides QA planning and quality control activities for individual projects or programs;
- Ensure that QA reviews are performed on various products and activities in NHSRC
- Ensure that continuous improvement is practiced in the implementation of the NHSRC quality system; and
- Ensure that adequate resources including

3 *Policy and Program Requirements for the Mandatory Agency-Wide Quality System*, CIO 2105.0, 2000, OEI, USEPA, Washington, D.C. http://www.epa.gov/irmpoli8/ciopolicy/2105-0.pdf

4 *Overview of EPA Quality System for Environmental Data and Technology*, EPA/240/R-02/003, 2002, OEI, USEPA, http://www.epa.gov/quality/qs-docs/overview-final.pdf

full-time equivalents (FTEs), contractor support, and travel funds are provided to implement the NHSRC QMP across the Center.

2.1.3 Program Areas

As shown in Figure 1, NHSRC has three divisions: Water Infrastructure Protection and the Threat and Consequence Assessment are based in Cincinnati, Ohio and the Decontamination and Consequence Management is located in Research Triangle Park, North Carolina. In addition, the Center's Response Capability and Enhancement team is located in Cincinnati and the Technology Testing and Evaluation Program is managed in Las Vegas, Nevada.

The Center's main program areas are Water Infrastructure Protection and Indoor/Outdoor Decontamination. The risk assessment activities and analytical methods development efforts are embodied in those two programs areas.

2.1.3.1 Water Infrastructure Protection Research

The focus of water infrastructure protection research is on improving the nation's ability to protect from and respond to terrorist attacks on our water and wastewater infrastructure. The thematic research areas include:

- Protection and prevention research, which involves developing tools and methods to address the vulnerabilities of drinking water and wastewater systems;
- Detection research, which involves developing tools and methodologies to detect, confirm, and measure accidental and intentional contamination events, and support the development of a laboratory network;
- Containment and mitigation research, which involves supporting the development of planning tools for contamination events, and tools and methodologies for responding to and mitigating such events; and
- Decontamination and water treatment research, which involves developing a better understanding of the treatment and decontamination of water infrastructure and contaminated water.

2.1.3.2 Indoor and Outdoor Decontamination Research

The main focus of indoor and outdoor

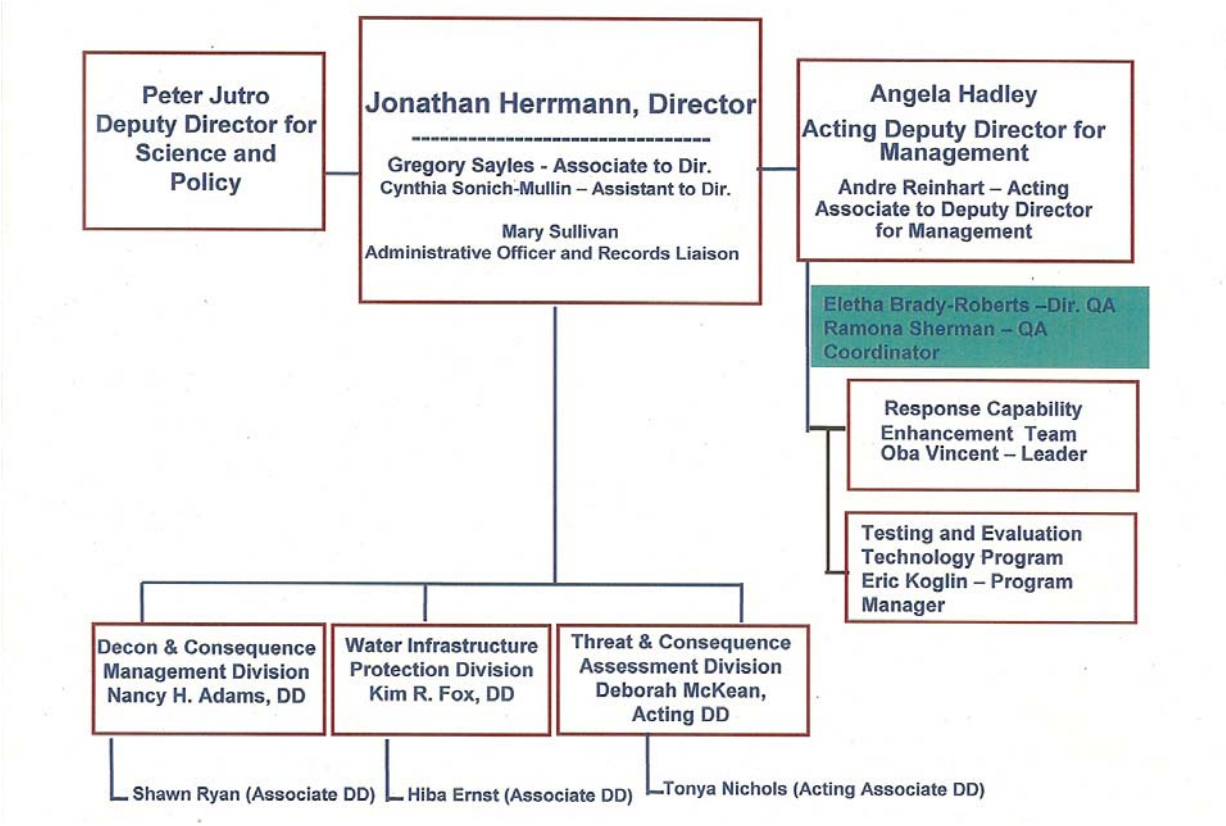

Figure 1 NHSRC Organization Chart

decontamination research is on improving the nation's ability to respond to terrorist attacks affecting indoor and outdoor environments. The thematic research areas include:

- Detection research, which results in detection techniques (e.g., laboratory methods, technology evaluations) that will enable the rapid characterization of threats and identification of contaminants;
- Containment and mitigation research, which results in reports, databases, and computer models that provide information on the movement and health effects of contaminants; and
- Remediation research, which delivers reports, techniques, and tools to support the remediation (decontamination and associated material disposal) of buildings and outdoor environments following contamination event associated with chemical, biological or radiological agents of concern.

2.1.3.3 Technology Testing and Evaluation Program

The Technology Testing and Evaluation Program (TTEP) provides reliable information regarding the performance of commercially available technologies that might be used during a homeland security related incident. Technologies are evaluated to specifically determine their abilities to:

- Detect contaminants in environmental matrices to determine which chemical or biological agents may be present and to characterize areas that may need to be restored after a terrorist attack; and
- Decontaminate buildings and water distribution systems in order to return them to a usable state after a terrorist attack.

2.2 NHSRC's Management of Quality Assurance

NHSRC's Director of Quality Assurance (DQA) is assigned to the NHSRC Immediate Office of the Director; therefore, the required independence of the QA function is maintained.

2.2.1 QA Roles and Responsibilities

2.2.1.1 Director

The Director of NHSRC is responsible for:

- Ensuring that EPA quality policy is implemented at NHSRC by including quality responsibilities as described in this QMP in the performance standards of the NHSRC Deputy Director, Division Directors (DD), QA staff, and PIs;
- Promoting (by words, actions, and involvement) the establishment of a quality culture at NHSRC;
- Promoting (by words, actions, and involvement) continuous quality improvement within NHSRC;
- Providing facilities that are conducive to the production of data of appropriate quality to meet the needs of the research being conducted;
- Ensuring that information disseminated by the NHSRC meets the Information Quality Guidelines;
- Providing adequate resources (including FTEs, contractor support, and travel) for the operation of the NHSRC quality system;
- Reviewing and approving the NHSRC QMP;
- Serving as the ultimate decision maker on unresolved quality issues; and
- Ensuring that any Request for Corrections (RFC) that affect NHSRC, the ORD IQG Officer will contact the NHSRC Center Director (or designee) to participate in the development of a draft response.

2.2.1.2 Deputy Director for Management (DDM)

The Deputy Director for Management has been designated by the NHSRC Director as the senior management designee for ensuring the NHSRC quality system is implemented NHSRC. The DD serves as the first-line supervisor for personnel responsible for quality assurance, extramural, budget execution, communication, information security, travel and personnel assigned to the RCE team and the TTEP effort. In the area of quality assurance, the Deputy Director for Management is responsible for:

- Informing the Center Director of QA program developments;
- Reviewing and recommending approval of the NHSRC QMP;
- Selecting the NHSRC DQA;
- Serving as the NHSRC arbitrator for quality issues that cannot be resolved at lower levels;
- Supervising and overseeing the activities of the DQA;

- Ensuring that the NHSRC QA system is implemented across the Center by including quality responsibilities as described in this QMP in the performance standards of all managers QA staff, and PIs in the Center;

- Promoting (by words, actions, and involvement) the establishment of a quality culture at NHSRC;

- Promoting (by words, actions, and involvement) the NHSRC quality system;

- Promoting (by words, actions, and involvement) continuous quality improvement within the Center;

- Providing adequate resources (including FTEs, contractor support, and travel funds) to implement the NHSRC QMP across the Center;

- Reviewing, approving, and subsequently ensuring that the NHSRC QMP is implemented and providing written review comments regarding the QMP to the DQA;

- Ensuring that the Center DQA attends planning meetings when proposed, new, and/or current research activities (any activity that generates or collects environmental data or uses secondary data for situations related to the environment) are discussed;

- Ensuring that the DQA is aware of all research activities in the center;

- Resolving disagreements within the Center (e.g., appropriate corrective action to an audit, Quality Assurance Project Plan (QAPP), or final product review finding);

- Ensuring that the responses to findings of Quality System Audits (QSAs) are appropriately addressed by the DQA (while this responsibility may be delegated, it is the Deputy Director's responsibility to ensure that this requirement is met); and

- Reviewing and approving the *Quality Assurance Annual Report and Work Plan* (QAARWP).

2.2.1.3 Deputy Director for Science and Policy (DDSP)

The Deputy Director for Science and Policy serves as the senior science adviser to the Director on homeland security policy and science issues that may impact EPA, ORD and/or NHSRC. The DDSP also serves as NHSRC liaison to other Federal agencies and program offices and:

- Coordinates closely with the Associate Director, especially on matters relating to science products, intra agency activities with other Centers and Labs;
- Promotes (by words, actions, and involvement) the NHSRC quality system and;
- Promotes (by words, actions, and involvement) continuous quality improvement within the Center.

2.2.1.4 Director of Quality Assurance (DQA)

The DQA is a member of the Center's Immediate Office and reports to the Deputy Director for Management. This arrangement alleviates any potential conflict of interest with program or data activities and provides an independent review of materials requiring quality assurance. Moreover, the DQA provides QA support to the Center and does not perform any tasks related to the research conducted by the RCE, TTEP, WIPD, TCAD or DCMD.

The DQA will attempt to resolve any issues pertaining to general QA requirements or audit close-out. However, if a dispute cannot be resolved, the DQA will present the issue to their immediate supervisor (DDM) and the Associate to Center Director.

The DQA is responsible for:

- Reporting all unresolved NHSRC-specific QA issues and information to the NHSRC Deputy Director;

- Coordinating the NHSRC Quality Team (including all Quality Assurance Managers supporting NHSRC research) and serving

as the facilitator for resolving quality issues;

- Leading Quality System Audits of the implementation of the NHSRC quality system;
- Approving the schedules for regular assessment of the quality system;
- Preparing for and conducting Technical Systems Audits (TSA) of NHSRC projects;
- Coordinating the preparation and updating, as necessary, of the NHSRC QMP;
- Serving as the NHSRC liaison to the Agency's Office of Environmental Information's (OEI) Quality Staff (QS);
- Assisting QS in the review of policy and concept documents;
- Coordinating the preparation of the NHSRC QA Annual Report and Work Plan (QAARWP) and submitting it to the NHSRC Deputy Director;
- Initiating discussions with the Center Director or Deputy Director to correct quality problems as needed;
- Identifying NHSRC quality training needs and assisting in the development and presentation of QA training courses;
- Leading continuous quality improvement efforts within NHSRC;
- Reviewing, signing, and dating Quality Assurance Review Form (QARF) for funding packages;
- Entering quality document tracking information into the QA tracking system; and
- Managing QA support contracts.

2.2.1.5 QA Coordinator (QAC)

The QAC provides QA support for projects either funded by or conducted by NHSRC PIs. The QAC is a member of the Director's Immediate Office and reports to the Deputy Director for Management. This arrangement alleviates any potential conflict of interest with program or data activities and provides an independent review of quality assurance matters. Moreover, the QAC provides QA support to the Center and does not perform any tasks related to the research conducted by the RCE, TTEP, WIPD, TTEP, TCAD, or DCMD. The responsibilities of Center's QAC are as follows:

- Reviewing, approving and signing the QARF for extramural funding packages;
- Entering information into the NHSRC Quality Assurance Tracking system (QATRAK) used to track QAPPs;
- Attending Center research project planning meetings (e.g., Center implementation plan meetings) when proposed, new, and/or current research activities are discussed;
- Reporting issues regarding NHSRC QA system noncompliance to the DQA for further action when resolution cannot be made;
- Assisting in the preparation of audit checklists and assisting the DQA in conducting audits;
- Participating in the NHSRC DQA's QSAs and/or internal audits and preparing audit reports for submission to the DQA;
- Tracking corrective action as required at project level;
- Assisting the DQA and/or QACs in support of the overall NHSRC quality system;
- Assisting in the review of the NHSRC QA program as needed;
- Assisting PIs with in-house research projects when requested. This may include assisting the PI in the development of the

QAPP; establishing appropriate project objectives, experimental design, analytical methods, sampling points; performing audits to ensure implementation of QAPP; and

- Performing some level of data validation and reviewing the final report.

