Contact: Clay Ogg, Quality Manager, OPEI/OCHP
EPA West 4339T, (1809T), 566-2315

OPEI's Quality Management Plan

Until recently, Federal Quality Assurance (QA) requirements only applied to measurement and collection of *primary* environmental data. The handful of individuals in OPEI and OCHP who managed the collection of primary data followed very detailed QA guidance for making environmental measurements. The rest of us, who used only *secondary* data (published data), remained largely unaffected by QA requirements.

This changed with the introduction of some QA requirements regarding use of secondary data. The OPEI/OCHP Quality Management Plan (QMP) was written two years ago with the aim of addressing these new, Federal QA requirements regarding use of secondary data. Our QMP mainly uses two approaches for work involving secondary data: 1) It modifies the Agency's existing peer review systems to provide greater emphasis on data quality and 2) it calls for alerting potential data users about any data limitations (transparency). During the past year, the Agency has released QA Guidelines regarding use of secondary data, and released an Agency Guidance (EPA QA/G- 5) that includes procedures for documenting secondary data. These documents are generally very supportive of the approach we took in our OPEI/OCHP QMP, but their release has led to the one- page Amendment to the OPEI/OCHP QMP. This Amendment commits each of us to maintain a file for our in-house work, and it assures that data quality will be addressed by various, existing review processes.

Our approach to quality management affects cooperative agreements, contracts, and work conducted in-house, and is summarized below:

QA for Cooperative Agreements - For our cooperative projects, the QMP simply modified the excellent peer review system already in place rather than create separate paper work to deal with data quality. For example, cooperative research projects undergo two outside peer reviews and one internal peer review, *before* we decide to fund the project. Addressing QA issues in this way, at the funding stage, offers two advantages: 1) Projects that propose to use questionable data can be avoided (not funded) and 2) QA is addressed as an integral part of the over-all quality of the project--using reviewers with appropriate expertise and without creating unnecessary paper work. (As noted below, QA for our in-house work is also addressed through planning and peer review processes.)

QA for Contracts - Contracts, on the other hand, require more QA procedures, and work assignment managers should be aware of our QA requirements covering contracts. For contracts, we have less peer review opportunity, and Agency guidances are much more specific regarding QA procedures. The OPEI/OCHP QMP therefore requires contractors to compete with each other based on QA, with some of the scoring points determined by their QA plans. Work assignments that involve environmental measurement or generation of environmental data using models must provide either a Quality Assurance Project Plan or a Supplement to the provider's QMP. These must be approved by the work assignment manager and by Clay Ogg, our quality manager.

QA for Work Conducted In-House - When using any type of secondary data (e.g., data

Contact: Clay Ogg, Quality Manager, OPEI/OCHP
EPA West 4339T, (1809T), 566-2315

from reports) we maintain a project file containing information on how we followed the data quality management steps outlined in the amendment to OPEI's Quality Management, and various reviews of work products specifically address data quality.

Summary - OPEI integrates quality assurance for secondary data through staff project files and through existing peer review processes, and generally does not require a separate set of forms to document QA procedures. However, projects which make environmental measurements (collect primary, not secondary data) and projects which involve contractors who generate environmental data using models, have to gain approval of QA documents.

APPROVAL:	
Reginald B. Cheatham Director, Quality Assurance Staff (Acting)	Date

AMENDMENT:

Section 3.2 "Training and Certification" is amended to add the following statement:

OCHP & OPEI staff will attend a one hour training on the quality assurance concepts, principles, and practices in the use of secondary data (as is relevant to the work conducted by our OCHP/OPEI) to be provided by the Quality Assurance (QA) staff. The content of the training will be developed by the QA staff based on input from OCHP and OPEI.

Section 2.1 "Use of Secondary Environmental Data in the OCHP/OPEI Programs" is amended to add the following statement:

OCHP/OPEI have established a quality system for the use of secondary data using the following criteria:

- Searches for secondary data sources will be conducted with the level of investigation merited by the data need/project.
- The source of secondary data will be cited in the project and/or noted in the project file. It is preferable that a copy of the source be maintained in conjunction with the project file.
- The source of secondary data will be reviewed by the user (project staff) for whether it is a reputable and available data source.
- Professional judgement in conjunction with existing Agency policies will be exercised in the determination of whether the data and source are of sufficient quality and appropriate for the given use/project.
- A relevant review will be conducted following the use of secondary data. The review type will vary depending on the given data use, and may include external peer review, peer-reviewed journal publication, internal agency or office review, or management review.

The OCHP/OPEI project staff (project manager or project team) maintain this quality system by maintaining project files that illustrate the preceding criteria have been considered. No specific forms will be used; however, any given project file should contain information on the search, source, use, and review of secondary data as outlined in the criteria above. The type and extent of the information in the project file will vary by project.

AMENDMENT to the
QUALITY MANAGEMENT PLAN
for the Office of Policy, Economics, and Innovation
and for the Office of Children's Health Protection

Amended Text and Approval Form

Document Title	Quality Management Plan (Amendment)
Organization	Office of Policy, Economics, and Innovation Office of Children's Health Protection
Address	U.S. Environmental Protection Agency 1200 Pennsylvania Ave, NW (Mail Code 1809T) Washington, DC 20460
QA Manager	Clayton Ogg 202-566-2315 Mail Code 1809T

CONCURRENCES:

Jessica L. Furey Assistant Administrator, Office of Policy Economics and Innovation	Date
Albert M. McGartland Director, Center for Environmental Economics	Date
Joanne Rodman Co-Director, Office of Children's Health Protection (Acting)	Date
Clayton W. Ogg Quality Assurance Manager, OCHP/OPEI	Date