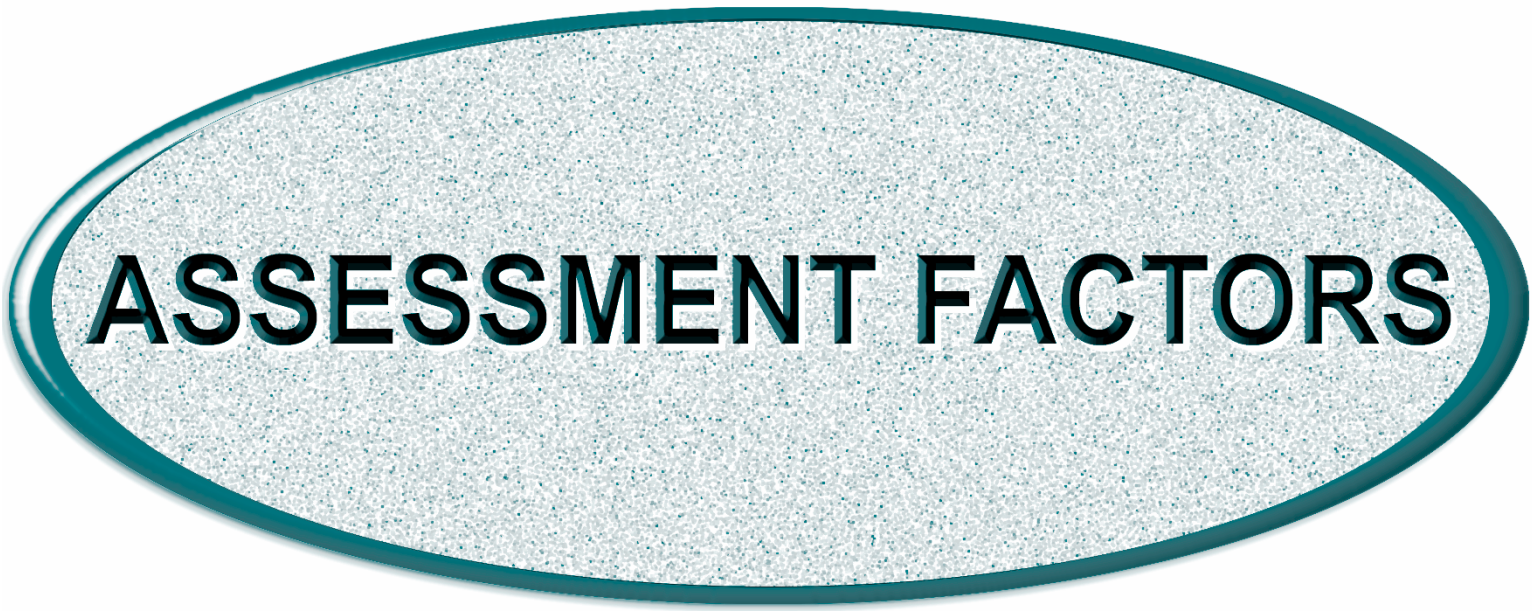
United States Environmental Protection Agency

Science Policy Council



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U.S. Environmental Protection Agency

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 Assessment Factors Workgroup, a group of the EPA's Science Policy Council

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FOREWORD

This document was prepared under the auspices of the Science Policy Council (SPC) to describe the assessment factors and considerations generally used by the Agency to evaluate the quality and relevance of scientific and technical information. These general assessment factors are founded in the Agency guidelines, practices and procedures that make up the EPA information and quality systems, including existing program-specific quality assurance policies. As such, the general assessment factors do not constitute new quality-related considerations, nor does this document describe a new process for evaluating information. This document is intended to raise the awareness of the information-generating public about EPA's ongoing interest in ensuring and enhancing the quality of information available for Agency use. Further, it complements the *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (EPA Information Quality Guidelines). This summary of Agency practice is also an additional resource for Agency staff as they evaluate the quality and relevance of information, regardless of source.

