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Guidance for Evaluating and Documenting the Quality of Existing Scientific and Technical Information

Addendum to: *A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information*

Prepared for the U.S. Environmental Protection Agency
by members of the Peer Review Advisory Group
a group of the EPA's Science and Technology Policy Council

Science and Technology Policy Council
U.S. Environmental Protection Agency
Washington, DC 20460

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1. Overview

In 2010, the U.S. Environmental Protection Agency's (EPA or Agency) Office of Inspector General (OIG) reviewed the process used by EPA to support its greenhouse gases endangerment finding (EPA, 2009a). The OIG's findings were published in the report, *Procedural Review of EPA's Greenhouse Gases Endangerment Finding Data Quality Processes* (EPA, 2011a). The report recommended that the Agency revise its guidance document, *A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information* (EPA, 2003), "to establish minimum review and documentation requirements for assessing and accepting data from other organizations." This Addendum responds to the OIG's recommendation by providing guidance for assessing and accepting existing scientific and technical information. It is relevant not only to data from other organizations, but to any existing scientific and technical information used to support Agency decision making.

This Addendum contains guidance for:

- assessing and accepting existing scientific and technical information, and
- documenting the review and analysis of existing scientific and technical information.

The Addendum also contains illustrative examples of approaches for applying the guidance.

2. Background

EPA uses and disseminates scientific and technical information obtained from a variety of sources, both internal and external. Information generated by the Agency, or obtained through EPA contracts, grants, and cooperative and interagency agreements, falls under the direct control of the Agency's internal information quality systems and various Agency-wide and program-specific policies and procedures (EPA, 1994; EPA, 2002; EPA, 2006; EPA, 2008a,b; EPA, 2009b; EPA, 2011b; EPA, 2012a,b). Information generated by or obtained from outside sources, such as local and state governments, tribes, industry, environmental organizations, other federal agencies, and the peer-reviewed literature, is evaluated by EPA using the guidance contained in the following documents to determine whether it meets the quality requirements of the Agency:

- *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (EPA, 2002)*;*

- *A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information* (the document to which this Addendum applies; EPA, 2003);
- *Guidance on Quality Assurance Project Plans* (EPA, 2012c)*;* and
- *Peer Review Handbook, 3rd Edition* (EPA, 2006) and its Addendum (EPA, 2009c).

Sometimes, information may be used for purposes other than those for which they were originally intended. An example is the use of historical municipal drinking water data in Agency studies of groundwater contamination. Another example is the use of information derived from the scientific literature, such as epidemiologic or experimental studies from peer reviewed journals identified in the PubMed or ToxNet databases. Such information is referred to as "existing" data or information. Regardless of its source, this information should be evaluated to verify that its quality is appropriate for its intended use by the Agency (EPA, 2002).

3. Guidance for Evaluating and Documenting Existing Scientific and Technical Information

3.1. Assessing and Accepting Existing Scientific and Technical Information

When collecting and assessing existing scientific and technical information, use the five general assessment factors (Soundness, Applicability and Utility, Clarity and Completeness, Uncertainty and Variability, and Evaluation and Review) found in the Assessment Factors guidance document (EPA, 2003) to determine whether the information complies with EPA's Information Quality Guidelines (EPA, 2002). Sample questions for evaluating the quality of the information are offered in Section 2.2 of the Assessment Factors guidance document. Refer to the peer review considerations found in Section 2.2.17 of the Agency's Peer Review Handbook, 3rd Edition (EPA, 2006) for help in addressing the "Evaluation and Review" factor. Section 2.2.17 of the Handbook states that scientific and technical work products important to EPA environmental decision making are candidates for peer review, regardless of whether they were produced by the Agency or by an outside organization. Often, the existing information has already undergone independent peer review, and in such cases, the review should meet the intent of the Agency's peer review policy and be commensurate with EPA's proposed use of the information.

The criteria for accepting existing information (called acceptance or performance criteria) should be tailored to the type of information under consideration based on the principle of a "graded approach," in which the level of quality assurance applied to the information is commensurate with the intended use of the information and the degree of confidence necessary in that information (EPA, 2002). A full discussion of acceptance criteria may be found in the guidance *Handbook for Developing Quality Assurance Project Plans* (EPA, 2012c), which includes definitions in Appendix B for six data quality indicators (Precision, Bias,

Representativeness, Completeness, Comparability, and Sensitivity, or PBRCCS) considered important to environmental studies.

Examples of the use of the five assessment factors, a graded approach, and the application of some acceptance criteria may be found in Section 4 of this Addendum.

