

QAPP REQUIREMENTS FOR SECONDARY DATA RESEARCH PROJECTS

Example Guidance by the QA Managers in EPA's National Risk Management Research Laboratory

A secondary data research 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 Divisional QA Manager should be consulted if necessary.

SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

- 1.1 The purpose of study shall be clearly stated in the QAPP.
- 1.2 Project objectives shall be clearly stated in the QAPP.
- 1.3 The secondary data needed to satisfy the project objectives shall be identified in the QAPP. 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 (i.e., data analysis), including formulas, units, definitions of terms, and statistical analysis, if applicable, shall be included in the QAPP.
- 1.5 Responsibilities of all project participants shall be identified in the QAPP, 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 required source(s) of the secondary data must be specified in the QAPP. If a hierarchy of sources exists for the gathering of secondary data, that hierarchy must be specified in the QAPP.

- 2.2 The rationale for selecting the source(s) identified shall be discussed in the QAPP.
- 2.3 The QAPP shall state that the sources of secondary data gathered 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 in the QAPP. 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 in the QAPP.
- 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 cannot be determined, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data is unknown. The wording for the disclaimer shall be included in the QAPP.

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

- 4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.
- 4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.
- 4.3 The expected product document that will be prepared shall be specified (e.g., journal article, final report, etc.).