Consistent with the Agency's approach to the development of the EPA Information Quality Guidelines, this document is the product of an open, collaborative process between EPA and the public. During the development of this document, EPA obtained public comments on a draft version of the document released in September 2002 and commissioned the National Academy of Sciences to host a workshop in January 2003 to discuss key aspects of this document from a scientific and technical perspective.

We want to acknowledge and thank the Assessment Factors workgroup for its steady and insightful work in assembling this document under stringent time constraints and scrutiny. We particularly appreciate the efforts of the co-chairs, Halûk Özkaynak (ORD) and Greg Schweer (OPPTS), who successfully led and shepherded the workgroup.

It is with great pleasure that we present the *Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information*.

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U.S. Environmental Protection Agency

A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information

1. Introduction

1.1 Overview

As part of the ongoing commitment of the United States Environmental Protection Agency (USEPA) to ensure the quality of the information it uses, the Agency is publishing this summary of general assessment factors in an effort to enhance the transparency about EPA's quality expectations for information that is voluntarily submitted to or gathered or generated by the Agency for various purposes. This Assessment Factors document is intended to inform information-generating scientists about quality issues that should appropriately be taken into consideration at the time information is generated. It is also an additional resource for Agency staff as they evaluate the quality and relevance of information, regardless of source. The general assessment factors are drawn from the Agency's existing information quality systems, practices and guidelines that describe the types of considerations EPA takes into account when evaluating the quality and relevance of scientific and technical information used in support of Agency actions. As such, the general assessment factors do not constitute new quality-related considerations, nor does this document describe a new process for evaluating information. This document is intended to raise the awareness of the information-generating public about EPA's ongoing interest in ensuring and enhancing the quality of information available for Agency use.

1.2 Purpose

The Agency believes that the summary of general assessment factors provided in this document will serve to increase the extent to which the information-generating public builds quality considerations into the generation and documentation of their information products. The Agency expects that the resulting improvements in the quality of such information will enable the Agency to more fully utilize and disseminate such information. Thus, this document is intended to complement the *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (EPA Information Quality Guidelines) (EPA, 2002) and other Agency efforts to ensure and enhance information quality, as discussed below in Section 1.3. This document is not a regulation and is not intended to create any legal rights or impose legally binding requirements or obligations on EPA or the information-generating public.

Although the assessment factors as presented are intended to most generally apply to individual pieces of information, they can also be used as part of a broader evaluation of a body of evidence that is collectively evaluated through a process typically referred to as a "weight-of-evidence" approach. The weight-of-evidence approach considers all relevant information in an integrative assessment that takes into account the kinds of evidence available, the quality and quantity of the evidence, the strengths and limitations associated with each type of evidence and explains how the various types of evidence fit together. Details as to the Agency's approach to integrating a body of evidence depend on the type of decision or action being undertaken, and are not the subject of this document. For instance, the *Guidelines for Carcinogen Risk Assessment, Review Draft* (EPA, 1999) provides guidance on characterizing the weight-of-evidence for carcinogenicity. Similarly, the *Guidelines for Ecological Risk Assessment* (EPA, 1998) describes the development of "lines of evidence" to reach a conclusion regarding an ecological risk estimate.

The general assessment factors are presented and discussed more fully in Section 2.1. Section 2.2 presents illustrative examples of the types of questions that consideration of these factors raise in the process of evaluating the quality and relevance of different types of information for different uses. The relationship between these general assessment factors and the elements of quality contained in the EPA Information Quality Guidelines is discussed in Section 2.3.

1.3 Background

In October 2002, EPA made available the EPA Information Quality Guidelines. The EPA Information Quality Guidelines were developed in response to guidelines issued by the Office of Management and Budget (OMB, 2002) under Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554; H.R. 5658). The EPA Information Quality Guidelines set forth the Agency's policy and procedural guidance for ensuring and maximizing the quality of information *disseminated* by EPA, regardless of the source of the information, and articulate the Agency's ongoing commitment to ensuring and maximizing information quality through existing policies, systems and programs. Thus, the EPA Information Quality Guidelines build upon the Agency's numerous existing systems, practices and guidelines that address information quality, and provide new policies and administrative mechanisms that respond to OMB's guidelines.