2.2.1.6 QA Manager (QAM)

As mentioned in section 2.1.3, the program areas that NHSRC is responsible for are broad in scope and involve numerous scientific and engineering disciplines; therefore, the Center must involve experts from outside of the Center to serve as PIs. The QAM from their respective L/C/O is responsible for the QA of the research project. Moreover, the PIs will be supported by their assigned L/C/O QAM. The responsibilities of the Center's QAM are listed below. The responsibilities of the QAMs from other L/C/Os should be listed in their QMP and should be comparable to the responsibilities listed below. Disagreement in responsibilities should be communicated to the Center DQA by the L/C/O QAM.

The NHSRC QAM is a member of the Center's Immediate Office and reports directly to the Deputy Director for Management. This arrangement alleviates any potential conflict of interest with program or data activities and provides an independent review of quality assurance matters. Moreover, the QAM will provide QA support to the Center and does not perform any tasks related to the research conducted by the RCE, WIPD, TTEP, TCAD or DCMD. The typical QAM responsibilities are responsible are as follows:

- Reviewing and signing the QARF form for funding packages;
- Reviewing and approving QAPPs, SOPs, published reports (both paper and electronic), journal articles, symposium/ conference papers, and extended abstracts;
- Entering quality document tracking information into the QA tracking system;
- Managing QA support contracts;
- Attending Center research project planning meetings (e.g., Center implementation plan meetings) when proposed, new, and/or current research activities are discussed;
- Compiling Center information for the QAARWP and submitting it to the NHSRC DQA;
- Negotiating whenever there is disagreement on the proposed resolution to an audit or review (QAPP, final report, journal article, symposium paper, extended abstract) finding (if agreement cannot be reached, negotiations will be elevated by the QAM to the DQA);
- Reporting issues regarding NHSRC QA system noncompliance to the DQA for further action when resolution cannot be made;
- Performing audits, as listed in Section 3.3, of support laboratories and projects and preparing audit reports for submission to the PIs and TLs;
- Participating in the NHSRC DQA QSAs and/or internal audits;
- Assisting in the development of QA guidance;
- Serving as a QA consultant for Center projects;
- Assisting in the preparation of the NHSRC QMP or any revisions to the NHSRC QMP by providing information to NHSRC DQA;
- Providing QA training courses;
- Developing and revising quality system forms as needed;
- Assisting in the development of internal QA system SOPs; and
- Tracking corrective action as required at project level.

Currently, the Center's DQA also serves as the QAM.

2.2.1.7 Associate Director (AD)

The Associate Director is a senior science advisor to the NHSRC Director conducting science planning, coordinating NHSRC's research program with other Federal research programs including those within EPA, promoting the quality of science underway, coordinating program-wide, external peer review, and reviewing the Center's science products. The Associate Director is responsible for:

- Serving as an NHSRC arbitrator for quality issues that cannot be resolved at lower levels. Either the DQA or Division Director can bring the unresolved issue to the AD for resolution;
- Promoting (by words, actions, and involvement) the NHSRC quality system;
- Promoting (by words, actions, and involvement) continuous quality improvement within the Center;
- As delegated by the Director, conducting the final review of products including examination of the QA review and resolution of this review;
- Reviewing and subsequently promoting the implementation of the NHSRC QMP and providing written review comments regarding the QMP to the DQA;
- Coordinating external, program-wide peer review such as that conducted by the Board of Scientific Counselors;
- Ensuring that the DQA is aware of all research activities in the center; and
- Resolving disagreements within the Center (e.g., appropriate corrective action to an audit, Quality Assurance Project Plan (QAPP), or final product review finding).

2.2.1.8 Division Director (DD)

The Division Director serves as first-line supervisor for individuals who are assigned to their division. The DDs are responsible for:

- Ensuring that the NHSRC QA system is implemented by their researchers and the Center's DQA is aware of all research activities; they are accountable for ensuring that the QA requirements identified in this QMP are implemented;
- Promoting (by words, actions, and involvement) the NHSRC quality system;
- Ensuring that quality planning documents (i.e., QAPPs, Standard Operating Procedures (SOPs)) are developed and implemented for all research activities occurring within their division (i.e., for all intramural and extramural projects). (For example, project-specific QAPPs need to be prepared and approved for research activities as soon as a PI is prepared to collect data/information to support Agency decisions or for inclusion in research products e.g., reports [both paper and electronic], journal articles, symposium/ conference papers, extended abstracts, computer products/software/models/ databases, or scientific data);
- Keeping the DQA informed of QA related issues;
- Participating in and ensuring team personnel participate in QA training sessions as appropriate;
- Ensuring that research products (i.e., published reports [both paper and electronic], journal articles, symposium/ conference papers) are reviewed by the DQA or QAC and approved prior to publication (research products shall be subjected to QA review prior to being distributed outside of NHSRC);
- Ensuring implementation of corrective actions; and
- Ensuring that responses to any internal audits are prepared and submitted to the DQA OR QAC or DQA to ensure that all unresolved QA issues are addressed.

2.2.1.9 Programmatic Team Leader (PTL) and Program Manager (PM)

The RCE Team Leader and TTEP Program Manager are responsible for:

- Ensuring that the NHSRC QA system is implemented by their team members;
- Keeping the Center's DQA abreast of all research activities;
- Promoting (by words, actions, and involvement) the NHSRC quality system;
- Resolving technical or administrative issues relating to quality within the team (e.g., appropriate corrective action to an audit, QAPP, or final product review finding);
- Ensuring that quality planning documents (QAPPs, Standard Operating Procedures) are developed and implemented for all research activities occurring within their team and/or program area (i.e., for all intramural and extramural projects by assigning team personnel the responsibility for developing project-specific QAPPs and SOPs). A quality assurance project plan needs to be prepared and approved for research activities as soon as a PI is prepared to collect data /information to support Agency decisions or for inclusion in research products e.g., reports [both paper and electronic], journal articles, symposium/conference papers, extended abstracts, computer products/software/ models/databases, or scientific data;
- Participating in and ensuring team personnel participate in QA training sessions as appropriate; and
- Ensuring that research products (i.e., published reports [both paper and electronic], journal articles, symposium/ conference papers) are reviewed by the DQA or QAC and approved prior to publication (research products shall be subjected to QA review prior to being distributed outside of NHSRC).

2.2.1.10 Cross Center Team Leaders (CCTLs)

The team leaders are responsible for:

- Ensuring that the NHSRC QA system is implemented by the team members;
- Promoting (by words, actions, and involvement) the NHSRC quality system;
- Keeping the DQA informed of QA related issues; and
- Resolving technical or administrative issues relating to quality within the team.

2.2.1.11 Principal Investigator (PI)

The PI is the person who is responsible for the project. For extramural contract work, the PI is typically known as the contracting officer's representative (COR) or the project officer (PO) on Interagency Agreements (IA); for intramural work, the PI is typically known as the lead researcher. PIs may be full-time or non-Center staff. The PI is responsible for:

- Preparing QARF form to be included in procurement package (e.g., full-time PIs should prepare the NHSRC QARF form and part-time PIs should prepare the QARF form and submit to their assigned QAM for approval);
- Ensuring that all extramural agreements (i.e., contracts, cooperative agreements, grants, interagency agreements) include appropriate QA requirements and that the requirements are met for their projects;
- Ensuring development of a planning document consistent with NHSRC policy for all intramural and extramural 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 (i.e., 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 research products (i.e., published reports [both paper and electronic], journal articles, symposium/ conference papers, and extended abstracts) are reviewed by the DQA or QAC and approved prior to publication (research products shall be subjected to QA review prior to being distributed outside of NHSRC);

- Ensuring that corrective action procedures are initiated in a timely manner and issuing documentation to DQA or QAC of all corrective actions;

- Requesting or cooperating with any project-specific audits as required in Section 2.3.5; and

- Preparing responses to audit or review (e.g., QAPP, final report, or journal article) findings.

This page left intentionally blank.

3.0
Quality System and Description

3.1 Quality-Affecting Activities

As indicated in the QA policy statement (Section 2.1.2), NHSRC's data generating research and testing activities always require QA oversight. However, NHSRC also performs other functions that may not always be attributed to project-specific efforts; certain aspects of NHSRC's operations, such as the use of in-house data and software systems, may be inherently part of projects and the quality of these systems is often not addressed in a QAPP. Establishing quality policy for these types of activities and monitoring these activities is typically performed through the development of SOPs, and in other cases, facility manuals (Section 3.2.7). In addition, there are some generally accepted laboratory practices that need to be implemented to ensure that at least a minimum level of quality is established in each laboratory. The list of minimum requirements for laboratory research activities is presented in Appendix E.

3.2 Principle Components of the Quality System

The following sections describe the key components of the NHSRC quality system.

3.2.1 NHSRC Quality Management Plan (QMP)

The purpose of this document is to provide details about the Center's quality system and to discuss management and technical activities necessary to plan, implement, and assess the effectiveness of QA and QC operations applied to all research and environmental programs. The NHSRC Director is responsible for the development of the NHSRC QMP, although its preparation is delegated to the NHSRC DQA. The QMP must be approved and signed by the Director, Deputy Director for Management, Division Directors, Associate to the Director, Programmatic Team Leader, and the DQA. The QMP is submitted to the Office of Environmental Information's Quality Staff (QS) for review. It must be approved and signed by the QS Director. It is reviewed annually by the NHSRC DQA and updated as needed. The Quality Assurance Annual Report and Work Plan (Section 3.2.2) will be used to identify changes in the QMP prior to the next scheduled revision of the document. The approved QMP is valid for five years unless there is a significant change in the organization or in the research areas emphasized. After five years, or a significant change, the QMP is reviewed and revised as needed and subjected to the same approval processes described above.

3.2.2 Quality Assurance Annual Report and Work Plan (QAARWP)

The Center assesses the effectiveness of its quality system on an annual basis to ensure that assessments and planned work activities for the coming fiscal year are documented in the QAARWP. The DQA prepares the QAARWP and submits it to the OEI's Quality Staff Director under the signature of the NHSRC Deputy Director for Management. More information regarding the QAARWP is available on the OEI Web site.[5]

3.2.3 Extramural Quality Management Plans (QMPs)

The EPA contractors, assistance agreement recipients, and some EPA program offices may be required to submit a QMP. A graded approach is used by the EPA PI in consultation with the DQA or QAC to determine if a QMP is necessary (see Section 5). If a QMP is required, it is reviewed and approved by the EPA PI and DQA or QAC. The NHSRC requirements for QMPs are given in Appendix B.

3.2.4 Systematic Planning

The NHSRC PI is responsible for using a systematic process when planning work. The systematic planning process must involve defining project objectives and then designing and refining a plan that meets these objectives. The graded approach is used to ensure that the level of detail is in accord with the intended data use and the resources available. Although not mandatory, the data quality objectives process developed by EPA is an example of a systematic planning process. This

5 http://www.epa.gov/quality/qaarwps.html

process is described in Appendix B, Section 7.0 of the QAPP requirement documents and in *Guidance on Systematic Planning Using the Data Quality Objectives Process*, EPA QA/G-4, EPA/240/B-06/01, 2006, OEI, USEPA, Washington, D.C. (http://www.epa.gov/quality/qs-docs/g4-final.pdf).

Depending on the scope of research, as well as on any contractual or Agency requirements, planning documents (including QAPPs) appropriate to the scope are developed. The NHSRC DQA and QAC participate in NHSRC planning meetings as directed by senior management.

The EPA PI for the project, in consultation with project participants and the QA staff, determines the appropriate QAPP requirements to be used. It is the PI's responsibility to identify and involve any and all appropriate sponsoring organizations, responsible official(s), project personnel, and stakeholders, scientific experts (e.g., all customers and suppliers) in the planning of the project. This is true for both intramural and extramural projects. 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 the field and laboratory, audits, technical assessments, performance evaluations); and
- 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 responsibility of the PI to submit the QAPP to the designated QA staff. The QA staff 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. The documentation from the QA staff shall include either an approval or a non approval. In the case of non approval, detailed review comments shall be provided to the PI. Resolution of all findings shall be accomplished and documented before any research is started. The document still needs to be approved before research is started.

3.2.5 Quality Assurance Review Form (QARF)

The Quality Assurance Review Form must be completed for extramural projects; preferably a QARF is completed for intramural projects. For intramural projects, the QARF is used by the NHSRC quality staff to track in-house research projects and Quality Assurance Project Plans. On the other hand, if procured services are involved in the environmental data collection or generation activities, the QARF[6] helps to inform the vendor regarding any QA requirements specific to the project. Additional information is provided in Sections 5.2.3 (Alternative Documentation) and 3.2.6 (Quality Assurance Project Plans) and, if so, which quality documentation and activities are required. If the project does not include data collection or generation, then the QARF is required only for levels above $50,000. The completed form is signed by the Contract Officer Representative (COR) or Project Officer (PO), and DQA or QAC; then the QARF is attached to the NHSRC extramural routing sheet (see Section 5.0).

