**SOW Attachment # 1**

**NHSRC QA Requirements/Definitions List**

**EPA’s Quality System Website: http://www.epa.gov/quality**

**EPA’s Requirements and Guidance Documents:** [**http://www.epa.gov/quality/qa\_docs.html**](http://www.epa.gov/quality/qa_docs.html)

**EPA’s Quality System Website:** [**http://www.epa.gov/quality/qs-docs/r5-final.pdf**](http://www.epa.gov/quality/qs-docs/r5-final.pdf)

In accordance with EPA CIO 2105.0 (Order), EPA 2105-P-01-0 (Manual), and conformance to ANSI/ASQC E4 must be demonstrated by submitting the quality documentation described herein. All Quality documentation shall be submitted to the Government for review. The Government will review and return the quality documentation, with comments, and indicate approval or disapproval. If the quality documentation is not approved, it must be revised to address all comments and shall be resubmitted to the Government for approval. Work involving environmental data collection, generation, use, or reporting shall not commence until the Government has approve the quality documentation. The Quality Assurance Project Plan (QAPP) shall be submitted to the Government at least thirty (30) days prior to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the Contractor shall also implement it as written and approved by the Government.

**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.

**NHSRC QA Requirements/Definitions List**

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

**Category A Project** – applies to research that is anticipated to result in high-visibility products. Research of this nature meets one or more of the following criteria:

* Has a high probability the results could be used in litigation or enforcement\
  + Is a HISA
  + Direct regulatory support
  + Results are ISI

The QAPP shall address all elements listed in “EPA Requirements for QA Project Plans, EPA QA/R-5.

**Category B Project** - applicable to projects involving applied research or technology evaluations. The QAPP shall address the applicable sections of “EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC’s QMP: QAPP** requirements for the specific project type (see below).

XX

**Project Types:**

**These outlines of NHSRC’s QAPP Requirements for various project types, from Appendix B of the NHSRC QMP (except where otherwise noted), are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended to serve as a starting point when preparing a QAPP.** These lists and their format may not fit every research scenario and QAPP’s must conform to applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to ensure that the data are of adequate quality and quantity to fit their intended purpose.

**Applied Research Project** - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. The QAPP shall address all requirements listed in “QAPP Requirements for Applied Research Projects” from Appendix B of the 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 the EPA Quality System document “Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation” G-11, at <http://www.epa.gov/quality/QS-docs/g11-final-05.pdf.> For additional information, you may refer to 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.

**Geospatial Data Quality Assurance Project** - pertains to data collection; data processing and analysis; and data validation of geospatial applications. The QAPP shall address requirements in the EPA Quality System document “Guidance for Geospatial Data Quality Assurance Project Plans” G-5S at [http://www.epa.gov/quality/QS-docs/g5g-final-05.pdf.](http://www.epa.gov/quality/QS-docs/g11-final-05.pdf.)

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

**Model Development Project** - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. The QAPP shall address requirements in the EPA Quality System document “Guidance for Quality Assurance Project Plans for Modeling” G-5M at [http://www.epa.gov/quality/QS-docs/g5m-final.pdf.](http://www.epa.gov/quality/QS-docs/g11-final-05.pdf.)

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

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

**Definitions:**

**Environmental Data** - These are any measurement or information that describe environmental processes, location, or conditions; ecological or health effects directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature. 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 literature.

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

**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, which are needed to acquire data of known and adequate quality.

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

R-2. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 [http://www.epa.gov/quality/QS-docs/r2-final.pdf.](http://www.epa.gov/quality/QS-docs/g11-final-05.pdf.)

R-5. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 [http://www.epa.gov/quality/QS-docs/r5-final.pdf.](http://www.epa.gov/quality/QS-docs/g11-final-05.pdf.)

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

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

**Abbreviations**

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