The EPA Information Quality Guidelines also recognize that, as part of its efforts to ensure information quality, the Agency does not wait until the point at which information is *disseminated* to consider important quality principles. Rather, the Agency recognizes that it is

important to assure the quality of information through processes that incorporate quality principles starting at the point at which information is *generated*.

The Agency uses and disseminates information that is generated by a variety of sources, including EPA itself as well as other parties that produce information through EPA contracts, grants and cooperative and interagency agreements or in response to a requirement under a statute, regulation, permit, order or other mandate. EPA generally has considerable control or influence over the quality of this information at the time the information is generated. Existing quality controls that EPA applies to the generation of information from these sources are based on EPA's Quality System (EPA, 2000a; EPA, 2000b), Peer Review Policy (EPA, 1994), Risk Characterization Policy (EPA, 1995) and other agency-wide and program-specific policies, as well as specific provisions in contracts, grants, agreements, regulations and statutes. A few additional useful web sites for obtaining further information on EPA's Quality System and various regulatory policies and decisions are provided under the References section at the end of this document.

The Agency also receives information that is voluntarily submitted by or collected from external sources, the generation of which does not come under the direct control of the Agency's internal information quality systems. This information may include scientific studies published in journal articles, testing or survey data, such as environmental monitoring or laboratory test results, and analytic studies, such as those that model environmental conditions or that assess risks to public health. Since EPA has placed great emphasis on the management of environmental issues on a cooperative basis with its many stakeholders, the amount of information submitted to EPA by external sources is increasing. Such sources include other federal, state, tribal, local and international agencies; national laboratories; academic and research institutions; business and industry; and public interest organizations. Although EPA's existing quality systems are not applied at the time this information is generated, EPA does apply appropriate quality controls when evaluating this information for use in Agency actions and for its dissemination consistent with the EPA Information Quality Guidelines. The Agency hopes this document will inform the public of EPA's objectives and enlist them in its effort to disseminate quality information and make quality decisions.

During the development of this document, EPA requested public input in a variety of ways. EPA distributed a draft document for public comment in September 2002 and hosted a public meeting in Washington, DC. In January 2003, EPA commissioned the National Academy of Sciences to host a workshop to discuss key aspects of this document from a scientific and technical perspective. EPA revised this document based on the input received through these public outreach opportunities.

2. Assessment Factors

2.1 General Assessment Factors

When evaluating the quality and relevance of scientific and technical information, the considerations that the Agency typically takes into account can be characterized by five general assessment factors:

- ***Soundness*** - *The extent to which the scientific and technical procedures, measures, methods or models employed to generate the information are reasonable for, and consistent with, the intended application.*

- ***Applicability and Utility*** - *The extent to which the information is relevant for the Agency's intended use.*

- ***Clarity and Completeness*** - *The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, sponsoring organizations and analyses employed to generate the information are documented.*

- ***Uncertainty and Variability*** - *The extent to which the variability and uncertainty (quantitative and qualitative) in the information or in the procedures, measures, methods or models are evaluated and characterized.*

- ***Evaluation and Review*** - *The extent of independent verification, validation and peer review of the information or of the procedures, measures, methods or models.*

These assessment factors reflect the most salient features of EPA's existing information quality policies and guidelines. Whether the information consists of scientific theories, computer codes for modeling environmental systems, environmental monitoring data, economic analyses, social survey or demographic data, chemical toxicity testing, environmental fate and transport predictions or a human health risk assessment, EPA generally evaluates information by weighing considerations that fit within these five assessment factors. Thus, these factors encompass considerations that are weighed in the process of evaluating the quality and relevance of information. The appropriate level of quality for any particular information product is necessarily related to how and in what context the information is to be used. If EPA chooses to later "disseminate" the information, that dissemination would be covered by the Information Quality Guidelines which describe EPA policy and procedures for reviewing and substantiating the quality of information before EPA disseminates it.