6 L:\NHSRC\Quality Assurance\NHSRC Quality System\ Forms and Templates or Appendix 46.1D in Contracts Management Manual at http://intranet.epa.gov/oamintra/policy/cmm.pdf

The Contracts Management Manual (CMM), Section 46.1.5.1 specifies that the QARF is used to ensure that quality requirements of FAR 46.202 and 52.246 are communicated to the Contracting Officer.

Therefore, the QARF must be completed for all solicitations and contracts, work assignments, delivery orders, and task orders; any modifications that involve a significant change to the Statement of Work; and simplified acquisitions except those under a purchase order (See Appendix C). The completed QARF is attached to the extramural package and forwarded to the contracts management division (CMD) or the Grants and Interagency Agreements Management Division (GIAMD). A QARF is not required if the amendment to the original SOW does not impact the contractor's work such as an incremental funding actions or project time extensions.

For the convenience of the NHSRC PI, the QARF is available in several locations: (1) Lotus Notes database under applications; (2) on the NHSRC share drive; and (3) listed on the EPA web forms system.

3.2.6 Quality Assurance Project Plans (QAPPs)

The Quality Assurance Project Plan (QAPP) documents the necessary quality and technical activities that must be implemented to ensure that the results of work performed will satisfy the stated performance criteria. The information in this section applies equally to both in-house (intramural) and extramural projects. Quality Assurance Project Plans (QAPPs) must be prepared to document QA/QC requirements for all research projects. A QAPP must be prepared before a research project begins.

For QA planning purposes, a research project begins as soon as a PI is prepared to collect data/information to support Agency decisions or for inclusion in research products (e.g., paper and electronic reports, journal articles, symposium/conference papers, extended abstracts, computer products/software/models/databases, or scientific data). Before proceeding with the collection of this data/information, a QAPP applicable to the project's QA category must be prepared. As part of the planning process for a research project, it may be necessary to perform preliminary work to gather information used to define its scope. This preliminary work must comply with the requirements specified in NHSRC's Minimum Requirements for Center Research Activities (Appendix A).

Guidance for QAPPs is available through the EPA Web site[7]. For more information, the OEI's R and G series documents can assist technical staff to further understand EPA's quality specifications[8].

For projects that require original environmental data collection and/or sampling and analysis or use of secondary data, a graded approach (see Section 3.2.7) is in place, and is used for both intramural and extramural activities. Secondary use of data is when data is used for a purpose other than which it was collected. Prior to using data for a use other than originally intended, the data must be qualified for acceptability. The graded approach is used to ensure that the level of detail is in accord with the intended data use and the resources available.

The overall intent is to allow flexibility, while still meeting NHSRC's interpretation of Agency policy for QA. NHSRC has summarized the Agency guidance for generic QAPPs (see Appendix B); the NHSRC guidance and QAPP template are available on the shared drive[9].

3.2.7 Graded Approach to Research Projects

The graded approach is used to ensure that the level of detail is in accord with the intended data use and the resources available. The NHSRC quality system utilizes a "graded approach" for establishing appropriate requirements for QAPPs for various types of research activities. Under the graded approach, the intended use of the data dictates the required level (or category) of quality. The graded approach utilizes four QA categories for research projects. The four QA categories are:

Category I: Research that directly and/or immediately supports specific Agency rule-making, enforcement, regulatory, or policy decisions. This category may also include research of significant national interest, such as tasks that might be monitored by the Administrator.

7 http://www.epa.gov/quality/qapps.html
8 http://www.epa.gov/quality/qa_docs.html).
9 L:\NHSRC/QA/QMP\QAPP Guidance

Category I projects require QA planning documents that comply with EPA R5/G5 requirements, including a statement of data quality objectives; an audit plan that at a minimum includes technical systems audits, audits of data quality, data quality assessments, and performance evaluation audits of measurement systems (if possible); QA review of products; and reports that have a readily identifiable QA section.

C**ategory II:** Research of high programmatic relevance that, in conjunction with other ongoing or planned studies, is expected to provide complementary support of Agency rule-making, regulatory, or policy decisions. Category II project QA requirements are the same as for Category I, but the audit plan will differ (the same minimum requirements apply but the frequency/intensity will differ).

Category III: Projects involving applied research or technology evaluation; method validation studies.

Category III projects require QA planning documents; QA review of products; and reports that have a readily identifiable QA section.

Category IV: Basic, exploratory, conceptual research to study basic phenomena or issues that typically result in a peer-reviewed journal article.

Category IV projects require QA planning documents.

For both Category I and Category II projects, NHSRC follows, in its entirety, the R-5 document[10] for QAPP preparation developed by EPA's Quality Staff (QS). If a particular R-5 requirement does not apply to an individual Category I/II project, the PI provides a brief explanation for why the specific requirement does not apply. 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 Appendix B. Quality Assurance Project Plan requirements are also presented in Appendix B for projects involving the use of secondary data, sampling and analysis, methods development, modeling, and software development/ data management. (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 Appendix B include short descriptions of the applicable types of research. The required quality level (or category) and associated QAPP requirements are determined by the EPA PI, in consultation with the QA staff, at the beginning of a project.

3.2.8 Facility Manuals

National Homeland Security Research Center facility managers, lead researchers, and QA staff develop facility manuals to assist technical staff (both EPA and contractor) in documenting the performance of routine operations. A facility is defined as a building (or portion of a building) housing a set of equipment designed for a particular area of research (such as a furnace to study the impact of combustion parameters on the pollutants emitted or a pilot plant to simulate a water distribution system). Facility manuals may contain the following information on a specific NHSRC facility:

1.0 Introduction
2.0 Facility Charter (purpose)
3.0 Management
4.0 Description
5.0 Equipment
6.0 Documentation
7.0 Operation
8.0 Quality Assurance
9.0 Quality Control
10.0 Data Handling
11.0 Corrective Action
12.0 Health and Safety
13.0 QA/Test Plans

Appendices may contain:
A. Current Facility Personnel
B. Operating Procedures
C. Standard Methods
D. Technical Systems Audit Checklist
E. Performance Evaluation Audit Ranges

10 http://www.epa.gov/quality/qs-docs/r5-final.pdf

Facility manuals are reviewed by the facility manager or lead researcher, QA staff, and health and safety (H&S) personnel if H&S requirements are included in the manual; they are maintained and updated by facility managers. Formal revisions and reviews are initiated when substantial changes are made to a facility manual. A facility manual documents instrumentation and procedures, provides a historical record of facility use, standardizes procedures, provides a training aid for new employees, and facilitates preparation of QAPPs (which can reference standard sections in the facility manual, with description of the specific tests and schedules for testing).

3.2.9 Standard Operating Procedures (SOPs) and Methods

The NHSRC encourages the development of SOPs for those operations which have become, or will become, routine, including analytical procedures, sampling procedures, and instrument calibration procedures which are used for more than one project or performed by more than one person. Before SOPs are implemented, they are reviewed by a second person in the specific technical area and the QA staff. Project-specific SOPs may also be written and are particularly recommended to facilitate updating the QAPP or when the procedure is performed by contract personnel. The purpose of the SOPs is to facilitate the uniform performance of routine procedures. When appropriate, NHSRC uses approved standard methods (e.g., SW-846, MCAWW, EPA 500 and 600 series, Standard Methods, CFR) to meet project-specific objectives.

3.2.10 QA Review and Response Procedures

As shown in Table 1, the DQA or QAC is responsible for scheduling, and conducting the following type of reviews. The DQA or QAC prepares written comments for each review and submits them to the PI. The PI's responsibility to address the comments and provide a disposition of comments to the QA staff.

3.2.11 Peer Review

Internal and external peer reviews are a vital component of the NHSRC quality system and will be used to ensure quality research products. Internal "technical" reviews are required for all scientific and technical products such as written material or data, technical reports, and published papers. National Homeland Security Research Center's products must meet the expectation of our clients outside of NHSRC and our Government Performance and Results Act (GPRA) goals. The policies and procedures used to implement peer review are contained in the *Science Policy Council Handbook on Peer Review*[11]. Since the final output of NHSRC research is often in the form of journal articles, another assessment of output quality is made through the peer review systems of the technical journals.

In addition to technical reviews of products, it is ORD policy that major research programs must undergo external peer review at least once every three years. These program peer reviews examine the underlying intent, scientific approach, direction, progress and results of large-scale research program areas, which are collections of individual research projects, but do not focus on the details of how the individual projects are conducted nor do they duplicate the peer reviews. The NHSRC often relies on the Board of Scientific Counselors (BOSC), the

11 Peer Review Handbook 3rd Edition, Science Policy Council, USEPA. 2006. EPA/100/B-06/002

Products Reviews	
Review of SOPs	all NHSRC developed SOPs
Review of QAPPs	all QAPPs
Final Research Products	all published reports (both paper and electronic), journal articles, symposium/conference papers, and extended abstracts

Table 1 Types of Product Reviews

National Academy of Science (NAS) and the EPA Science Advisory Board (SAB) for these types of reviews.

3.2.12 Information Quality Guidelines

The EPA's Information Quality Guidelines[12] contain EPA's policy and procedural guidance for ensuring and maximizing the quality of information we disseminate, and complements EPA's Quality Management System for assuring the quality of EPA's product and information. The term "Information" generally includes any communication or representation of knowledge or position/policy such as facts or data, in any medium or form. This includes "preliminary" information that EPA has endorsed or adopted, and also conclusions or facts drawn from or based upon other existing information (secondary uses of information).

Information that is either adopted endorsed or used by EPA to support an Agency decision or position is generally considered "information" for the purposes of the IQG and should be subject to pre-dissemination review. The pre-dissemination review procedures are intended to provide assurance that quality has been built into the information we disseminate. To be in compliance with the IQG concept, NHSRC reports must document the quality of information and include a disclaimer that clarifies the intended use and limitation of the product, when appropriate. Usually, quality related discussion can be found in a separate section of the report titled, Quality Assurance.

3.2.12.1 Request for Correction

If a person believes information disseminated by EPA does not meet the Information Quality Guidelines, they have the opportunity to submit a Request for Correction[13] (RFC). The Office of Environmental Information manages the database for RFCs and posts all RFCs to the IQG Web site[14.] For any RFCs that affect NHSRC, the OEI IQG Officer will contact the NHSRC Center Director (or designee) to participate in the development of a draft response. The draft response goes through many reviews including ORD, Office of General Council, (OGC), OEI, and Office of Management and Budget (OMB). Once the response is approved, OEI staff will post the final response on the IQG Web site. A flow chart of the RFC process is found on the IQG intranet[15].

3.2.12.2 Request for Reconsideration

The Request for Reconsideration (RFR) process is the appeal process for the results of an RFC. If a person is not satisfied with the Agency's response to an RFC, they can submit an RFR[16.] The OEI manages the database for RFRs and posts all RFRs to the IQG Web site[17.] For any RFRs that affect NHSRC, OEI IQG Officer will contact the NHSRC Director to participate in the development of a draft recommendation for review by a panel of senior staff. The Review Panel makes their decision and prepares a draft response. The draft response goes through review at OMB. Once the response is approved, OEI staff will post the final response on the IQG Web site. A flowchart of the RFR process is found on the IQG intranet[18].

3.13 A Stop Work Order

Quality assurance 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 NHSRC PI or line manager for in-house projects. For extramural projects, if the PI concurs that work practices are unacceptable, the PI should notify the Contracting Officer, who may issue a Stop Work Order (SWO). When a SWO is issued the work is halted until the issue (technical, quality or safety) is resolved. The CO must cancel the SWO before work can be resumed.

3.3 Assessments

The NHSRC conducts quality assessments to determine if data collection operations and/or the

12 Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (*EPA/ 260R-02-008, October 2002, available at* http://www.epa.gov/quality/informationguidelines

13 http://www.epa.gov/quality/informationguidelines/iqg-faqs.html

14 ibid

15 http://intranet.epa.gov/quality/informationguidelines/pdf/rfc_process.pdf

16 http://www.epa.gov/quality/informationguidelines/iqg-faqs.html#disagree

17 http://www.epa.gov/quality/informationguidelines/iqg-list.html

18 http://intranet.epa.gov/quality/informationguidelines/pdf/rfr_process.pdf

organization are adhering to the prevailing quality management structure, policies, and procedures; and the existing structure, policies, and procedures are adequate for ensuring that the necessary quality of data is obtained. Assessments are used to determine the effectiveness of the quality program and the adequacy of resources and personnel provided to ensure quality in all activities.
For measurement activities, NHSRC conducts assessments to verify the integrity and accuracy of the generated data, and to identify opportunities for improvement. Quality assessments may include internal/external audits, observations, internal reviews, quality control checks/audits, performance evaluations, and management reviews. For more information regarding NHSRC assessments, please refer to Section 10.

Internal assessments of the quality program will be conducted annually. The internal assessments place priority on projects that are high visibility projects and have new test procedures or equipment, or as determined by observation. Internal assessments may focus on a selected division or program to serve as a sample representative of NHSRC's quality system. A more frequent internal review cycle may be required if serious deficiencies exist. Results of the assessment will be documented and archived and included in the appropriate Quality Assurance Annual Report and Work Plan.

External audits are scheduled for specific systems, programs, and projects based on required periodic review, the importance of, or public interest, in the program or project, problems in the measurement system (noted by the PI or QA staff), requests by the PI, managers, or selection by the QA staff. The audits planned by the PI at the beginning of a project or required by the program are specified in the QAPP or QMP.