3.2. Documenting the Review and Analysis of Existing Scientific and Technical Information

EPA organizations are expected to develop and use a Quality Assurance Project Plan (QAPP), or an equivalent form of documentation, to document the procedures used in the review and analysis of existing scientific and technical information. Such documentation is part of EPA's mandatory Quality Program (EPA, 2012c; see Chapter 3 for relevance to existing data). The QAPP or its equivalent should include a description of the type and quality of information needed for a specific decision or use, it should establish the acceptance criteria or quality determinations against which the information will be evaluated, and it should document the review and analysis process for the 5 assessment factors. And finally, the QAPP should describe how the outcomes (or results) of the review and analysis process will be documented and reported. The graded approach applies as well to documentation; i.e., the level of effort expended to document the review and analysis process should be commensurate with the intended use of the information and the degree of confidence required. The requirements for a QAPP may be found in Annex B of CIO 2106-S-01 (for EPA organizations) and CIO 2106-S-02 (for non-EPA organizations) (EPA, 2012a,b).

A checklist of QAPP elements that may be applied during documentation is provided in Annex B of *Handbook for Developing Quality Assurance Project Plans* (EPA, 2012c), and examples of documentation, both simple and detailed, are included in Section 4 below.

4. Examples

The following examples have been included for illustrative purposes only to demonstrate how the five assessment factors can be reviewed and documented. They indicate a range of options and different levels of complexity, taking into account the graded approach. Users may adapt these examples as models for developing their own quality review and documentation of the assessment factors. Note that this process may be one piece of an overall evaluation for deciding whether to accept or reject existing data or information.

Quality Assurance Project Plan (QAPP) Template

The following QAPP template was developed by ORD's National Center for Environmental Assessment (NCEA). It has been shared with scientists in the Agency and with EPA contractors as a model for developing a QAPP for conducting a literature search and analyzing the quality of existing studies. General guidance and a checklist for evaluating key studies are included.

Elements of a Quality Assurance Project Plan (QAPP) For Collecting, Identifying, and Evaluating Existing Data/Information
http://www.epa.gov/stpc/pdfs/assess4.pdf

Sample Quality Assurance Project Plans (QAPPs)

The following QAPP example is intended to be applicable to both existing data as well as existing literature. An example for documenting the evaluation of the five assessment factors is included as Appendix 1: Reference Evaluation Template.

Data and Literature Evaluation for the EPA's Study of the Potential Impacts of Hydraulic Fracturing (HF) on Drinking Water Resources
http://www.epa.gov/hfstudy/pdfs/literature-review-qapp.pdf

The following QAPP illustrates the use of the graded approach in planning and documenting a data collection study based on the compilation and use of existing data. In order to assess and report on the ecological health of the NJ-NY Harbor Estuary, the New England Interstate Water Pollution Control Commission (NEIWPCC) developed this QAPP to describe the activities needed to identify and evaluate existing data used in the final report. Historically, the term "secondary data" used in this QAPP was interchangeable with the term "existing data".

State of the Estuary Report QAPP
http://www.epa.gov/region1/measure/qapp_examples/pdfs/SOE-QAPP.pdf

The following example illustrates how the quality and relevance of existing information can be evaluated for use by reviewing and documenting the assessment factors.

Illustrative Example for Applying Assessment Factors in Collecting, Identifying and Evaluating Existing Literature
http://www.epa.gov/stpc/pdfs/assess5.pdf

Sample Checklist

The following checklist, used by Region 10, considers three criteria that existing information should demonstrate: traceability, accessibility, and documentation. Traceability provides the original source and publication information; accessibility gives the exact location and format of the information; and documentation provides information to support legal scrutiny covering *quality, usability, integrity, objectivity and reproducibility*.

Checklist for the Assessment of Existing Information
http://www.epa.gov/stpc/pdfs/assess6.pdf

Criteria and Evaluations – Overall Process Example

The following example provided by the IRIS Program illustrates how the assessment factors can be applied to searches for mechanistic evidence in published data and information as part of a broad evaluation of a body of evidence—also referred to as a weight-of-evidence approach.

Defining Assessment Factors (e.g., exclusion/inclusion criteria)
http://www.epa.gov/stpc/pdfs/assess7.pdf

The following table, also provided by the IRIS program, demonstrates the documentation of an analysis of findings in the scientific literature. It incorporates the process for evaluating and accepting information in the context of the overall project.

Evaluating the Quality of Individual Studies
http://www.epa.gov/stpc/pdfs/assess8.pdf

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