When EPA considers using information for a particular purpose, careful judgment is applied to evaluate the information for quality and relevance in the context of the specific Agency action being developed. For instance, in the context of a given action, EPA may need to weigh the appropriateness of using information with significant, but known uncertainties to fill "data gaps," relative to using default assumptions or committing additional resources to generate new information.

2.2 Examples of Questions Raised by Consideration of the Assessment Factors

Example questions that could be raised by the consideration of each of the assessment factors for various types of information are provided below. Given the very general nature of these assessment factors, the Agency felt that a compilation of such illustrative questions would most clearly convey the intended nature and breadth of the assessment factors, and how they would be reflected in an evaluation of various types of information. However, the applicability of these factors depends on the individual situation, and EPA retains discretion to consider and use factors and approaches on a case-by-case basis that may differ from the illustrative considerations presented below.

2.2.1 *Soundness*

The extent to which the scientific and technical procedures, measures, methods or models employed to generate the information are reasonable for, and consistent with, the intended application.

a) Is the purpose of the study reasonable and consistent with its design?

b) To what extent are the procedures, measures, methods, or models employed to develop the information reasonable and consistent with sound scientific theory or accepted approaches?

c) How do the study's design and results compare with existing scientific or economic theory and practice? Are the assumptions, governing equations and mathematical descriptions employed scientifically and technically justified? Is the study based on sound scientific or econometric principles?

d) In the case of a survey, have the questionnaires and other survey instruments been validated (e.g., compared with direct measurement data)? Were checks for potential errors made during the interview process?

e) How internally consistent are the study's conclusions with the data and results presented?

2.2.2 *Applicability and Utility*

The extent to which the information is relevant for the Agency's intended use.

a) How useful or applicable is the scientific or economic theory applied in the study to the Agency's intended use of the analysis?

b) How relevant are the study's purpose, design, outcome measures and results to the Agency's intended use of the analysis (e.g., for a chemical hazard characterization)?

c) Are the domains (e.g., duration, species, exposure) where the model or results are valid useful to the Agency's application?

d) How relevant is the study to current conditions of interest? For example, in the case of a survey, are conditions likely to have changed since the survey was completed (i.e., is the information still relevant)? Is the sampled population relevant to the Agency's current application? How well does the sample take into account sensitive subpopulations?

2.2.3 *Clarity and Completeness*

The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, sponsoring organizations and analyses employed to generate the information are documented.

a) To what extent does the documentation clearly and completely describe the underlying scientific or economic theory and the analytic methods used?

b) To what extent have key assumptions, parameter values, measures, domains and limitations been described and characterized?

c) To what extent are the results clearly and completely documented as a basis for comparing them to results from other similar tests?

d) If novel or alternative theories or approaches are used, how clearly are they explained and the differences with accepted theories or approaches highlighted?

e) Is the complete data set accessible, including metadata, data-dictionaries and embedded definitions (e.g., codes for missing values, data quality flags and questionnaire responses)? Are there confidentiality issues that may limit accessibility to the complete data set?

f) In the case of a modeling exercise, have the definitions and units of model parameters been provided? To what extent have the procedures for applying the model been clearly and completely documented? How available and adequate is the information necessary to run the model computer code?

g) To what extent are the descriptions of the study or survey design clear, complete and sufficient to enable the study or survey to be reproduced?

h) Have the sponsoring organization(s) for the study/information product and the author(s) affiliation(s) been documented?

i) To what extent are the procedures for quality assurance and quality control of the data documented and accessible?

2.2.4 *Uncertainty and Variability*

The extent to which the variability and uncertainty (quantitative and qualitative) in the information or in the procedures, measures, methods or models are evaluated and characterized.

a) To what extent have appropriate statistical techniques been employed to evaluate variability and uncertainty? To what extent have the sensitive parameters of models been identified and characterized?

b) To what extent do the uncertainty and variability impact the conclusions that can be inferred from the data and the utility of the study? What are the potential sources and effects of error and bias in the study design?

c) Did the study identify potential uncertainties such as those due to inherent variability in environmental and exposure-related parameters or possible measurement errors?