For all assessments, the lead auditor/assessor (usually either the DQA or a QAC) must ensure that auditor(s)/assessor(s) have no real or perceived conflicts of interest with the project/system/organization being assessed.

3.3.1 Quality Systems Audit (QSA)

The EPA quality system, in conformance with national consensus standards, requires that each organization assess the effectiveness of its quality systems' implementation. It is expected NHSRC will conduct a self assessment. EPA's Quality Staff also performs assessments of NHSRC's Quality Systems on a 3-year cycle. A 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 NHSRC DQA schedules QSAs of the Center annually to assess the implementation of the quality system and may enlist the help of personnel from other L/C/Os. In any event, the DQA is always invited as a member of the evaluation team to witness first hand the implementation of the QMP observed during the QSA and to respond to questions as needed.

3.3.2 Technical Systems Audits (TSAs)

A 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. Independent TSAs are most often scheduled by the PI and conducted by the DQA. Assistance for the TSA is available to each DQA from other L/C/Os or from QA support contractors. Technical Systems Audits 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.

The NHSRC DQA may schedule project-specific TSAs to assess the quality system for individual projects and may enlist the help of personnel in other L/C/Os. In any event, the DQA is always invited as a member of the evaluation team.

Technical System Audits are required for all Category I & II projects (both intramural and extramural). For Category III & IV projects, the Center may audit two Category III /IV projects each fiscal year. At least one Category III/IV project must be an intramural project.

3.3.3 Audit of Data Quality (ADQ)

An 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. An ADQ is conducted as required by specific programs or as requested by the PI or other EPA stakeholder. ADQs may be conducted by EPA or contractor personnel.

3.3.4 Performance Evaluations (PE)

A 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. Performance evaluations are conducted as required by specific programs or projects or at the request of the PI or other EPA stakeholder.

3.3.5 Laboratory Surveillances

Laboratory surveillances are conducted using the Minimum Requirements for Laboratory Research Activities contained in Appendix A. The Center may conduct surveillances of several in-house and extramural laboratories per year. A laboratory surveillance is less formal than a technical systems assessment (TSA), which is based on the project specific QAPP.

3.3.6 Data Quality Assessments

A Data Quality Assessment 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 Data Quality Assessment process is described in Guidance for the Data Quality Assessment: A Reviewer's Guide (QA/G-9R)[19], and the companion document Data Quality Assessment: Statistical Tools for Practitioners (QA/G-9S)[20,] EPA/240/B-06/002, February 2006 and EPA/240/B-06/003 February 2006, respectively. For research projects, these assessments are normally conducted by the PI, and they should be performed routinely on all projects.

3.3.7 QA Review of Research Products

Product reviews are conducted to determine if the product (i.e., draft or final) of a research activity is clear, complete, consistent, correct, and coherent. These reviews evaluate the credibility of data, realization of project goals, comparability of data, validity of conclusions, and quality of data. Research products should be subjected to QA review prior to being distributed outside of NHSRC. The NHSRC Product QA/QC Verification Report Form[21] must be completed on-line on NHSRC@work. The product (e.g., reports, journal articles, symposium papers, conference papers, extended abstracts, computer products/software/models/databases) that contains environmental data can be attached using the "attach" button at the top of the form. Environmental data are defined in EPA CIO 2105.0 (formerly Order 5360.1 A2) as any measurements or information that describe environmental processes, location, or conditions; health effects and consequences; or the performance of environmental technology. Moreover, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as databases or the literature.

3.3.8 Computer Tracking System

Computer tracking systems for the various elements of the quality system are in place in the Center. The NHSRC intranet system[22] is available to the

19 *Data Quality Assessment: A Reviewer's Guide*, EPA QA/G9-R, EPA/240/B-06/002, 2006, OEI, USEPA, Washington, D.C. (http://www.epa.gov/QUALITY/qs-docs/g9r-final.pdf) http://www.epa.gov/quality/qs-docs/g9r-final.pdf

20 *Data Quality Assessment: Statistical Methods for Practitioners*, EPA QA/G-9S, EPA/240/B-06/003, 2006, OEI, USEPA, Washington, D.C. http://www.epa.gov/quality/qs-docs/g9s-final.pdf)

21 http://nhsrc.intra.epa.gov/qa.aspx

22 http://nhsrc.intra.epa.gov/qa.aspx

staff for entering their QA product review forms. The QARF is available on-line through the Lotus Notes database (see Appendices C and D). The Lotus Notes system is used to track QAPPs, QMPs, SOPs, audits, and the NHSRC@work Web site is used to track products.

3.3.9 Training

Mandatory quality system training for all NHSRC management and technical personnel is described in Section 4.0.

This page left intentionally blank.

4.0
Personnel Qualifications and Training

It is the policy of NHSRC that all persons managing or directing NHSRC 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., PI), by those managing persons performing a technical activity (e.g., team leaders), or by surveying NHSRC staff. 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.

NHSRC staff is encouraged to participate in various types of training courses and continuing education programs which are identified in their Individual Development Plan (IDP).

4.1 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 (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/PI for a given NHSRC project may be described in the QAPP or facilities manual. The QAPP is prepared by the project officer/principal investigator/PI, reviewed by the TL, and DQA (see Section 2.6.6). General technical training needs for facility or team members may also be identified by NHSRC managers. Each employee is responsible for submitting his/her training records to the Center's Human Resources Management Representative who keeps a record of each NHSRC employee's formal technical training.

4.2 Project Management Training

For extramural project management, NHSRC adheres to the Agency's requirements regarding initial and ongoing training, including requirements for training as a Project Officer (PO), or Contract Officer's Representative (COR). The Center's Immediate Office of the Director keeps records of project management training for NHSRC personnel. A certification that the designated EPA extramural project manager or COR has the appropriate training is also required as part of each funding package.

4.3 Quality System Training

Training in NHSRC's Quality System policies and procedures is planned and performed by NHSRC's QA staff. The DQA will retain copies of the training certificates. Additional training needs are usually identified by the QA staff through interactions with NHSRC technical and managerial staff. Surveys have also been used to identify quality system training needs. Quality training is generally designed to: (1) inform NHSRC staff of new QA policies and procedures, (2) refresh NHSRC staff of current QA policies and procedures, (3) provide QA training to new staff member, or (4) describe services provided by the NHSRC QA staff (document review, and technical assistance).

At a minimum, the staff are expected to complete the following training modules: (1) Quality System training module prepared by the Office of Environmental Information; (2) NHSRC quality management plan; and (3) How to prepare a quality assurance review form. Additional training might include: (1) How to prepare a quality assurance project plan; and (2) How to define data quality objectives. The researchers are strongly encouraged to contact the QA staff for assistance regarding any QA related issue.

4.4 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 Center/locality safety officers and other health and safety personnel.

4.5 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, a Records Management Officer (RMO) will assist personnel with the implementation of the agency's National Records Management Program (NRMP). The NHSRC records file plan is available from the NHSRC's records liaison officer or on the NHSRC share drive. Further training and assistance is available online at www.epa.gov/records/policy/manual/index.htm.

4.6 Information Security Training

4.6.1 Information Security (INFOSEC) and Physical Security Programs

The NHSRC possesses a mature INFOSEC program for safeguarding, managing and using classified information. Designated Review Authorities (DRA) and the Security Manager assess risk in all NHSRC SOWs, IAs and work products under the RASP program, ensuring that sensitive and classified information is identified immediately and properly managed. Guidance and training is provided for classified materials safeguarding and management. Guidance for identification and classification/designation of information is provided. These programs are run by the Security Manager directly. References: *National Security Information Handbook, 2007*, *Identifying, Safeguarding and Sharing Homeland Security Risk Information, 2009* and *NHSRC Policies and Procedures Manual, 2008.*

4.6.2 Personnel Security (PERSEC)

The NHSRC requires all hires to be capable of acquiring a National Security clearance, but does not require all staff to possess a clearance. Justifications for clearances are coordinated by the Assistant Security Manager, who helps facilitate the process with Personnel Security Branch. Training is provided for new hires orientation, cleared personnel orientation and annual refresher, foreign travel and foreign contacts. Reference: *Personnel Security Handbook* and *NHSRC Policies and Procedures Manual, 2008.*

4.6.3 Automated Information Systems (AIS) and Communications Security (COMSEC)

The NHSRC controls and manages classified computer assets in order to support classified research. The NHSRC controls and manages COMSEC assets, such as STEs and HSDN. Training for classified AIS operation and COMSEC is provided as needed. AIS and COMSEC programs are run by the Assistant Security Manager. References: *National Security Information Handbook, 2007*, and *NHSRC Policies and Procedures Manual, 2008.*

5.0
Procurement of Items and Services

EPA policies require that parties to procurement agreements or assistance agreements shall have in place a quality system consistent with EPA requirements. Procurement agreements include contracts and simplified acquisitions, and parties to these agreements include primary contractors, subcontractors, and vendors. Assistance agreements include grants, cooperative agreements, and interagency agreements (IAs). 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 solicitation, award, and/or agreement documents.

Text Box 1: Quality Assurance related language for Statement of Work

In addition to completing the QARF, the COR must include the following statement, preferably under Task 1 of the SOW: **The awardee shall comply with all requirements as delineated on the "Quality Assurance Planning Requirements Form (QARF)" included with this extramural action, see attachment #1 and #2. The contractor shall prepare a QAPP in accordance with http://www.epa.gov/quality/qs-docs/r5-final.pdf for Category or II projects. In most cases, the QAPP can be based on the type of research that is being conducted. For guidance on preparing a category III or IV research-specific QAPP, the preparer should refer to the project specific requirements provided in NHSRC's QMP in Appendix B. The QAPP must be approved prior to the start of any laboratory work. Additional information related to QA requirements can be found at www.epa.gov/quality**

The Center utilizes the services of Cincinnati Procurement Office Division (CPOD) and its internal Simplified Acquisition Contracting Officers (SACO) (procurement under $100,000.00) for the procurement of items and services. Both the CPOD and the SACOs follow the Federal Acquisition Regulations[23] (FAR) which establishes government-wide policies and procedures governing the acquisition process. Two EPA publications, the Contracts Management Manual[24] and the EPA Acquisition Regulations[25] (EPAAR), were developed to supplement the FAR.

Only Contracting Officers (COs), including Simplified Acquisition Contracting Officers, are authorized to procure items and services, unless purchased via the U.S. Government Purchase Card program[26]. The Federal government is not bound by any commitments made by personnel other than those authorized.

Requests for purchases and identification of funds begin at the planning stages of any project. Items and services should be identified and specifications to meet the government's minimum needs should be detailed. These specifications will be required during the procurement process and assure that the requestor receives the proper item or service. It also reduces the chances of purchase delays or incorrect purchases being made because of inadequate product specification.

All procurements are documented using EPA Form 1900-8 Procurement Request (PR). The Contract Officers Representative (COR) or Project Officer (PO) is responsible for originating the PR and

23 http://www.arnet.gov/far/
24 http://intranet.epa.gov/oamintra/policy/cmm.pd
25 http://intranet.epa.gov/oamintra/policy/epaar.pdf
26 See Section 13.3 of Contracts Management Manual, http://intranet.epa.gov/oamintra/policy/cmm.pdf. EPA-NHSRC Purchase Card Standard Operating Procedures is found in shared drive I:\share\PurchaseCardInformation\Pcd_Guidance

identification of funding. The PR is then sent for approval to the divisional management. PRs are reviewed for completeness and accuracy by the appropriate Approving Officials (AO). Funds are certified as available by the Center's Funds Certifying Official who assigns a document control number (DCN).

5.1 Procurement of Services

It is NHSRC policy that any funding action that falls into one of the following accounting and object classification structures must include a Quality Assurance Review Form (QARF) form,

With appropriate signatures:

25.32	Programmatic Research and Development Contracts
25.05	Program Contracts
25.63	Programmatic Occupational Health Monitoring
25.71	Programmatic - Research Interagency Agreements.
41.00	Grants, Subsidies and Contributions

For contracts and IAs (Object Class 25.XX), funding actions include the initial award funding and any modifications that add additional funds. For assistance agreements (Object Class 41.XX), funding actions include the initial award funding, incremental funding (partial funding, no new work), and supplemental funding (additional funding of new work).

All funding actions and agreement documents are reviewed by NHSRC DQA or the QACs to ensure the appropriate requirements are included in each action.

5.1.1 Mechanisms for Procuring Services

Generally, two types of mechanisms are used to procure services; contracts and assistance agreements (e.g., grants, cooperative agreements, and interagency agreements). There are certain activities of a policy-making and/or decision-making nature that remain the sole authority of EPA[27] and can not be contracted.

It is required that an individual completes the contract administration training[28] prior to serving as a COR. Similarly for Project Officers who manage assistant agreements, completion of grants administration training[29] is required prior to being designated a grants project officer. Project officers who manage interagency agreements are required to take Interagency Grant Certification/Recertification training.[30]

5.1.2 Preparing the Extramural Package for Procuring Services

The procurement package is initiated by the COR or PO by completing the PR form and getting all the required signatures. The COR is responsible for preparing statements pertaining to the services to be delivered, and the acceptance criteria related to the quality of the service. Although, the COR has overall responsibility to oversee the service that is being provided, they must work through the CO's authority. The CO is the only individual who can enter into contractual agreements or amendments with the supplier.

