

## **Elements of a Quality Assurance Project Plan (QAPP) For Collecting, Identifying and Evaluating Existing Scientific Data/Information**

This is a suggested template for EPA scientists and contractors

- 1. Title and Approval Page**  
*Include signature lines for the contractor, his/her quality system personnel, the NCEA project officer, and his/her quality assurance manager.*
  
- 2. Quality System Components**  
*Describe the contractor's current organizational quality assurance program, including but not limited to:*
  - a. Who has responsibility for the quality control of projects?
  - b. Where is this person in the organizational hierarchy?
  - c. What quality control and assurance procedures are planned or in place for projects like the proposed, and are these procedures documented?
  - d. How does the person responsible for quality assess and document the quality control exercised in projects and implement any necessary corrective actions, including those that require approval from the project's client?
  
- 3. Project Definition and Background**  
*This information may be found in the Project Plan, Statement of work or narrative for the contract.*
  
- 4. Data Quality Objectives (DQOs)**  
*Include an explanation of data use and acceptance criteria (precision, accuracy, representativeness, completeness, and compatibility). Some of DQOs may be specified in the Statement of Work or narrative for the project.*
  
- 5. Project Organization and Responsibilities of the Researcher**  
*Briefly describe how the project will be executed and who has responsibility for the various tasks. List licenses, certifications, and accreditations that are applicable to this project. Document how any items and services procured under this project will be determined to be of good quality and applicable to the needs of this project.*
  
- 6. Project Description, Documentation, and Reporting**
  - A. Literature Search
  - B. Extracting, Proofing, Presenting Data from Literature Searches

General Considerations and QA Requirements for the following issues:

- a. Source(s) of the existing data/information and rationale for selecting the source(s):  
*Sample selection, collection and preparation (describe the planning process for data gathering operations and how the organization ensures that data or information collected for a project are of sufficient quality to satisfy the needs of the project);*
- b. Non-quality constraints on the existing data/information (e.g., legal, programmatic, CBI) that affect its use in the project;
- c. How the existing data/information will be used in the project, e.g., augment or replace existing data/information, verify or validate existing data/information;
- d. Procedures for determining the quality of the existing data/information, i.e., how and to what degree will the accuracy, precision, representativeness, completeness, and comparability of the data/information be determined for the purposes of the project; what are the limitations or uncertainties associated with the data/information;
- e. Reduction/validation procedures, including calculations and equations, for the existing data/information that are specific to the project (*for data gathered from publication, see the accompanying "Quality Assurance Instructions for Researchers Citing Secondary Information"*); and
- f. Plans for review of the project during operation (oversight) (*discuss how the contractor will test for quality problems with this project. Who is normally responsible for this process of testing? Who changes the methods within the project if change is indicated by these tests?*).

**7. Reconciliation with Data Quality Objectives**

*Describe how issues which come up during the project and require adjustment to the DQOs will be resolved.*

**Quality Assurance Instructions for Researchers Citing Existing Data/Information**

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in *67 FR 8452*, 2/22/02, underscore the need for EPA/NCEA to assess the quality and credibility of the existing data/ information cited in its criteria and assessment documents.

Existing data/information is defined as data/information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Existing information usually originates from such primary sources as journal articles, books, government and industry reports,

databases and models. The set of processes that follows serves as a guide to evaluate the strength of existing data/information gathered from these primary sources.

To begin, researchers must list the sources for the references they use. The source list will include but not be limited to the names of any commercially available or local databases of literature that the researcher searches by computer or by hand along with the search terms, search strategies, and time periods used in these searches. The list also will include any print sources such as books or journal articles which provided references from their respective bibliographies and databases or models of observational information related to the physical environment, effects on the ecosystem, or effects linked to human health.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate these studies for quality. Key studies are those most crucial or pivotal to answer the research questions posed in the project. Though the key study may show only negative results or may even be all that is currently available on the research topic, it is crucial, nonetheless, to any discussion of the topic. (In the case of databases or models or observational information, either may constitute a key study.) Sometimes, the key study is not recognizable until all of the information is gathered and sifted through. Key studies should exhibit at least most of the general attributes defined below, which bear comparison to the OMB guidelines to federal agencies mentioned above.

- FOCUS:** the work not only addressed the area of inquiry under consideration but also contributes to its understanding;
- VERITY:** the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;
- INTEGRITY:** the work is structurally sound and hangs together; the design or research rationale is logical and appropriate;
- RIGOR:** the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;
- UTILITY:** the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic; and
- CLARITY:** the writing is clear and the writing style is appropriate to the nature of the study.

Use the EPA Assessment Factors Guide (available at [www.epa.gov/spc/assess.htm](http://www.epa.gov/spc/assess.htm)) and the following checklist to critically evaluate the key studies:

**QUALITY EVALUATION FOR KEY STUDIES**

**1. Study identifiers:**

**Author(s):**

**Title:**

**Citation:**

**Storage location (e.g., library, facility archive, personal archive);**

**2. Why is this a key study compared to other studies reviewed for this particular project (Check all boxes as applicable or add why if not listed)?**

- study is an example of new research
- study confirms previous key study
- study replaces weaker previous key study
- best or only available study
- other \_\_\_\_\_

**3. The different aspects of a study listed below are important to consider in an evaluation of the quality of a key study. In your evaluation of the quality of a key study identified above, check the box that best describes the degree to which the key study addresses these aspects, i.e., as Acceptable (Accept.), Marginal (Marg.), or Unacceptable (Unaccept.); if the aspect is not applicable to the study, check (N/A); or if there is insufficient information available in the study report to evaluate the aspect, check Indeterminate (Indeter.).**

Accept.	Marg.	Unaccept.	N/A	Indeter.	
<input type="checkbox"/>	Clearly stated hypotheses with null and alternate indicated				
<input type="checkbox"/>	Overall design of the study				
<input type="checkbox"/>	Appropriateness of statistical methods used and reporting of results				
<input type="checkbox"/>	Specification of the units of analysis				
<input type="checkbox"/>	Identification and explanation of missing data				
<input type="checkbox"/>	Consistently reported quantities among abstract, text, tables and graphs				

- |                          |                          |                          |                          |                          |   |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|---|
| <input type="checkbox"/> | Data reported in the study sufficiently detailed and complete to make the assessment required (e.g., human health effects; results from animal testing; ecological impact; occurrence, persistence, and interaction in the atmosphere or other media) |
| <input type="checkbox"/> | Adequacy of discussion of results, alternative hypotheses, and confounding factors  |
| <input type="checkbox"/> | Study conducted at a credible facility, published in a credible peer-reviewed source, subjected to internal peer-review if not published.   |
| <input type="checkbox"/> | Other:  |

**Please include a brief comment on less than acceptable ratings; attach additional pages(s) as needed:**

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- 4. If the study uses any data from sources outside of the study, what does the study offer in terms of an assessment of the quality of these data? State any professional opinions one may have about the data in question.**

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**Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_



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