2.2.5 *Evaluation and Review*

The extent of independent verification, validation and peer review of the information or of the procedures, measures, methods or models.

a) To what extent has there been independent verification or validation of the study method and results? What were the conclusions of these independent efforts, and are they consistent?

b) To what extent has independent peer review been conducted of the study method and results, and how were the conclusions of this review taken into account?

c) Has the procedure, method or model been used in similar, peer reviewed studies? Are the results consistent with other relevant studies?

d) In the case of model-based information, to what extent has independent evaluation and testing of the model code been performed and documented?

2.3 Relationship Between the General Assessment Factors and the Elements of Quality in EPA's Information Quality Guidelines

The definition of quality in the EPA Information Quality Guidelines consists of three components, consistent with the definition of quality in OMB's Guidelines: *objectivity*, *utility* and *integrity* of disseminated information. "Objectivity" focuses on the extent to which information is presented in an accurate, clear, complete and unbiased manner; and, as a matter of substance, the extent to which the information is accurate, reliable and unbiased. "Utility" refers to the usefulness of the information to the intended users. "Integrity" refers to security, such as the protection of information from unauthorized access or revision, to ensure the information is not compromised through corruption or falsification.

The five general assessment factors presented in this document are consistent with the quality elements of *objectivity* and *utility*, but do not extend to the distinct element of *integrity* (which refers to the separate matter of security issues). The assessment factor *applicability and utility* is most directly related to the element of *utility* in the OMB and EPA Information Quality

Guidelines. The other four assessment factors relate to the element of *objectivity*, which itself encompasses a number of issues related to both presentation and substance. In particular, the factor *clarity and completeness* is most directly related to some aspects of the presentation of information (including whether the information is "presented in an accurate, clear, complete and unbiased manner"). The factors *soundness*, *uncertainty and variability* and *evaluation and review* most directly relate to the substantive aspects of the element of *objectivity* (related to whether the information itself is "accurate, reliable and unbiased"), although they also play a role in enhancing aspects of the presentation of the information. Thus, the general assessment factors are fully consistent with the related information quality elements described in the OMB and EPA Information Quality Guidelines, and do not constitute a conceptually different or unrelated basis for evaluating information quality.

It is important to note that the EPA Information Quality Guidelines apply to "information" that EPA disseminates to the public. The EPA Information Quality Guidelines apply to information generated by third parties if EPA distributes information prepared or submitted by an outside party in a manner that reasonably suggests that EPA endorses or agrees with it; if EPA indicates in its distribution that the information supports or represents EPA's viewpoint; or if EPA in its distribution proposes to use or uses the information to formulate or support a regulation, guidance, policy or other Agency decision or position (EPA 2002). Please refer to the EPA Information Quality Guidelines for additional information regarding their applicability to information EPA disseminates.

3. Summary

This document describes the assessment factors and considerations generally used by the Agency to evaluate the quality and relevance of the broad range of scientific and technical information used by the EPA. These factors are founded in the Agency guidelines, practices and procedures that make up the EPA information and quality systems including existing program-specific quality assurance policies. Consistent with the Agency's approach to the development of the EPA Information Quality Guidelines, this document is the product of an open, collaborative process between EPA and the public.

The Agency believes that the summary of general assessment factors provided in this document will serve to increase the extent to which the information-generating public builds quality considerations into the generation and documentation of their information products. The Agency expects that the resulting improvements in the quality of such information will enable the Agency to more fully utilize and disseminate such information. Thus, this document is intended to complement the EPA Information Quality Guidelines and other Agency efforts to ensure and enhance information quality.

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US Environmental Protection Agency, 2002, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency,* EPA 260R-02-008, Office of Environmental Information, http://www.epa.gov/oei/qualityguidelines

US Office of Management and Budget, 2002, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, (67 FR 8452), http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf

Additional Useful Web Sites

EPA Quality System web site: http://www.epa.gov/quality

EPA Science Policy Council web site: http://www.epa.gov/osp/spc

EPA Information Quality Guidelines web site: http://www.epa.gov/oei/qualityguidelines