The statement of work (SOW)[31] is a tool for the COR to ensure that adequate services or deliverables are provided. The COR must develop a SOW that accurately defines the minimum acceptable requirements for the service. The SOW must succinctly state the expectations of the product or service and the required format for the deliverable. The following statement should be included in NHSRC SOWs: Products developed under this SOW must conform to the requirements of EPA's Handbook for Preparing Office of Research and Development Reports (EPA/800/K-95-002). Substantive portions of this handbook can be found at www.epa.gov/nhsrc under the policy and guidance tab.

Usually, the quality documentation required from the contractor is a quality management plan[32] or

27 See Chapter 7.3.5.5 Advisory and Assistance Services and Vulnerable Services in the Contracts Management Manual; http://intranet.epa.gov/oamintra/policy/cmm.pdf. See EPA Order 1900.2 Contracting at EPA; http://intranet.epa.gov/rm-policy/ads/orders/1900_2.pdf

28 See Chapter 42 Contract Administration and Audit Services in the Contracts Management Manual; http://intranet.epa.gov/oamintra/policy/cmm.pdf

29 http://intranet.epa.gov/ogd/on_line_training/main/training.htm

30 http://intranet.epa.gov/ogd/on_line_training/main/training-infoiag.htm

31 See Chapter 11.1 Statements of Work in the Contracts Management Manual; http://intranet.epa.gov/oamintra/policy/cmm.pdf

32 http://www.epa.gov/quality/qmps.html

equivalent and a quality assurance project plan[33] or equivalent. For extramural agreements, the QMP is an organization or program-specific document; it describes the general practices of an organization or program. Project-specific details of individual projects of the organization or program are documented in a QAPP. In some cases where the objective of the work and needs of NHSRC do not require rigorous quality documentation, a combined QMP and QAPP may be developed. This agreement is detailed on the QA Review Form.

5.1.2.1 Contracts

Contracts are used when the government derives sole benefit from a particular product or service. The document which defines the authority requiring quality assurance documentation is 48 CFR 46[34]. Through tailoring language to 48 CFR 46, EPA requires that applicants submit a quality management plan or equivalent and a quality assurance project plan or equivalent when environmental data collection or generation activities are present in the contract.

5.1.2.2 Assistance Agreements

Assistance agreements are used when both parties (EPA and the group providing the service) derive benefit out of the service. This usually occurs with grants or cooperative agreements where universities, states, or non-profit organizations derive benefits. Grants are assistance agreements where EPA has no substantial involvement in the project. Cooperative agreements are assistance agreements where EPA has substantial involvement in the project.

Assistance agreement statements of work are usually developed jointly. However, once the SOW is complete, the parties must also agree on the quality standards for assuring the product or service. It is the responsibility of the PO to be knowledgeable of EPA's and NHSRC's quality policies and to present these standards during the development of the project's SOW.

Special conditions are usually included in assistance agreements. Assistance agreements will use the QA Review Form during the pre-award planning process and include quality documentation requirements (or similar requirements) in final agreements.

5.1.2.3 Interagency Agreements

For interagency agreements (IA) funded by EPA, NHSRC cannot require other Federal agencies to comply with EPA quality system requirements. The quality specifications must be negotiated between EPA and the other agency. When agreement is reached on the quality specifications, the specifications must be included in the interagency agreement.

When EPA receives funding from another agency through an interagency agreement, the EPA quality requirements shall apply in addition to any specifications provided by the funding agency.

5.2 Competitive Extramural Actions

5.2.1 Single-Project Effort

For a single-project effort, the PI typically requires that an offeror applicant address **NHSRC's** Quality System Specifications for Extramural Actions in their proposal (before award). The five specifications are:

(1) A description of the organization's Quality System (QS) and information regarding how the 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.

After-award, the PI typically requires the awardee to prepare a QAPP that meets the project-specific requirements specified on the QARF form. The before-award documentation, in concert with the after-award QAPP, constitutes a joint QMP/QAPP.

33 http://www.epa.gov/quality/qapps.html
34 http://ecfr.gpoaccess.gov/cgi/t/text/text- idx?c=ecfr&sid=7f97a455bf850e10849c341f7fc9cb71&rgn=div5&view=text&node=48:1.0.1.7.45&idno=48

5.2.2 Multiple-Project Effort

As part of the solicitation of a large contract with multiple work assignments and large assistance agreements with more than one level of development, the PI typically requires that an offeror or applicant submit a QMP (before award).

The QMP needs to meet the requirements of EPA (which includes compliance with the American National Standards Institute ANSI/ASQ E4-2004. Quality Systems for *Environmental Data and Technology Programs - Requirements with Guidance for Use* - see EPA Procedure CIO 2105-P-01-0) and is submitted by the offeror/applicant as part of the proposal. NHSRC has developed a set of requirements (see Appendix B) based on *EPA Requirements for Quality Management Plans*, EPA QA/R-2, March 2001. NHSRC's requirements are to be addressed in QMPs submitted as part of a proposal responding to a NHSRC solicitation. Each QMP is evaluated by the technical evaluation panel (TEP) to determine its acceptability. The specific evaluation procedures are determined and agreed to by the DQA or QAC, the PI, and the contracting officer prior to issuing the solicitation.

After-award, the awardee must revise the QMP according to comments received from the TEP. For each subsequent funding action where environmental data are used, generated, or collected, the PI typically requires the awardee to prepare a QAPP that meets the project-specific requirements specified on the QARF form.

5.2.3 Alternative Documentation

The QA documentation (QMP, QAPP or both) required is based on the type of extramural action. For example, if the COR is conducting a "Request for Proposals" (RFP) action then he/she must use the "before Award of Contract" identified in steps 1-6. On the other hand, if the COR is using an existing vehicle, then the suitable option would be steps 5 and 6.[35]

Before Award of Contract

STEP 1. Review the Statement of Work with the QA Manager (or the appropriate QA personnel) to determine if QA requirements apply. If not, complete Sections I, II, and III of the QA Review Form and sign the form and attach to the extramural package.

STEP 2. If QA requirements apply, determine what standards apply as allowed by your organization's Quality Management Plan (with the assistance of the QA Manager).

STEP 3. Complete the QA Review Form and obtain a concurrence signature of the QA staff as part of the acquisition package.

For each type of documentation selected in Section II a and II b of the QA Review Form, identify (with the assistance of the QA Manager) whether the documentation should be prepared in accordance with the standard EPA requirements [i.e., *EPA Requirements for Quality Management Plans (QA/R-2)* and *EPA Requirements for Quality Assurance Project Plans (QA/R-5)]* or whether other NHSRC-approved requirements will be used. The standard EPA requirements should be used unless the NHSRC QA staff agrees to different requirements identified in this Quality Management Plan.

STEP 4. If the potential value of the procurement exceeds $500,000; or the estimate of the percentage of costs or level-of-effort allocated to activities requiring quality requirements exceeds 15%; or procedures defined in the Agency-approved Quality Management Plan of the organization sponsoring the work apply; then the quality documentation (i.e., the Quality Management Plan or equivalent documentation) shall be included as part of the Technical Evaluation Criteria. The QA Manager, QA Officer, or authorized QA designee as defined in the organization's approved Quality Management Plan, shall: (1) assist the Project Officer with development of the Technical Evaluation Criteria, and any associated technical instructions, for the Request for Proposal, and (2) serve as a member of the Technical Evaluation Panel for the purpose of evaluating the QA aspects

35 Quality Assurance Requirements in Contracts Management Manual Chapter 46 http://epawww.epa.gov/oamintra/policy/cmm.pdf

of the technical proposals when a Technical Evaluation Panel is convened.

After Award of Contract - Perform these steps for each Statement of Work under the contract.

STEP 5. Review the project and determine if it requires quality documentation (for example, a QA Project Plan). Incorporate the requirement to develop this documentation and to implement the EPA-approved documentation into the project's Statement of Work. If the project will be based on previously prepared and current EPA-approved quality documentation, incorporate the requirement to implement this documentation into the project's Statement of Work.

STEP 6. Complete a QA Review Form for each project and attach it to the project's Statement of Work (e.g., statement of work, delivery order, task order). Obtain a concurrence signature of the QA Manager.

Alternative documentation may be selected by the PI in consultation with the DQA. For example, acceptable alternative documentation includes:

Before-Award:
NHSRC's Quality System Specifications

After-Award:
QMP and QAPP for the entire effort

Before-Award:
NHSRC's Quality System Specifications

After-Award:
QMP for the entire effort and QAPP for each applicable project

Before-Award:
QMP for the entire effort
After-Award: QAPP for the entire effort

Additional documentation may be allowable after consultation with the QAM and contracting officer.

5.2.4 Additional Requirements for Competitive Extramural Actions Exceeding $500,000

In addition to the requirements in Section 5.1, the following requirement exists for competitive contract and assistance agreement solicitations exceeding $500,000.

Part of the process for procurements where the estimated value exceeds $500,000 or the percentage of cost allocated to activities requiring quality requirements exceeds 15% includes the use of a Technical Evaluation Panel (TEP). The TEP must include the Director of Quality Assurance or a QA representative who is knowledgeable about the service being procured. The TEP rates each potential contractor against a standard set of criteria including quality documentation such as the quality management plan or equivalent. Portions of the criteria can include various assessments such as on-site audits and the analysis of performance evaluation materials. Prior to solicitation for bid, it must be determined what proportion of the TEP rating will be allocated to quality activities; it is suggested that a minimum of 10% of the overall TEP rating be allocated to quality activities.[36]

The role of the QA Manager, QA Coordinator, or authorized QA designee as defined in this Quality Management Plan, shall: (1) assist the Project Officer with development of the Technical Evaluation Criteria, and any associated technical instructions, for the Request for Proposal, and (2) serve as a member of the Technical Evaluation Panel for the purpose of evaluating the QA aspects of the technical proposals.

5.3 Non-Competitive Extramural Actions

Similar requirements (as described in Section 5.2) apply to non-competitive extramural actions. These requirements shall be incorporated into the award/agreement documentation. The PI must complete the QARF Form (see Appendix C).

36 Quality Assurance Requirements in Contracts Management Manual Chapter 46 http://epawww.epa.gov/oamintra/policy/cmm.pdf

5.4 QA Approval Process for Extramural Actions

For each extramural action, the COR must prepare a routing sheet, which is tool that is used to track and process all extramural packages, see Appendix G. In addition to the standard extramural forms and the QARF, it is required that NHSRC extramural packages contain a RASP form. When NHSRC project planning reaches final definition, a RASP review is required to assess the project's potential to generate classified or sensitive products. Because R&D projects are ordinarily dynamic in scope, the scope of information generated may also change substantially.

5.5 Evaluation of Quality Deliverables

In order to ensure that extramural organizations provide quality services that satisfy EPA QA/QC requirements, the DQA (or their designees) and PIs review QMPs, QAPPs, SOPs, and final products and audit projects and programs. Review comments generated by the QAM (or designee) are provided to the PI. The PI and QAM (or their designee) perform final review and issues approval. The PI is ultimately responsible for the quality of services provided.

5.6 Evaluation of NHSRC's Compliance with QMP

The NHSRC DQA schedules and conducts reviews of QA procedures pertaining to the procurement of items and services in the Center as part of the routine internal QSAs.

6.0
Documentation and Records

Quality Management Plans, QAPPs, facility manuals, and SOPs are prepared, reviewed, approved, issued, used, and revised. As described in Sections 3, 8, and 9, all these documents, including revisions, must be reviewed for conformance with the quality system requirements and approved by authorized personnel before general use. The following is a discussion of NHSRC procedures for documents and records, including computer-resident records. Records shall be maintained by the PI or PO so that all NHSRC research activities can be reconstructed.

6.1 EPA Records Management Policy

EPA records management policy is established by Office of Information and Resources Management and documented in the *Records Management Manual EPA 2160*.[37] 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 NHSRC 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. 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. National Homeland Security Research Center has a person designated as the Records Liaison.

37 www.epa.gov/records/policy/manual/index.htm

6.2 Project Documentation and Records

Documentation developed on a project-specific basis is the responsibility of the EPA PI for that project and is subject to EPA records management policy. The level of documentation required is dependent upon the type of project. Specific requirements are identified in the project QAPP. When a project is completed as determined by the PI, the project file is archived. This is accomplished by the PI in conjunction with the Records Liaison.

Because of the type of documents and records that are created within the Center, procedures are in place to protect sensitive information from being shared with unauthorized individuals. Information regarding NHSRC's security procedures is available on the intranet at NHSRC@work or by contacting NHSRC's Information Security Specialist.

6.3 Research Laboratory-Specific Documentation and Records

Documentation and records that may not be directly applicable to individual projects, (e.g., temperature logbooks, instrument logbooks, standard preparation logbooks, SOPs, balance calibration logbooks) are maintained in the location where they are used. All staff using the equipment or preparing standards are responsible for recording the appropriate information. When the logbooks are full or no longer needed, the logbooks or outdated SOPs are turned over to Records Liaison for appropriate retention, storage, and disposition. Personal laboratory notebooks are the responsibility of the individual. When full, they may be retained by the individual; or when no longer needed or wanted by the individual, they shall be turned over to the Records Liaison.

Table 2 provides the retention schedule for typical research documents either developed or used by NHSRC researchers. National Homeland Security Research Center staff is responsible for following the procedures for maintaining and retaining important research files and extramural documents. The unauthorized disposition is against the law (44U.S.C. 3106). In addition to ORD's research project file

retention schedules, NHSRC has a file plan for other both scientific and administrative records located on the NHSRC share drive.[38]

6.4 Software Documentation and Records

Center personnel are required to maintain software quality documentation and records consistent with EPA Office of Environmental Information (OEI) manual on Information Resources Management Policy[39].

Draft	Retention Time
• Scientific Research Project Files Related to Rulemaking 501	• 20 **years** after file closure – Permanent transfer to National Archives
• Instrument Logbooks 502	• **5 years** after file closure - Disposable except for projects that fall under 501 and 503.
• Scientific Research Project Files R elated to Basic, Exploratory Research 503	• **20 years** after file closure – Disposable
• Research Project Logbooks or Index R ecords (list of project status) 504	• **2 years** after file closure = Disposable
• Summary Research Projects Status R eports 506	• **3 years** after file closure -

Table 2 Selected Scientific Schedules for ORD Research Activities[1]

1 National Records Management Policy (NRMP) drafts: intranet.epa.gov/records/schedule/draft/

6.5 NHSRC Quality Documentation and Records

Any documents (e.g., the NHSRC QMP and other specific QA documents) developed directly by the NHSRC DQA, QAM, or at the direction of the QA staff shall be controlled by NHSRC. Although the QAMs may keep copies, records of reviews of QMPs, QAPPs, Facility Manuals, SOPs, final reports, and journal articles, internal audit reports, are the responsibility of the PI.

38 Public/NHSRC-PUB/NHSRC/NHSRC FILE PLAN 2006. xls

39 http://www.epa.gov/irmpoli8/archived/polman/

7.0
Computer Hardware and Software

The Center follows guidance published by OEI's and ORD's Office of Science and Information Management regarding the use of computer systems, including purchase of computers, purchase or development of software, design of databases, records management, security, and data standards. To assist in the implementation of software and hardware standards, the Cincinnati location has an OSIM representative who serves as the local IT coordinator.

Project-specific requirements for hardware configurations and for configuration control are specified by the PI in specific project QAPPs. Project-specific requirements and plans for software testing, validation, and documentation, whether the software is developed or purchased from an outside source, are also described by the PI in the QAPPs for those projects. Funding packages and plans for all NHSRC projects involving software development or purchase or computer purchase must undergo review and be approved by the Center Deputy Director to ensure that this guidance is followed and quality is ensured.

The EPA ORD QA staff has also developed an abbreviated guidance on model and software development which is available from the QA staff, and under QAPP requirements for these projects are presented in Appendix B.

Once proper planning has been performed (as described in Section 3.2.4), it is important that the implementation of the required procedures be done. It is the responsibility of the EPA PI to ensure that the required procedures are properly implemented.

This page left intentionally blank.

8.0
Implementation of Work Processes

8.1 QAPP Development, Review, and Approval

The EPA PI develops a QAPP based on NHSRC guidance (see Section 3.2.6). The QAPP must be reviewed and approved by the DQA or QAC before the project begins. A research project begins as soon as the PI is prepared to collect data/information to support Agency decisions or for inclusion in research products (e.g., paper and electronic reports, journal articles, symposium/conference papers, extended abstracts, computer products/software/models/databases, or scientific data). QA comments are documented in a memo to the PI, with a copy forwarded to the PI's first line supervisor.

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 PI or DQA or QAC. SOPs must be reviewed and approved by the DQA OR QAC and approved by an EPA person other than the author.

It is recommended that SOPs contain the following sections as appropriate:

1.0	Scope and Application
2.0	Method Summary
3.0	Sample Preservation, Containers, Handling, and Storage
4.0	Reagents
5.0	Equipment/Apparatus
6.0	Procedure
7.0	Calculations
8.0	Quality Assurance/Quality Control
9.0	References

8.3 QAPP/SOP Implementation

It is the responsibility of the PIs to ensure that the general procedures utilized throughout the Center are implemented during data collection activities. It is the responsibility of the EPA PI to ensure that the required procedures specified during the planning process for a specific project are implemented during data collection activities. This is done by personally observing the procedures being performed or by requesting that the QA staff perform an audit of the project activities outlined in a QAPP and/or SOP. In either 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 negative impacts 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 to revise QAPPs and/or SOPs. 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. QAPPs and project-related SOPs need to be reviewed on a yearly basis for long term projects. Center SOPs need to be reviewed every two years. Revisions (as necessary) in the form of an addendum or fully revised document must be made as soon as a significant change is identified. Significant revisions to a QAPP/SOP must be reviewed and approved by the DQA or QAC. It must then be verified that the revised procedures are being implemented properly, as discussed in Section 8.3. Copies of the most current document must be made available to the appropriate project personnel.

All previous document versions must be archived.

Table 3 provides information regarding who has the responsibility for revising, distributing, and archiving both the Center's QAPPs and SOPs.

Document	Revision Responsibility	Distribution of Revised QAPP/SOP	Archival of Previous Versions
QAPP	PI	PI	PI
Project-related SOP	PI	PI	PI
Center SOP	DQA or designee	DQA or designee	DQA or designee

Table 3 Distribution and archival of QAPPs/SOPs

9.0 Assessment and Response

The Center conducts a variety of assessments at the NHSRC-wide 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 includes: a review of the various assessment techniques, plans for appropriate response, and the process by which management determines the assessment activities appropriate for each level.

9.1 Assessment Techniques and Practices

Basic assessment categories were described in Section 3.3.5. In NHSRC, peer review is a separate function from QA. Program peer reviews are not performed by QA staff unless directed by the NHSRC Director or Deputy Director. The NHSRC QA staff responds to issues regarding data quality identified during the peer review process and provided to the QA staff.

9.2 Types of Assessments

A description of the four types of assessments is provided in this section.

9.2.1 Self-Assessment of a Quality System

A quality system self-assessment is a qualitative assessment of a quality system's operations by those immediately responsible for overseeing and/or performing the work to establish whether the prevailing quality structure, policies, practices, and procedures are adequate for ensuring that the type and quality of results needed are obtained.

9.2.2 Independent Assessment of a Quality System

An independent quality system assessment is a qualitative assessment of a quality system's operations by someone other than the group performing the work to establish whether the prevailing quality structure, policy, practices, and procedures are adequate for ensuring that the type and quality of results needed are obtained.

9.2.3 Technical Self-Assessment

A technical self-assessment is the evaluation process used by those immediately responsible for overseeing and/or performing the work to measure the performance or effectiveness of a technical system and its elements with respect to documented specifications and objectives. Such assessments may include qualitative and quantitative evaluations.

9.2.4 Independent Technical Assessment

An independent technical assessment is the evaluation process used by someone other than the group performing the work to measure the performance or effectiveness of a technical system and its elements with respect to documented specifications and objectives. Such assessments may include qualitative and quantitative evaluations.

9.3 Roles and Responsibility of the Assessors

The role of the assessor(s) is to provide information to the NHSRC PI as to the best practices and to clearly point out errors observed in the implementation of the QAPP. Some of the errors might 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.

9.3.1 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 NHSRC projects under the authority of, and with the permission of, the NHSRC PI and NHSRC management. Assessors do not have the direct authority to change project procedures or to alter project goals.

9.3.2 Conflict of Interest

The DQA is responsible for ensuring that audit personnel have no real or perceived conflict of interest, and have no direct involvement or responsibility for the work being assessed. The

selection of auditors shall ensure objectivity and impartiality of the audit process. At the discretion of the DQA, the auditors might be asked to sign a Conflict of Interest disclosure form prior to participating in the audit.

9.3.3 NHSRC-Wide Assessment and Response Procedures

The NHSRC DQA is responsible for planning, scheduling and/or conducting the assessments shown in Table 4. The NHSRC DQA may be assisted in the performance of assessments by Center researchers who possess the expertise necessary to conduct the assessment. 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 as described in EPA quality documents.

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)

Draft assessment reports are generated by the assessor within two weeks of the audit. Reports are sent as drafts to the NHSRC PI and to the auditee, for correction of factual errors and addition of any pertinent comments or responses to audit findings. Three weeks are generally allowed for this response and review.

Self-Assessment of NHSRC Quality System	
NHSRC QMP review	yearly, as part of QAARWP
Review of NHSRC Quality System	yearly, as part of QAARWP
Independent Assessment of the Application of the NHSRC Quality System	
Quality System Audit	every 3 years
Self-Assessments and Independent Assessment	
Technical System Audits	as needed or requested by senior management
Quality System Audit of Programs	as directed by senior management or Program Manager
PEs, ADQ,	are conducted as scheduled in planning documents or as requested by management
Surveillances	Surveillances are conducted as described in Section 3.3.5.5

Table 4 Types and Frequency of QA Assessment

NOTE: The conduct of TSAs will probably be performed very infrequently by the DQA. Technical Systems Audits conducted by the DQA intend to focus mainly on larger projects involving more than one NHSRC location.

9.4 Assessment Reports and Corrective Action

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

At the conclusion of each assessment, the assessment shall include a description of the type of corrective actions required to resolve any findings of nonconformance as described in EPA quality documents

9.5 Assessment Response Procedures

As mentioned in Section 9.5, the assessment reports are submitted to the PI. For an extramural project, the draft reports are distributed to the PI, the PI's

immediate supervisor, and to the auditee. It is the responsibility of the PI to ensure that the auditee addresses all of the findings and prepares a response to findings. The final reports are also distributed to the NHSRC PI, the PI's immediate supervisors, and to the auditee.

For intramural projects, the draft reports are distributed to the PI and the PI's immediate supervisor. It is the responsibility of the NHSRC PI to resolve audit findings. If findings can not be resolved by the NHSRC PI, the PI's immediate supervisor' 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 PI's project files.

For surveillances, a checklist serves as the report to the supervisor in charge of the laboratory area. A copy of the checklist is retained by the DQA, and another copy should be given to the PI of the area.

9.6 Audit Close-out

The final step of the process is called the audit close-out. The NHSRC quality assurance staff is responsible for ensuring that audit findings are addressed and that specific corrective actions have been implemented. When a dispute concerning audit close-out can not be resolved by the PI's immediate supervisor, the issue will be resolved by the Deputy Director for Management and/or the Associate to Center Director.

This page left intentionally blank.

10.0
Quality Improvement

Policies and procedures described in this manual were developed to continuously improve NHSRC quality system and to document QA planning and implementation. Two levels of quality improvement processes combine to evaluate the effectiveness of the NHSRC quality system and ensure continual quality improvement. At the QA Program level, QSAs discussed in Section 10.4 are performed by the NHSRC DQA. Any problems or areas where quality improvement can be made are identified and reported to the NHSRC Director, who is responsible for implementing the necessary corrective action. At the Project QA level, the document reviews and audits discussed in Section 10.5 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 PI, 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 DQA and QAC to monitor the quality procedures which are implemented on a day-to-day basis. This is done via audits, discussions with researchers, 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.

10.1 Quality System Opportunities for Improvement

The DQA will review the Quality Management Plan annually to determine if the document is still relevant to the Center's mission and reflects current practices.

To ensure that the current QA practices effectively accomplish the goals of the NHSRC quality system, the DQA and QAC meet on a weekly basis to discuss possible modifications to in-house QA procedures. If new procedures need to be incorporated into the quality system, the development will be led by the Director of Quality Assurance with the assistance of key personnel, determined on a case-by-case evaluation.

10.2 Quality Assurance Tracking System

The Center's tracking systems are used to monitor QARF submissions, and QAPP approvals. The tracking system provides real-time status of QAPPs that are missing, pending, or approved. This information is used to send reminders to the PIs regarding the status of their QA documentation.

In addition, the PIs are required to submit their products for QA review via the NHSRC@work intranet site.

10.3 Center-wide Opportunities for Improvement

The Center strives for continuous improvement of its processes, services and products by encouraging personnel to identify areas for improving our overall quality system. The quality staff periodically will solicit input from the staff regarding QA needs and/or satisfaction. This information will be used to develop training modules.

This page left intentionally blank.

11.0
Supplemental References

American National Standards Institute (ANSI)/ ASQC E4-1994, Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs, 1994, Milwaukee, WI.

U.S.EPA 2000. Quality Manual for Environmental Programs, CIO 2105 (formerly 5360.1, A2), US EPA Quality Staff, Office of Environmental Information (OEI), Washington, D.C.

U.S.EPA 2006. Requirements for Quality Management Plans EPA QA/R-2, EPA/240/B-01/002, OEI, Washington, D.C.

U.S.EPA 2006. Requirements for Quality Assurance Project Plans EPA QA/R-5, EPA/240/B-01/003, OEI, USEPA, Washington, D.C. (http://www.epa.gov/quality/qs docs/r5 final.pdf)

U.S.EPA 1992. System Life Cycle Management Guidance, US EPA Office of Solid Waste and Emergency Response, Washington, D.C.

U.S.EPA 1984. Records Management Manual (EPA 2160), US EPA National Records Management Program, Washington, D.C.

U.S.EPA. 2006. Guidance for the Data Quality Objectives Process, EPA QA/G-4, EPA/600/R-96/055, OEI, Washington, D.C.

U.S. EPA 2006.Data Quality Assessment: A Reviewer's Guide, EPA QA/G9-R, EPA/240/B-06/002, OEI, USEPA, Washington, D.C. (http://www.epa.gov/QUALITY/qs-docs/g9r-final.pdf)

U.S.EPA.2006. Data Quality Assessment: Statistical Methods for Practitioners, EPA QA/G-9S, EPA/240/B-06/003, 2006, OEI, USEPA, Washington, D.C. (http://www.epa.gov/quality/qs-docs/g9s-final.pdf)

U.S.EPA 2000. Quality Manual for Environmental Programs, CIO 2105-P-01-0, OEI, USEPA, Washington, D.C. (http://www.epa.gov/irmpoli8/ciopolicy/2105-P-01-0.pdf)

U.S.EPA 2007. Records Management Manual, 2007 NRMP, USEPA, Washington, D.C. (http://www.epa.gov/records//policy/index.htm http://www.epa.gov/records//policy/manual/index.htm)

U.S.EPA. 2006. Guidance on Systematic Planning Using the Data Quality Objectives Process, QA/G-4, EPA/240/B-06/01, 2006, OEI, USEPA, Washington, D.C. (http://www.epa.gov/quality/qs-docs/g4-final.pdf)

U.S.EPA. 2002. Overview of EPA Quality System for Environmental Data and Technology, EPA/240/R-02/003, 2002, OEI, USEPA, Washington, D.C., (http://www.epa.gov/quality/qs-docs/overview-final.pdf)

U.S.EPA. 2000.Policy and Program Requirements for the Mandatory Agency wide Quality System, CIO 2105.0, 2000, OEI, USEPA, Washington, D.C. (http://www.epa.gov/irmpoli8/ciopolicy/2105-0.pdf)

This page left intentionally blank.

Appendix A:
NHSRC Minimum Requirements for Center Rsearch Activities

The following requirements are to be implemented by NHSRC researchers/center personnel to ensure that data generated for publication are of adequate, documented quality. Additional requirements established for a specific project (as specified in QAPPs, SOPs, or facility manuals) supersede these minimum requirements.

SECTION 1.0, CENTER RESEARCH DOCUMENTATION

Center Research Documentation may be made in laboratory notebooks maintained by the researcher or in logbooks maintained in the laboratory.

1.1 Research activities shall be sufficiently documented to allow reconstruction of those activities. Documentation shall include the background and the objectives of the activities, as well as a detailed account of the activities performed.

1.2 Research documentation shall include project identification, date, and researcher identification. The use of bound notebooks with pre-numbered pages is recommended. Other forms of documentation may be used (e.g., pre-printed forms, electronic records) as long as research activities can be reconstructed. The PI is responsible for ensuring that research activities are adequately documented.

1.3 Center research documentation shall be in ink and use the single line method of correcting entries with the date and initials of the person making the correction.

1.4 Upon project completion, project-specific research documentation shall be maintained in the project file, or the project file shall identify where the documentation is stored.

1.5 Research documentation which applies to multiple projects (e.g., equipment and instrument logbooks) shall be maintained near the applicable equipment/instrument.

SECTION 2.0, SAMPLE STORAGE

2.1 Refrigerators used to store samples shall be monitored for temperature daily. Sample storage refrigerator temperature monitoring shall be documented.

2.2 Samples shall be maintained to ensure their integrity. For example, samples that require refrigeration (as specified in a project-specific QAPP/SOP) shall be refrigerated prior to analysis if the analysis is not performed immediately and returned to refrigeration immediately following analysis, until it is determined that additional analyses are not needed.

2.3 Samples shall be stored away from standards, samples, and other materials which could potentially cross-contaminate them. For example, aqueous/soil samples for volatile organic compounds should not be stored in the same refrigerator as concentrated volatile organic compound standards.

SECTION 3.0, EQUIPMENT CALIBRATION AND MAINTENANCE

3.1. Balance calibration shall be checked periodically in the range of use (daily with use is recommended unless justification for less frequent checking is documented in a QAPP, SOP, or facility manual). Balance calibration checks shall be documented. Documentation shall include the balance identification, date, calibrator's identification, and calibration check data.

Analytical balances will be serviced yearly and have their calibrations re-certified against ANSI/ASTM class 1 weight.

3.2 Analytical instrumentation (e.g., GCs, GC/MSs, ICPs, and AAs) shall be calibrated prior to use with standards of known and documented uncertainty traceable to a recognized standard organization if applicable. Initial calibration shall be verified using a standard from a different source than that used for the initial calibration. (If this second source check is not done, justification shall be documented in a QAPP, SOP, or facility manual.) Calibration shall be checked periodically during use. Analytical instrumentation calibration, calibration verification, and calibration checks shall be documented. Documentation shall include the instrument identification, date, calibrator's identification, and calibration data.1

3.3 Prior to project initiation, the PI shall ensure the accuracy of supporting equipment, as applicable (e.g., flow meters, thermometers/thermocouples, variable pipettes). Applicable documentation shall be maintained.

3.4 If temperature is critical, refrigerators, ovens, incubators, and constant temperature baths used during the implementation of analytical procedures (e.g., incubator for microbiological tests) shall be monitored to ensure that the required temperature is maintained. Temperature monitoring shall be documented.

3.5. All analytical instruments shall be properly maintained. Maintenance procedures shall be documented and kept near the instrument. Documentation shall include the instrument identification, date, analyst identification, and the maintenance performed.

SECTION 4.0, STAND OPERATING PROCEDURES (SOP)

4.1 SOPs shall be prepared to document analytical procedures (if a standard procedure is not implicitly followed) that will be performed routinely or that will be implemented by multiple personnel.

4.2 SOPs shall be maintained in the laboratory area where the procedure is implemented.

SECTION 5.0, STANDARD PREPARATION

5.1 Standard preparation shall be documented. Documentation shall include the date, analyst identification, the identity of the stock/intermediate standard used, preparation procedures, and applicable expiration dates.

5.2 Standards shall be stored to maintain their integrity.

SECTION 6.0, QUALITY ASSURANCE AND QUALITY CONTROL CHECKS

6.1 QA/QC checks shall be performed as defined in applicable SOPs/QAPPs/facility manuals.

6.2 When QA/QC checks are not defined in SOPs/QAPPs/facility manuals, positive controls (e.g., blank spikes, matrix spikes), negative controls (e.g., blanks), and replicates (e.g., duplicates) shall be performed periodically to demonstrate the accuracy and precision of a method for each unique matrix.

6.3 Method detection limits (MDLs) shall be determined when results below the low calibration standard will be reported.

SECTION 7.0, DATA REVIEW

7.1 For each analysis, the analyst shall review results for QC checks performed to determine compliance with acceptance criteria specified in the applicable QAPP, SOP, or facility manual. If acceptance criteria are not met, the analyst shall perform corrective action as required by the applicable QAPP, SOP, or facility manual.

7.2 Data generated shall be reviewed by a second technical person for a representative sample for each method performed (10% is recommended). (Note that this may not be possible for very specialized analyses). If problems are identified, additional review will be performed to determine the extent of the problem. Review shall be documented.

SECTION 8.0, DATA STORAGE

Documentation of research activities, including analytical data, shall be maintained as required by EPA's record management policies.

This page left intentionally blank.

Appendix B:
QAPP Requirements and Guidance

REQUIREMENTS AND GUIDANCE

For Category I (enforcement, litigation, or projects involving human subjects) and Category II (development of environmental regulations or standards), NHSRC's requirements are those listed in *EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5*, EPA/240/B-01/003, March 2001. *Guidance for Quality Assurance Project Plans, EPA QA/G-5*, EPA/240/R-02/009, December 2002 may be used to help address these requirements. (These documents are available at http://www.epa.gov/quality/qa_docs.html)

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/240/R-02/009, December 2002 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 Secondary Data Research Projects are presented in this appendix. *Guidance for Quality Assurance Project Plans, EPA QA/G-5*, EPA/240/R-02/009, December 2002 referenced above may be used to help address the requirements listed for Secondary Data Research Project QAPP; however, only the requirements listed in this appendix need to be addressed.

QAPP requirements for Sampling and Analysis 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 DQA OR QAC 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 NHSRC 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), 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) shall be described.

2.11 Requirements for shipping samples shall be described.

2.12 Holding time's 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

1.1 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]

1Provide details in text, as necessary, if standard method or SOP cannot be referenced
2Both 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

1Include all QA/QC checks (experimental and analytical, as applicable) for accuracy, precision, detection limits, mass balance (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 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 staffs and their relationship in the organizations (i.e., location within each organization) shall be identified with evidence that the QA staff 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.

2.4 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 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 PI, 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 sample shall be described.

4.12 Sample preservation methods (e.g., refrigeration, acidification), 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) 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). The contents of this document can be referenced to a NHSRC 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 RESEARCH MODEL DEVELOPMENT AND APPLICATION PROJECTS

A research model project is a study performed to develop a new model or apply an existing model to provide information to support non-regulatory environmental research or decision-making. A QAPP must be submitted at the beginning of a research model development or application project. The QAPP should specify the quality requirements needed to ensure the quality of the results produced by the model. The recommended format for research model development QAPPs is presented below; guidance for completing each section is provided in italics. (For model application projects, a smaller subset of requirements needs to be addressed, as appropriate; e.g., information on code development would not be included.) If data will be generated to develop or calibrate the model, a separate QAPP is needed and should address the requirements applicable to the type of research project (e.g., basic research, applied research). If a model will be developed to support regulatory environmental decision-making, additional requirements may apply.

SECTION 1.0, PROJECT DESCRIPTION

1.1 Discuss the scope and purpose of the model. Provide a brief statement of the scope and purpose. The specific problem which needs to be addressed should be discussed, including the intended users of the model.

1.2 Identify the project's objectives. Discuss the specific objectives for this project, including the expected product and a timetable for completion.

1.3 Identify the roles and responsibilities of all project participants and support facilities. Identify project personnel and key support facilities (including computer facilities). Discuss the duties/responsibilities for each. An organizational chart can be used to show lines of authority and communication.

SECTION 2.0, MODEL DESCRIPTION

2.1 Discuss the model parameters, including the theoretical approach for the model and the mathematical relationship between input and output variables.

Provide an overview of the model parameters, including:

- model origin and its original purpose, if applicable
- parameters and variables
- the algorithms and equations that have been developed to support the model theory, along with the sources of the algorithms
- spatial extent (individual, group, population)
- spatial resolution (location independent/dependent, dimensionality)
- temporal extent (length of modeling period)
- temporal resolution (time step)
- model structure (e.g., stochastic vs. deterministic, structural framework).

2.2 Discuss any initial assumptions regarding model development/application. Initial assumptions made during model development should be identified.

2.3 Specify required sources for model databases and any requirements for these data (e.g., quality, quantity, spatial, and temporal applicability). If data sources are not currently known, describe the criteria used to identify sources.

The purpose of assessing data quality is to evaluate, to the extent possible, the reliability of the existing data base(s). Procedures for determining precision, accuracy, representativeness, completeness, and comparability of existing data should be summarized. Specific parameters to be discussed include:

- source of data and criteria for acceptance or rejection
- any modifications from existing data
- data format, maintenance, and archiving.

SECTION 3.0, MODEL DEVELOPMENT

3.1 Discuss requirements for code development. Quality Assurance procedures for code development should include complete record keeping of the model development and of modifications made in the code. Required records include:

- parameter values and sources
- changes and verification of changes made in code
- output of model runs and interpretation
- assumptions.

If any modifications are made to the model coding, the code should be tested again; all QA procedures for model development should again be applied, including accurate record keeping and reporting.

The code documentation should include:

- model specifications
- model description
- flow charts
- description of routines
- data base description
- source listing
- error messages.

3.2 Discuss computer requirements for both hardware and software.

Identify computer requirements, including:

- programming language (FORTRAN, BASIC, etc.) and ANSII standard
- model portability
- memory requirements
- required hardware/software for application
- data standards for information storage and retrieval (refer to Office of Environmental Information guidance.

When appropriate, a review of existing software should first be considered to determine capability for implementing the new model.

3.3 Discuss how the code will be verified.

The objective of the code verification process is to check the correctness and accuracy of the computational algorithms used to solve the governing equations and to assure that the computer code is fully operational.

The inspection of the computer code is part of the model review process. In this inspection, attention is given to the manner in which modern programming principles have been applied with respect to code structure, compliance with programming standards, efficient use of programming languages, and internal documentation. This step may reveal programming or logic errors that are difficult or impossible to detect in verification runs.

3.4 Describe the requirements for model documentation. Model documentation is defined as the information recorded during the design, development, and maintenance of the model, in order to explain pertinent aspects, including purposes, methods, logic, relationships, capabilities, and limitations. It is the principle instrument of communication\ used by the model author, the model user, and the system operator.

Good documentation includes a description of (some of these may have been discussed previously): the equations on which the model is based;

- the underlying assumptions
- the boundary conditions that can be incorporated in the model
- the method used to solve the equations
- limiting conditions.

The documentation may also include:

- user's guide (electronic or paper)
- source code
- instructions for preparing data files
- example problems complete with input and output
- programmer's instructions
- computer operator's instructions
- report of the initial code verification
- documentation of significant changes to the model
- procedures for maintenance and user support, if applicable.

SECTION 4.0, MODEL CALIBRATION

Model calibration is defined as the process of refining the model to achieve a desired degree of correspondence between the model output and actual observations of the environmental system that the model is intended to represent. Model development is an evolutionary process responding to new research results, developments in technology, and changes in user requirements. Model calibration needs to follow this dynamic process and should be applied each time the model is modified.

4.1 Discuss how the model will be calibrated.

Identify the type and source of data (e.g., new data, existing data, professional judgment, expert opinion elicitation) that will be used to calibrate the model. If data sources are not currently known, describe the criteria used to identify sources.

4.2 Describe any requirements for the data that will be used to calibrate the model. Calibration data requirements with respect to quality, quantity, and spatial and temporal applicability should be specified, as applicable.

4.3 Specify criteria which need to be met for the difference between predicted and observed data during model calibration.

The acceptance criteria which need to be met for the difference between predicted and observed data should be specified. The statistical methods to be used (e.g., goodness-of-fit, regression analyses) should also be discussed. If criteria cannot be specified, this should be discussed.

SECTION 5.0, MODEL ASSESSMENT (VALIDATION) AND APPLICATION

5.1 Discuss the assessments planned to ensure the acceptability of model outputs. This element of the QAPP documents the types of assessments to be performed throughout the various stages of model development and application, the purpose of each assessment and the specific model features that each assessment is to address, and the expected periods of time in which the assessments will take place. Details regarding how the assessments will be performed and by who need to be provided. The specific assessments are based on a clear understanding and statement of the purpose of the model and the accuracy of the model outputs needed (predictions).

In general, this QA Project Plan element specifies the following types of information:

- a description of the assessment/ oversight strategies and schedule of assessment activities, including the order in which the assessments will be conducted and how the total set of assessments is structured to provide a complete and comprehensive oversight;
- a description of how each assessment will be planned and conducted and;
- the organizations and individuals that are expected to participate in assessments, including peer reviews and;
- the information expected success criteria, and documentation for each assessment.

Additional guidance on assessments is provided in EPA QA/G-5M (www.epa.gov/quality/qa_docs.html).

5.2 Identify any restrictions on the use of the model. Restrictions on model application should be outlined. Categories of restrictions include:

1. assumptions
2. parameter values and sources
3. boundary and initial conditions
4. validation/calibration of the model output and interpretation of model runs

If any of these items has been presented and discussed previously, inclusion here is not necessary.

SECTION 6.0, REFERENCES

Provide references to methods and applicable publications.

EPA, Environmental Research Laboratory. Quality Assurance Guidelines for Modeling Development and Application Projects, November 1991.

EPA QA/G-5M. 2002. Guidance for Quality Assurance Project Plans for Modeling. van der Heijde, P.K.M. 1989.

Quality Assurance and Quality Control in Groundwater Modeling. IGWMC Groundwater Modeling Publications, Holcomb Research Institute, Butler University, Indianapolis, IN:25.

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).

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, 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)?

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], 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) or subsampling (e.g., mixing sample before taking subsample for analysis) 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, and surrogates.

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).

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, and 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 B-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 DQA OR QACs.

SECTION 1.0, PROJECT DESCRIPTION and APPROVAL

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.

The EPA Technical Lead Person (PI) 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 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 NHSRC, 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 B-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 B-1 QAPP Elements according to the QA Category

	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 a. Development of SOPs b. QC for Implementation	I, II*
7.	Testing a. Individual Module Tests b. Integration Tests c. System Tests d. Retesting after Changes e. Acceptance Testing (if applicable) f. Beta Testing (if applicable)	I, II, III, IV*
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 B- 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 staff's option

Appendix C:
NHSRC Quality Assurance Review (QARF) Forms

NHSRC QUALITY ASSURANCE REVIEW FORM
FOR EXTRAMURAL ACTIONS

Name :_____

Division:_____

Project ID Number: _____ Security Classification: _____

I. General Information

a. Select Action Type:

In-house Research 0 (Skip to Section II) or Extramural Research 0

b. Select *all* that apply: Vehicle Type:

0 New Vehicle (must complete Section IVa (before award) and IVb (after award))

0 Existing Vehicle (must complete Section IVb (after award))

Existing Vehicle No _____

0 Contract
0 Sole Source
0 Simplified Acquisition
0 Assistance Agreement
0 IAG*
0 CRADA*

0 Work Assignment No. _____
0 Delivery/Task Order No. _____
0 Modification No. _____
0 Other: _____
_____

II. QA related Information

a. QA Category

0 1 (established QA requirements for projects involving enforcement, litigations or human subjects)
02 (established QA requirements for projects supporting the development of environmental regulations or standards)
0 3 (established QA requirements for projects involving applied research or technology evaluations)

---

* *If you are processing an **IAG** or **CRADA**, the responsibility for QA must be negotiated within the agreement. The PI 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 PI from each organization, and the QA requirements that will be adhered to during the agreement. Include this info in the IAG/CRADA package.*

0 4 (established QA requirements for projects involving basic research or preliminary data gathering activities)

b. Project type (Choose all that apply):

0 Applied Research
0 Basic Research
0 Secondary Data
0 Design/Construction/Operation of Environ. Technology
0 Model Development
0 Sampling and Analysis
0 Method Development
0 Software Development and Data Management

Descriptive Title:_____

_____

III. Scope of Work

a. Does this extramural action involve the collection, generation, use, and/or reporting of environmental data; the design, construction, and operation of environmental technologies; or development of software, models, or methods? (If ANo@ then skip to Section IV, and sign the form.) 0 YES 0 NO

b. Will the SOW or any subsequent work assignments or task orders involve any cross-organizational efforts within EPA? If so, which organization will take the lead for QA? 0 YES 0 NO

c. Has a QAPP already been approved for the activities specified in the SOW? 0 YES 0 NO
If yes, please provide the necessary information.

1. Provide the title, date or revision number, and date of QA approval:

_____

_____

2. Does the QAPP require any revision by the contractor*? 0 YES 0 NO 0 N/A

d. Is an applicable QAPP in the process of being prepared, revised, or approved by EPA personnel for future use by the contractor? 0 YES 0 NO 0 N/A
(QA approval must be obtained before the contractor can start work.)

1. Provide the expected title and approximate date for submission to QA staff for approval:

_____

_____

IV. QA Documentation Options: For solicitations, complete items 1-4; for all actions other than solicitations, complete items 3-4. All documentation specified under "Other" must be defined in the NHSRC Quality Management Plan and be consistent with requirements defined in EPA CIO 2105-P-01-0[41] (formerly

---

* *The term "contractor" applies loosely here, such that as applicable, this term can also mean Aawardee@, Acooperator@ and/or Agrantee@. Likewise, the term Acontract@ includes Aagreements@ and other vehicles.*

41 *EPA Quality Manual for Environmental Programs*, CIO 2105-P-01-0, 2000, OEI, USEPA, Washington, D.C. http://www.epa.gov/irmpoli8/ciopolicy/2105-P-01-0.pdf

known as 5360 A1). For all items checked below, there must be adequate information in the SOW (or its appendices) for the offeror to develop this documentation. Where applicable, reference a specific section of the SOW. *(R-2 refers to EPA Requirements for Quality Management Plans (QA/R-2) (EPA/240/B-01/002, 03/20/01) and R-5 refers to EPA Requirements for Quality Assurance Project Plans (QA/R-5) (EPA/240/B-01/003, 03/20/01). Copies of these documents are available at http://www.epa.gov/quality/qa_docs.html.)*

a. Before Award Documentation

1. ___ Documentation of an organization's Quality System: Either 0QMP developed in accordance with R2 or 0 Other: _____

___ Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by contract: Either developed in accordance with 0 R2 and R5 or 0 Other: _____

2. ___ Programmatic QA Project Plan developed in accordance with 0 R5 or 0 Other: _____

___ Application of QA and QC activities to the single project covered by contract: Either 0QA Project Plan developed in accordance with R-5 or 0 Other: _____ _____

___ Not applicable.

b. After Award Documentation

3. ___ Documentation of an organization's Quality System: Either 0 QMP developed in accordance with R2 or 0 Other:_____

___ Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by the contract: Developed in accordance with either 0 R2 and R5 or 0 Other: _____

___ Not applicable.

4. ___ Documentation of the application of QA and QC activities to applicable project(s): Either developed in accordance with 0 R-5; 0 Supplement to the following Programmatic QA Project Plan _____; or 0 Other: _____

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

___ Existing documentation of the application of QA and QC activities will be used: Either 0 Documentation developed pre-award; 0 Documentation will be identified in individual Statements of Work or 0 Documentation identified in Section ____ of the Statement of Work.

V. Signature Block: The signatures below verify that the Statement of Work (SOW) has been reviewed to ascertain the necessary QA and QC activities required to comply with EPA Order 5360.1 A2, that the COR understands these requirements, and that the COR will ensure that the quality requirements indicated on the previous pages of this form are incorporated into all associated SOWs. *(Sign/date below, obtain a concurrence*

signature from the QA Staff, and submit the form along with the other extramural action documentation.)

NHSRC Technical Lead Person (PI)	Date	NHSRC QA Staff Member	Date

Appendix D:
NHSRC QA Requirements/Definitions List

NHSRC QA Requirements/Definitions List

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

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

Category I: Research that directly and/or immediately supports specific Agency rule-making, enforcement, regulatory, or policy decisions. This category may also include research of significant national interest, such as tasks that might be monitored by the Administrator. The QAPP shall address all elements listed in EPA Requirements for QA Project Plans, http://www.epa.gov/quality/qs-docs/r5-final.pdf

C**ategory II:** Research of high programmatic relevance that, in conjunction with other ongoing or planned studies, is expected to provide complementary support of Agency rule-making, regulatory, or policy decisions. The QAPP shall address all elements listed in EPA Requirements for QA Project Plans, http://www.epa.gov/quality/qs-docs/r5-final.pdf

Category III: Projects involving applied research or technology evaluation; method validation studies.

Category IV: Basic, exploratory, conceptual research to study basic phenomena or issues that typically result in a peer-reviewed journal article.

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 AQAPP Requirements for Applied Research Projects@ from Appendix B of the NHSRC 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 AQAPP Requirements for Basic Research Projects@ from Appendix B of the NHSRC 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 A 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 AQAPP Requirements for Method Development Projects@ from Appendix B of the NHSRC 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 AQAPP 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 AQAPP Requirements for Sampling and Analysis Projects@ from Appendix B of the NHSRC 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 AQAPP Requirements for Secondary Data Projects@ from Appendix B of the NHSRC 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 AQAPP Requirements for Software Development Projects@ from Appendix B of the NHSRC 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.

NHSRC'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 ARequirements for Quality Management Plans@ in Appendix B of the NHSRC 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 (PI) - This person is technically responsible for the project. For extramural contract work, the PI is typically the contracting officer's representative (COR). For intramural work, the PI is typically the Principal Investigator.

Appendix E:
NHSRC Product QA/QC Verification Report Form

Attach to all products when submitted for Quality Assurance (QA) review

Date Submitted: __ EPA PI:_____

Project No.: _____

Product Title: _____

Product Type:
0 Journal Article
0 Symposium Paper/Conference Paper
0 Extended Abstract
0 Report (Published, Unpublished, Internal)
0 Other_____
0 Computer Product/Software/Model/Database
0 Scientific Data
0 Guidance

Date QA Review Needed:

Quality Assurance Project Plan (QAPP) STATUS:

Was a QAPP prepared and reviewed by Quality Assurance Manger (DQA OR QAC), prior to collecting data/information included in product? **YES** 0 or **NO** 0

If yes, QA ID No. /Review Date: _____

If no, explain: _____

DATA QUALITY SUMMARY:

Please mark the following as appropriate:

0 All project QA requirements were met (i.e., all QA/QC checks specified in the QAPP were performed and acceptance criteria were met).

0 Some project QA requirements were not met. Product quality IS NOT adversely affected. (Consult DQA OR QAC if needed.)

0 Some project QA requirements were not met. Product quality IS adversely affected. (Consult DQA OR QAC if needed.)

0 Not Applicable. Explain: _____

Discussion of Data Limitations: _____

-

Signed By: _____ **Date: __**
(EPA PI

This page left intentionally blank.

Appendix F: Requirements for Quality Management Plans (QMPs)

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 staff 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 staff(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) 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).

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).

4.2 **Procurement Technical and Quality Requirements.** Describe procedures for ensuring that procurement documents (e.g., formal contract with subcontractor, purchase order for equipment) 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).

5.2 **Document Control.** Identify which documents require control (e.g., technical manuals, operating procedures, QAPPs, SOPs, final reports). 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) 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).

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) 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.

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.

This page left intentionally blank.

Appendix G:
Routing Slip for Extramural Packages

ROUTING SLIP FOR NHSRC EXTRAMURAL PACKAGES

Project Number:

Project Title:
Type (choose one)

- O IAG (new) Interagency Agreement with:
- O Cooperative Agreement (new) with:
- O Contract (new)
- O Work Assignment Name of Contractor:
- O R&D Funded Small Purchases
- O Incremental Funding
  - O Contract O Cooperative Agreement O Interagency Agreement
- O Task order under GSA schedule
- O Other (specify):

ROUTING / APPROVALS:

	Initials	**Reviewer**: Please mark review status	Date
PI / Originator:			
NHSRC Division Director:		☐ Reviewed	
NHSRC Extramural Management Specialist:		☐ Reviewed	
NHSRC Security Officer:		☐ Reviewed	
QA Officer:		☐ Reviewed	
Center Deputy Director:		☐ Reviewed	
Funds Control Officer:			

Send original funded package to:

- ☐ Contract specialist _____ (name, if known)
- ☐ IAG specialist _____ (name, if known)
- ☐ Contract level COR _____ (name, if known)
- ☐ Return to originator
- ☐ Other:

COMMENTS: