

1 **Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity**
2 **of Information Disseminated by the Environmental Protection Agency**

3 **BACKGROUND AND DISCUSSION**

4 **1 OMB Guidelines**

5 In Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001
6 (Public Law 106-554; H.R. 5658), Congress directed the Office of Management and Budget (OMB)
7 to issue government-wide guidelines that "provide policy and procedural guidance to Federal agencies
8 for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including
9 statistical information) disseminated by Federal agencies..."

10 The OMB guidelines¹ direct agencies subject to the Paperwork Reduction Act (44 U.S.C. 3502(1)) to:

- 11 • Issue their own information quality guidelines to ensure and maximize the quality, objectivity,
12 utility, and integrity of information, including statistical information, by no later than one year
13 after the date of issuance of the OMB guidelines;
- 14 • Establish administrative mechanisms allowing affected persons to seek and obtain correction of
15 information maintained and disseminated by the agency that does not comply with OMB
16 guidelines; and
- 17 • Report to the Director of OMB the number and nature of complaints received by the agency
18 regarding agency compliance with OMB guidelines concerning the quality, objectivity, utility,
19 and integrity of information and how such complaints were resolved.

20 OMB guidelines provide some basic principles for agencies to consider when developing their own
21 guidelines including:

- 22 • Guidelines should be flexible enough to address all communication media and variety of scope
23 and importance of information products.
- 24 • Some agency information may need to meet higher or more specific expectations for
25 objectivity, utility, and integrity.
- 26 • Ensuring and maximizing quality, objectivity, utility, and integrity comes at a cost, so agencies
27 should consider using a cost benefit approach.
- 28 • Agencies should adopt a common sense approach that builds on existing processes and
29 procedures. It is important that agency guidelines do not impose unnecessary administrative
30 burdens.

¹ Office of Management and Budget, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies." 67 Fed. Reg. 8452 (Feb. 22, 2002) www.whitehouse.gov/omb/fedreg/reproducible.html

31 **2 EPA Mission and Commitment to Quality**

32 **2.1 EPA’s Mission**

33 The mission of the U.S. Environmental Protection Agency (EPA) is to protect human health and to
34 safeguard the natural environment - air, water, and land - upon which life depends. The Agency is
35 committed to making America's air cleaner, water purer, and land better protected and to work closely
36 with its federal, state, tribal, and local government partners; with citizens; and with the regulated
37 community to accomplish its mission.

38 **2.2 Information Management in EPA**

39 The collection, use, and dissemination of information of known and appropriate quality is integral to
40 ensuring that EPA achieves its regulatory and policy mission. Information about the environment --
41 environmental characteristics; physical, chemical, and biological processes; and chemical and other
42 pollutants -- underlies all environmental management decisions. The availability of and access to
43 information and the analytical tools needed to understand it are essential for assessing environmental
44 and human health risks, designing appropriate and cost-effective policies and response strategies, and
45 measuring environmental improvements.

46 To ensure that information collected and disseminated by EPA programs is of acceptable quality for its
47 intended use, the primary responsibility for establishing appropriate standards for data quality, for
48 developing and managing processes to assure and control information quality, and for complying with
49 Agency-wide data quality requirements resides within EPA’s Program and Regional offices. The EPA
50 Office of Environmental Information (OEI) was created in 1999 to strengthen the Agency's ability to
51 manage information resources and their public dissemination. OEI supports the Agency's mission to
52 protect public health and the environment by working with stakeholders to provide reliable and useful
53 information on environmental quality, status, and trends. Working in concert with EPA Program and
54 Regional Offices, OEI develops policies for the Agency’s Quality System and information security
55 program, assuring the quality and integrity of EPA data and information. In addition, OEI establishes
56 and oversees information-related policies and procedures that reflect the concerns of EPA; local, state,
57 tribal and federal governments; the regulated community; interest groups; and the general public.

58
59 **2.3 EPA’s Commitment to Public Access**

60 EPA articulates its commitment to expanding and enhancing access to environmental information in its
61 Strategic Plan². EPA works every day to expand the public’s right to know and understand their
62 environment by providing and facilitating access to a wealth of information about local environmental

²EPA Strategic Plan can be found at <http://www.epa.gov/ocfo/plan.htm>

63 issues and conditions. This expands citizen understanding and involvement and gives people tools to
64 protect their families and their communities. Increased information transparency among scientists, public
65 health officials, businesses, citizens, and all levels of government fosters greater knowledge about the
66 environment and what can be done to protect it.

67 **2.4 How EPA Uses Information**

68 EPA receives a large amount of information from external parties that provide information to the
69 Agency both voluntarily and under statutory and other mandates. EPA also generates information and
70 gathers information from various sources. Much of the environmental information that is collected and
71 documented is processed and stored in Agency information management systems. The information is
72 maintained in program-specific databases, many of which are managed by the National Program
73 Offices within EPA.

74 Upon placement in EPA information management systems, information is then available for use by a
75 variety of people and systems. Internally, users can include program managers, information product
76 developers, or financial tracking systems. Depending on the extent of public release, users can also
77 include city planners, homeowners, teachers, engineers, or community activists, to name a few. In order
78 to satisfy the needs of this broad spectrum of users, it is critical that EPA information be presented in an
79 unbiased context with thorough documentation.

80 EPA is moving beyond the administration of regulatory data and working in concert with States and
81 other stakeholders to generate new information products that are responsive to identified user needs.
82 Increasingly, information products are derived from data originally collected to support state or federal
83 regulatory programs or management activities. Assuring the suitability of these data for new applications
84 is of paramount importance.

85 **2.5 EPA's Relationship with State, Tribal and Local Governments**

86 As mentioned in the previous section, EPA's mission is not achieved alone. In addition to the role of
87 EPA's data providers, key government partners work with EPA to manage and implement programs
88 and communicate with the public about issues of concern. Most of EPA's programs are not managed
89 from Washington, DC. Instead, a vast network of federal, state, tribal and local governments implement
90 programs required by law and even some voluntary programs. This same network collects, uses and
91 disseminates a wide range of information. Therefore EPA needs to consult with these partners to ensure
92 that the EPA Information Quality Guidelines are appropriate and effective.

93 **3 Existing Policies and Procedures**

94 EPA is dedicated to the collection, generation, and dissemination of high quality information. The OMB
95 guidelines encourage agencies to avoid the creation of "new and potentially duplicative or contradictory

96 processes.” Further, OMB stresses that its guidelines are not intended to “impose unnecessary
97 administrative burdens that would inhibit agencies from continuing to take advantage of the Internet and
98 other technologies to disseminate information that can be of great benefit and value to the public.” In
99 this spirit, EPA has sought to enhance and integrate existing activities and programs to address the
100 OMB guidelines. As illustrated with the four examples outlined below, the Agency has numerous
101 systems and practices in place that address the quality, objectivity, utility, and integrity of information.

102 The EPA Agency-wide Quality System helps ensure that EPA organizations maximize the quality,
103 objectivity, utility and transparency of information disseminated by the Agency. The Quality System is
104 documented in EPA Order 5360.1 A2, “Policy and Program Requirements for the Mandatory
105 Agency-wide Quality System” and the “EPA Quality Manual³.” To implement the Quality System, EPA
106 organizations (1) Assign a quality assurance manager, or person assigned to an equivalent position, who
107 has sufficient technical and management expertise and authority to conduct independent oversight of the
108 implementation of the organization's quality system; (2) Develop a Quality Management Plan, which
109 documents the organization's quality system; (3) Conduct an annual assessment of the organization's
110 quality system; (4) Use a systematic planning process to develop acceptance or performance criteria
111 prior to the initiation of all projects that involve environmental data collection and/or use; (5) Develop
112 Quality Assurance Project Plan(s), or equivalent document(s) for all applicable projects and tasks
113 involving environmental data; (6) Conduct an assessment of existing data, when used to support
114 Agency decisions or other secondary purposes, to verify that they are of sufficient quantity and
115 adequate quality for their intended use; (7) Implement all Agency-wide Quality System components in
116 all applicable EPA-funded extramural agreements; and (8) Provide appropriate training, for all levels of
117 management and staff.

118 The EPA Quality System requirements may also apply to non-EPA organizations. These requirements
119 are defined in the applicable regulations governing extramural agreements. EPA Quality System
120 requirements may also be invoked as part of negotiated agreements such as memoranda of
121 understanding. Non-EPA organizations that may be subject to EPA Quality System requirements
122 include: (a) Any organization or individual under direct contract to EPA to furnish services or items or
123 perform work (i.e., a contractor) under the authority of 48 CFR 46, (including applicable work
124 assignments, delivery orders, and task orders); (b) Institutions of higher education, hospitals, and other
125 non-profit recipients of financial assistance (e.g., Grants and Cooperative Agreements) under the
126 authority of 40 CFR 30; (c) State, local, and Tribal governments receiving financial assistance under the
127 authority of 40 CFR 31 and 35; and (d) other government agencies receiving assistance from EPA
128 through interagency agreements.

³EPA Quality Manual for Environmental Programs 5360 A1. May 2000.
<http://www.epa.gov/quality/qs-docs/5360.pdf>

129 In addition to the Quality System, EPA's Peer Review Policy provides that major scientifically and
130 technically based work products (including scientific, engineering, economic, or statistical documents)
131 related to Agency decisions normally should be peer-reviewed. For those work products that are
132 intended to support the most important decisions or that have special importance in their own right,
133 external peer review is the procedure of choice. Agency managers within Headquarters, Regions,
134 laboratories, and field components determine and are accountable for the decision whether to employ
135 peer review in particular instances and, if so, its character, scope, and timing. These decisions are made
136 consistent with program goals and priorities, resource constraints, and statutory or court-ordered
137 deadlines. For those work products that are intended to support the most important decisions or that
138 have special importance in their own right, external peer review is the procedure of choice. Peer review
139 is not restricted to the penultimate version of work products; in fact, peer review at the planning stage
140 can often be extremely beneficial. The basis for EPA peer review policy is articulated in *Peer Review
141 and Peer Involvement at the U.S. Environmental Protection Agency*.⁴ The Peer Review Policy
142 was first issued in January, 1993, and was updated in June, 1994. In addition to the Policy, EPA has
143 published a Peer Review Handbook which provides detailed guidance for implementing the Policy. The
144 Handbook was last revised December, 2000.

145 The Agency's Action Development Process also serves to ensure and maximize the quality of EPA
146 disseminated information. Top Agency actions and OMB Economically Significant actions as
147 designated under Executive Order 12866 are developed as part of the Agency's Action Development
148 Process. The Action Development Process ensures the early and timely involvement of senior
149 management at key decision milestones to facilitate the consideration of a broad range of regulatory and
150 non-regulatory options and analytic approaches. Of particular importance to the Action Development
151 Process is ensuring that EPA scientists, economists, and others with technical expertise are
152 appropriately involved in determining needed analyses and research, identifying alternatives, and
153 selecting options. Program offices and regional offices are invited to participate to provide their unique
154 perspectives and expertise. Effective consultation with policy advisors (e.g., Regulatory Policy Council,
155 Science Policy Council), co-regulators (e.g., states, tribes, and local governments), and stakeholders is
156 also part of the process. Final Agency Review (FAR) generally occurs before the release of substantive
157 information associated with these actions. The FAR process ensures the consistency of any policy
158 determinations, as well as the quality of the information underlying that policy determination and its
159 presentation.

160 The Agency's Integrated Error Correction Process⁵ (IECP) is a method for reporting and resolving
161 data errors identified by the public in EPA's information holdings. This process builds upon existing data
162 processes through which errors in Agency data systems are reported to EPA. The IECP has made

⁴Peer Review and Peer Involvement at the U.S. EPA. June 7, 1994.
<http://www.epa.gov/osp/spc/perevmem.htm>

⁵Integrated Error Correction Process for Environmental Data. <http://www.epa.gov/cdx/iecp.html>

163 these tools more prominent, accountable and easier to use. Individuals who identify potential data
164 errors on the EPA web site can contact EPA through the IECF by using the "Report Error" button or
165 error correction hypertext found throughout EPA's web pages. EPA reviews the error notification and
166 assists in bringing the notification to resolution with those who are responsible for the data. The IECF
167 tracks this entire process from notification through final resolution.

168 EPA currently ensures the integrity of the information it disseminates in a variety of ways. EPA's
169 Information Resources Manual⁶ describes how the Agency maintains and ensures information integrity.
170 Specifically, EPA believes that maintaining information integrity refers to keeping information
171 "unaltered," i.e., free from unauthorized or accidental modification or destruction. All information has
172 integrity standards; inappropriately changed or modified data, or system and application software,
173 impacts information integrity and compromises the value of the information system. Because of the
174 importance of the Agency's information to the decisions made by the Agency, its partners, and the
175 public, it is EPA's responsibility to ensure that the information is, and remains, as accurate and credible
176 as possible.

177 In addition to the Agency-wide systems and procedures described above, Program Offices and
178 Regions implement many office-level and program-specific procedures to ensure the quality of
179 individual activities which result in the distribution of information of the quality needed to meet its
180 intended use. The guidelines recognize and build on those existing procedures and encourage EPA to
181 provide increased transparency for the purpose of OMB guidelines and to better meet the EPA
182 Mission.

183 **4 EPA Guidelines Development**

184 EPA has created a new web site to serve as the home for the EPA Information Quality Guidelines
185 through the development and implementation process. Please visit that site at
186 <http://www.epa.gov/oei/qualityguidelines>. EPA's guidelines are a living document and may be revised as
187 we all learn more about how best to address, ensure and maximize information quality.

188 **4.1 On-line Public Comment Session held March 19-22, 2002**

189 EPA requested public comments during a March online comment session available via the EPA web
190 site. The following seven topic areas were presented for public input:

- 191 • Basic standard of quality

⁶ EPA Directive 2100 Information Resources Management Policy Manual.
<http://www.epa.gov/irmpoli8/polman/>

- 192 • "Influential" information
- 193 • Reproducibility
- 194 • Pre-dissemination review
- 195 • Administrative Mechanisms for timely correction
- 196 • Applicability of Guidelines to Third Party Information
- 197 • Other comments and/or suggestions regarding the EPA Information Quality Guidelines

198
199 EPA received approximately 100 comments. EPA considered these comments as it developed these
200 draft guidelines. All comments submitted via the Online Comment Session are available for the public.
201 EPA has established a public docket for these draft Information Quality Guidelines under Docket ID
202 No. OEI-10014. The docket is the collection of materials available for public viewing at 401 M Street,
203 Northeast Mall, Room B607, Washington, DC 20460, phone number: 202-260-0660. This docket
204 consists of a copy of the guidelines, public comments received during the public comment period on
205 these guidelines, and other information related to the guidelines. The docket is open from 12:00 PM to
206 4:00 PM, Monday through Friday, excluding legal holidays. An index of docket contents will be
207 available at <http://www.epa.gov/oei/qualityguidelines>.

208 In the following sections, EPA will discuss the factors that were considered and how EPA developed
209 key aspects of these draft guidelines.

210
211 **4.2 Influential Information and Reproducibility**

212 OMB Guidelines call for agencies to define "influential" -- in relation to scientific, financial, or statistical
213 information for which its dissemination will have or does have a clear and substantial impact on
214 important public policies or important private sector decisions -- in ways appropriate for the agency in
215 the context of its mission and duties, and given the nature and multiplicity of issues for which it is
216 responsible. Influential information will be subject to a high degree of transparency about data and
217 methods to facilitate the reproducibility of such information by qualified third parties, to an acceptable
218 degree of imprecision. Within the class of information defined as influential, agencies are to distinguish
219 between (1) analytic results, and (2) original and supporting data.

220 A high degree of transparency with respect to analytic results includes the following factors:

- 221 • source of the data used,
- 222 • various assumptions employed,
- 223 • analytic methods applied, and
- 224 • statistical procedures employed.

225 If sufficient transparency is achieved on each of these factors, then an analytic result should meet the
226 "capable of being substantially reproduced" standard. The appropriate degree of rigor with which each
227 of these factors is presented and discussed can be scaled as appropriate, but it is important that all be

228 presented. In addition, if access to data and methods will not occur due to other compelling interests
229 such as privacy, trade secrets, intellectual property, and other confidentiality protections, the agency
230 should apply especially rigorous robustness checks to analytic results and document what checks were
231 taken.

232 Original and supporting data are not necessarily subject to the high and specific degree of transparency
233 required of analytic results. Agencies may identify those particular types of original and supporting data
234 that can practicably be subjected to a reproducibility requirement given ethical, feasibility, or
235 confidentiality constraints. To help make that determination, agencies are to consult with relevant
236 scientific and technical communities. If agencies apply the reproducibility test to specific types of original
237 or supporting data, the associated guidelines should provide relevant definitions of reproducibility (e.g.,
238 standards for replication of laboratory data).

239 Several participants in the EPA online comment session expressed concern that the OMB
240 reproducibility standard could expose confidential information and voiced concerns about privacy and
241 security of information. Both OMB and EPA guidelines exclude confidential information and information
242 that would compromise national security from the reproducibility standard. Rather, agencies are
243 directed to develop and publish robustness checks to ensure a high degree of transparency in these
244 special cases. Several additional comments emphasized the need for consultation with the scientific
245 community on reproducibility. EPA intends to do so. EPA agrees with another comment provided that
246 described the reproducibility concept as complicated and one that will be refined over time. The
247 Agency does not intend to “categorically exclude” large amounts of influential information from a
248 reproducibility guideline, as was expressed by a commenter during the online comment session. These
249 comments were very useful to EPA. They helped to inform the Agency’s position on this issue at this
250 time.

251 As a regulatory agency with a strong science program and function, EPA takes reproducibility of data
252 and results very seriously and understands the importance of ensuring that data and methods are
253 transparent and credible. EPA works to improve the quality of information it collects, stores, uses and
254 disseminates through the development of new or revised orders, guidelines, and policies related in
255 particular to quality assurance and peer-review procedures. In determining how to achieve a high
256 degree of transparency about data and methods for influential scientific, financial, and statistical
257 information disseminated by the Agency, consistent with the OMB Guidelines, EPA plans to draw
258 heavily upon our existing quality assurance and peer review procedures.

259
260 In this draft, EPA has developed general language on this concept of reproducibility and intends to
261 revise and add more detail throughout the guideline process after appropriate consultation with scientific
262 and technical communities, as called for by OMB in its guidelines. The Agency has already begun to
263 consult relevant scientific and technical experts within the Agency, and will soon begin to consult with
264 those outside the Agency. These consultations will allow EPA to constructively and appropriately refine
265 the application of existing policies and procedures, to the extent that they may not fully already provide

266 for the appropriate degree of transparency, so as to create guidelines that satisfy the reproducibility
267 standard.

268 **4.3 Risk Assessment**

269 EPA conducts many risk assessments every year. These assessments are conducted and presented to
270 EPA policy makers to inform their risk management decisions. EPA currently has numerous policies
271 that direct internal risk assessors on how to conduct a risk assessment and characterize risk. The *EPA*
272 *Risk Characterization Policy*⁷ and associated guidelines are designed to ensure that critical
273 information from each stage of a risk assessment is used in forming conclusions about risk and that this
274 information is communicated from risk assessors to policy makers.

275 OMB stated that, with respect to influential information regarding health or safety, or environmental risk
276 assessments, agencies should either adopt or adapt the quality principles applied by Congress in the
277 Safe Drinking Water Act (SDWA) Amendments of 1996⁸. In reviewing EPA's experience with the
278 SDWA principles, existing policies in place at EPA, and the applicability and appropriateness of the
279 SDWA language with regards to the variety of risk assessments conducted by the Agency, EPA has
280 decided to adapt the SDWA principles with minimal changes for use with all human health risk
281 assessments that are disseminated as part of influential scientific EPA information. The Agency should
282 ensure, to the extent practicable and in conformance with Agency guidelines, the use of (i) the best
283 available, peer-reviewed science and supporting studies available at the time of the assessment, and (ii)
284 data collected by accepted methods or best available methods. In the original SDWA language,
285 Congress included both provisions: subparagraph (i) called for the use of “best available, peer-
286 reviewed science” and subparagraph (ii) called for “data collected by accepted methods or best
287 available methods.” EPA has interpreted these provisions as being independently applied. The
288 Agency’s intention is to apply both principles to the extent practicable.

289 In preparing these draft Information Quality Guidelines, EPA primarily focused on human health risk
290 assessments. EPA believes that it would be more appropriate to modify these SDWA principles to
291 better target them for use with environmental or safety risk assessments conducted by EPA. During the
292 online comment session on the Information Quality Guidelines that EPA held in March 2002, a
293 commenter recommended that EPA adopt rather than to adapt the SDWA principles for risk
294 assessment. However, the Agency intends to adapt the SDWA principles for human health assessments
295 and work further to refine the applicability of these principles across program areas. The Agency is
296 seeking public comment on an adaptation of the SDWA quality principles for use with environmental
297 and safety risk assessments.

⁷United States Environmental Protection Agency, Office of Research and Development, Office of Science Policy. *Science Policy Council Handbook, Risk Characterization*. EPA 100-B-00-002. December 2000 (pps. A1 - A7).

⁸Safe Drinking Water Act Amendments of 1996, 42 U.S.C. 300g-1(b)(3)(A) & (B)

298 4.4 Sources of Information

299 During the development of these guidelines, EPA considered how to address information that is not
300 generated by the Agency but is later disseminated by EPA in a publication or a regulatory or policy
301 decision. For example, EPA receives and/or collects information from a variety of external sources
302 including States and other governments, business and industry, and the research and academic
303 community. Although this type of information may not be covered by the guidelines when it is first
304 generated by outside parties (or external sources), it may be covered by the guidelines if EPA uses the
305 State or third party information in a publication, policy, or regulatory decision at a later date. EPA
306 recognizes that this issue is complex and requires more thought and collaboration with our key
307 government partners and data/information providers to best ascertain how these guidelines may apply
308 to external sources of information. EPA plans to consult with States and data/information providers
309 during the 30-day public comment period in May 2002, and throughout the Guidelines development
310 process to ensure the EPA Information Quality Guidelines are sufficiently flexible to encourage the
311 appropriate use of information provided by external sources, yet also ensure and maximize the quality
312 of information EPA disseminates.

313 EPA is taking, and will continue to take, steps to address the quality of data and information provided
314 by outside parties so that the data and information are suitable for the purposes EPA intends to use
315 them. Waiting until after the information is disseminated by EPA to address the quality of the
316 information, can be difficult and may limit EPA's use of the information. It is, therefore, important for
317 outside parties to know and consider the quality expectations associated with any information they
318 gather or generate, especially for information which is subsequently submitted to EPA.

319 EPA has varying levels of quality controls over information developed or collected by outside parties.
320 This information generally falls into one of four categories:

- 321 • Information collected through contracts with EPA. Examples of this information include studies
322 and collection and analysis of data by parties that are under a contractual obligation with EPA.
323 Since EPA is responsible for managing the work assigned to contractors, EPA retains varying
324 degrees of control over the quality of this information.

- 325 • Information collected through grants and cooperative agreements with EPA. Examples of this
326 information include scientific studies that are performed under research grants and data
327 collected by State agencies or other grantees to assess regulatory compliance or environmental
328 trends. Although EPA has less control over grantees than contractors, EPA can and does
329 include conditions in grants and cooperative agreements requiring recipients to meet certain
330 criteria.

- 331 • Information submitted to EPA as part of a requirement under a statute, regulation, permit, order
332 or other mandate. Examples of this information include required test data for pesticides or
333 chemicals, Toxics Release Inventory (TRI) submissions and compliance information submitted

334 to EPA by States and the regulated community. EPA ensures quality control of such
335 information through regulatory requirements, such as requiring samples to be analyzed by
336 specific analytical procedures and by certified laboratories. However, each EPA program has
337 specific statutory authorities which may affect its ability to impose certain quality practices.

- 338 • The final category of information that is not included in any of the above three categories
339 includes information that is either voluntarily submitted to EPA in hopes of influencing a decision
340 or that EPA obtains for use in developing a policy or regulatory decision. Examples of this
341 information include scientific studies published in journal articles and test data obtained from
342 other federal agencies, industry, and others. EPA may not have any financial ties or regulatory
343 requirements to ensure the quality of this type of information.

344 In general, EPA has considerable influence over the quality of information generated in the first three
345 categories. EPA's Quality System and Peer Review Policy set out EPA's policies regarding the quality
346 criteria information should meet when it is generated. Many other program-specific policies also apply.
347 Existing language in contracts, grants, and regulations also gives EPA authority to require that this
348 information meet quality criteria when it is generated. EPA's Quality System and Peer Review Policy
349 also cover the fourth category at the time EPA uses the information from external sources. These
350 policies do not, however, apply to this information when it is generated. EPA relies heavily on this type
351 of information and when EPA obtains information that is not of sufficient quality or transparency, it may
352 not be able to use the information in its decision making. As an example, EPA may receive many
353 studies concerning a particular issue. In evaluating the studies, EPA may not be able to rely on some of
354 the studies submitted because EPA cannot determine that the quality and transparency of the data are
355 sufficient for their intended use. In making this evaluation of voluntary submissions to EPA or
356 information that EPA has gathered for a decision, the Agency recognizes the need to take into
357 consideration ethical, feasibility, and confidentiality constraints on the availability of the data underlying
358 this information, and that obtaining and publicizing the data underlying all studies on which EPA relies
359 would be impractical and unnecessary. For example, such data are often the property of scientific
360 investigators and are often not readily available because of proprietary interests or confidentiality
361 arrangements.

362 To address this issue, EPA intends to work with States and other governments, the scientific and
363 technical community and other interested data providers to develop and publish factors that EPA would
364 use in the future to assess the quality of voluntary submissions or information that the Agency gathers for
365 its own use. Publishing the assessment factors early-on will enable external providers of information to
366 be aware of EPA quality expectations as they develop and/or collect information that may later be used
367 by EPA. Furthermore, to the extent practicable, EPA would publish the results of the suitability
368 assessment to further increase the transparency of EPA assessments of information submitted by
369 outside parties.

370 **4.5 Complaint Resolution**

371 EPA looked to incorporate existing policies and procedures into the complaint resolution
372 decision-making and reporting process called for by the OMB guidelines. Based on the existing
373 infrastructure and tracking system already in place with the Integrated Error Correction Process
374 managed by the OEI, EPA has developed an internal process to ensure timely response to complaints,
375 appropriate resolution and annual reporting to OMB beginning in 2004. EPA focused a lot of attention
376 on determining the best and most objective means of Agency decision-making on initial complaints and
377 appeals.

378
379 EPA asked the public for their input on this issue during the March Online Comment Session.
380 Comments received emphasized the need for EPA to provide an objective appeals process to enable
381 external groups to feel confident that their concerns are being heard and addressed in an objective
382 manner.

383 **5 Schedule and Next Steps**

384 Based on the schedule presented in the OMB guidelines, EPA has adopted a guideline development
385 schedule that includes opportunities for public involvement.

386 Key events	Dates
387 Public comment period on Draft EPA Information Quality Guidelines	May 1 - 31, 2002
388 Public Meeting held in Washington, DC	May 15, 2002
389 Consultation with Scientific Community and other Stakeholders	June 2002
390 Final EPA Information Quality Guidelines	October 1, 2002
391 Initiate Complaint Resolution Process	October 1, 2002

392 For more information on public involvement opportunities, please consult that EPA Information Quality
393 Guidelines web site at <http://www.epa.gov/oei/qualityguidelines>.

394 **DRAFT GUIDELINES**

395 **Overview, Scope, and Applicability**

396 **1.1 What is the purpose of these guidelines?**

397 These guidelines describe EPA’s policy and procedures for reviewing and substantiating the quality of
398 information before EPA disseminates it. They describe EPA’s administrative mechanisms allowing
399 affected persons to seek and obtain, where appropriate, correction of information disseminated by EPA
400 that they believe does not comply with these guidelines.

401 This document provides guidance to EPA staff and informs the public of EPA’s policies and
402 procedures. These guidelines are not a regulation. They are not legally enforceable and do not create
403 any legal rights or impose any legally binding requirements or obligations on EPA or the public. Nothing
404 in these guidelines affects any otherwise available judicial review of EPA action. The guidelines may not
405 apply to a particular situation based on the circumstances, and EPA retains discretion to adopt
406 approaches on a case-by-case basis that differ from the guidelines, where appropriate. Any decisions
407 regarding a particular case, matter or action will be made based on applicable statutes, regulations and
408 requirements. Interested parties are free to raise questions and objections regarding the substance of
409 the guidelines and the appropriateness of using them in a particular situation. EPA will consider whether
410 or not the guidelines are appropriate in that situation. The guidelines are a living document and may be
411 revised periodically to reflect changes in EPA’s approach or as we all learn more about how best to
412 address, ensure and maximize information quality. EPA welcomes comments on the guidelines at any
413 time and will consider those comments in any future revision of the guidelines.

414 **1.2 When do these guidelines apply?**

415 Materials that constitute “information” that EPA “disseminates” to the public would be covered by these
416 guidelines and would be subject to complaints by affected persons who seek to obtain correction of
417 information maintained and disseminated by EPA that they believe does not comply with EPA
418 guidelines or OMB guidelines. Factors such as imminent threats to public health or homeland security,
419 statutory or court-ordered deadlines, or other time constraints, may limit or preclude applicability of
420 these guidelines.

421 These guidelines apply to “information” EPA disseminates to the public. “Information” for purposes of
422 these guidelines generally includes any communication or representation of knowledge such as facts or
423 data, in any medium or form. Preliminary information EPA disseminates to the public is also considered
424 “information” for purposes of the guidelines. Information generally includes material that EPA
425 disseminates from a web page. However not all web page content is considered "information" under
426 these guidelines (e.g. certain information from outside sources).

427 EPA disseminates information to the public for purposes of these guidelines when EPA initiates or
428 sponsors the distribution of information to the public.

- 429 • EPA initiates a distribution of information if EPA prepares the information and
430 distributes it to support or represent EPA’s viewpoint, to formulate or support a
431 regulation, guidance, or other Agency decision or position.
- 432 • EPA initiates a distribution of information if EPA distributes information prepared or
433 submitted by an outside party in a manner that reasonably suggests that EPA endorses
434 or agrees with it, if EPA indicates in its distribution that the information supports or
435 represents EPA’s viewpoint, or if EPA in its distribution proposes to use or uses the
436 information to formulate or support a regulation, guidance, policy, or other Agency
437 decision or position.
- 438 • Agency-sponsored distributions may include instances where EPA reviews and
439 comments on information distributed by an outside party, or adopts or endorses it.
- 440 • In general, distributions by outside parties are not considered to be “sponsored” by
441 EPA unless the Agency is using the outside party to disseminate information on the
442 Agency’s behalf.

443 EPA may clarify whether distributions are initiated or sponsored by EPA by using disclaimers to explain
444 the status of the information.

445 **1.3 What is not covered by these guidelines?**

446 If an item is not considered “information,” these guidelines do not apply. Items that are not considered
447 information include but are not limited to:

- 448 • Internet hyperlinks and other references to information disseminated by others
- 449 • Opinions, where EPA’s presentation makes it clear that what is being offered is
450 someone’s opinion rather than fact or EPA’s views
- 451 • EPA may identify other materials that are not “information” for purposes of these
452 guidelines

453 "Dissemination” for purposes of these guidelines does not include distributions of information that EPA
454 does not initiate or sponsor. EPA may clarify whether distributions of information are initiated or
455 sponsored by EPA by using disclaimers or notices to explain the status of the information. Under the
456 following circumstances, information would not generally be considered disseminated by EPA to the
457 public, and would not be covered by these guidelines.

- 458 • Distribution limited to government employees (EPA and non-EPA) or EPA contractors
459 or grantees: Information distributed only to government employees would not generally

460 be covered by these guidelines because it is not directed to the public. This includes
461 both intra- and inter-agency distribution of information. For example, if EPA wanted to
462 get feedback from a number of other agencies regarding an action it is considering
463 undertaking, the communications between the agencies would not be covered by the
464 guidelines.

465 • Intra- or inter-agency use or sharing of government information: These guidelines do not
466 apply to intra- or inter-agency use or sharing of government information. Intra-agency
467 use of information includes use of information pertaining to basic agency operations,
468 such as management, personnel and organizational information, even if the information
469 becomes public at some point.

470 • EPA responses to requests for agency records: EPA's guidelines do not apply to
471 EPA's release or other distribution of records, regardless of form or format, as a result
472 of requests for agency records under the Freedom of Information Act (FOIA), the
473 Privacy Act, the Federal Advisory Committee Act (FACA), or other similar laws.

474 • Distribution of information in correspondence with individuals or persons: These
475 guidelines do not apply to any correspondence with individuals or persons, regardless
476 of format. "Persons" for purposes of this provision includes any individual or person,
477 including a partnership, association, corporation, business trust, legal representative,
478 organized group of individuals, State, territorial, tribal, or local government or branch
479 thereof, a political subdivision of a State, territory, tribal, or local government or a
480 branch of a political subdivision, or any federal governmental branch including members
481 of Congress and their staff.

482 • Distribution of information in press releases and similar announcements: These
483 guidelines do not apply to press releases, fact sheets, press conferences or similar
484 communications in any medium that announce, support the announcement or give public
485 notice of information EPA has disseminated elsewhere.

486 • Distribution of background and outdated or superseded information: These guidelines
487 do not apply to background information such as published articles, distributed by
488 libraries or by other distribution methods that do not imply that EPA has adopted or
489 endorsed the materials. The guidelines do not apply to outdated or superseded EPA
490 information that is provided as background information but no longer reflects EPA
491 policy or influences EPA decisions, where EPA indicates (in a disclaimer or otherwise)
492 that the materials are provided as background materials and do not represent EPA's
493 current view.

494 • Distribution of information by federal employees and recipients of grants, cooperative
495 agreements, and contracts: These guidelines do not apply to information distributed by

496 recipients of contracts, grants, or cooperative agreements, unless the information is
497 disseminated on EPA's behalf, as when EPA specifically directs or approves the
498 dissemination. These guidelines do not apply to distribution of any type of research by
499 federal employees and recipients of EPA grants, cooperative agreements, or contracts,
500 where the researcher (not EPA) decides whether and how to communicate and publish
501 the research, does so in the same manner as his or her academic colleagues, and
502 distributes the research in a manner that indicates that the research does not represent
503 EPA's official position (for example, by including an appropriate disclaimer).
504 Distribution of research in this manner is not subject to these guidelines even if EPA
505 retains ownership or other intellectual property rights because the Federal government
506 paid for the research.

507 • Distribution of information in public filings: Public filings include information submitted to
508 EPA by any individual or person (as defined above). The guidelines do not apply where
509 EPA distributes this information simply to provide the public with quicker and easier
510 access to materials submitted to EPA that are publicly available. This will generally be
511 the case if EPA has not authored the filings, and is not distributing the information in a
512 manner that suggests that EPA endorses or adopts the information, and EPA does not
513 indicate in its distribution that it is using or proposing to use the information to formulate
514 or support a regulation, guidance, or other Agency decision or position.

515 Examples of public filings submitted to EPA include:

- 516 a Submissions of information under mandates or requirements, such as filings
517 required by statutes, regulations, orders, permits, or licenses. This includes
518 submissions of information by applicants for a permit, license, approval,
519 authorization, grant, or other benefit or permission.
- 520 b Information submitted voluntarily to EPA. Examples include information in
521 submissions relating to an EPA program, process or activity, such as public
522 comments submitted in a rulemaking; information submitted by a participant in a
523 voluntary program; and other information voluntarily provided to EPA by third
524 parties, such as data, studies, analyses, and other types of comments or input.

525 Information in public filings submitted by EPA to other agencies or governmental
526 agencies, such as public comments EPA submits in a state rulemaking, also would not
527 be covered by these guidelines.

528 • Distribution related to subpoenas or adjudicative processes: Distributions of information
529 related to subpoenas or adjudicative process are not covered by these guidelines. An
530 adjudication is a matter involving specific parties that determines the rights and liabilities
531 of the parties to the action. Adjudications have well-established procedural safeguards

532 and rights to address the quality of adjudicatory decisions and provide persons with an
533 opportunity to contest decisions. This includes:

- 534 a Distribution of information in documents filed in a judicial case in any court.
 - 535 b For enforcement purposes, distribution of information in documents developed
536 during the conduct of any criminal or civil action or administrative enforcement
537 action, investigation, or audit involving an agency against specific parties.
 - 538 c Distribution of information in documents related to any formal or informal
539 administrative action determining the rights and liabilities of specific parties,
540 including documents that provide the findings, determinations or basis for such
541 actions. Examples include the processing or adjudication of applications for a
542 permit, license, registration, waiver, exemption, or claim; actions to determine
543 the liability of parties under applicable statutes and regulations; and
544 determination and implementation of remedies to address such liability.
- 545 • EPA may identify other instances where information is not “disseminated” by EPA
546 because EPA does not initiate or sponsor the distribution of information.

547 **1.4 What happens if information is initially not covered by these guidelines, but EPA**
548 **subsequently disseminates it to the public?**

549 If a particular distribution of information is not covered by these guidelines, the guidelines may still apply
550 to a subsequent distribution of the information in which EPA adopts, endorses or uses the information to
551 formulate or support a regulation, guidance, or other Agency decision or position. For example, if EPA
552 simply makes a public filing (such as facility data required by regulation) available to the public, these
553 guidelines would not apply to that distribution of information. However, if EPA later includes the data in
554 a background document in support of a rulemaking, these guidelines would apply to that later
555 dissemination of the information in that document.

556 **1.5 How does EPA ensure the objectivity, utility, and integrity of information that is not**
557 **covered by these guidelines?**

558 These guidelines apply only to information EPA disseminates to the public, outlined in Section 1.2,
559 above. Other information distributed by EPA that is not covered by these guidelines would still be
560 subject to applicable EPA policies, quality review processes, and correction procedures. These include
561 quality management plans for data systems, peer review, and other procedures that are specific to
562 individual programs and, therefore, not described in these guidelines. It is EPA’s policy that, to the
563 extent possible, all of the information it distributes meets a basic standard of information quality, and
564 that its utility, objectivity, and integrity be scaled and appropriate to the nature and timeliness of the
565 planned and anticipated uses. The need to ensure the quality of EPA information is not necessarily
566 dependent upon any plans to disseminate the information. EPA continues to plan to produce, collect,
567 and use information that is of the appropriate quality, irrespective of these guidelines or the prospects
568 for dissemination of the information.

569 **Defining Information Quality**

570 **2.1 What is “quality” according to the guidelines?**

571 Consistent with the OMB guidelines, EPA is issuing these guidelines to ensure and maximize the quality,
572 including objectivity, utility and integrity, of disseminated information. Objectivity, integrity, and utility
573 are defined here, consistent with the OMB guidelines. “Utility” refers to the usefulness of the information
574 to the intended users. “Objectivity” focuses on whether the disseminated information is being presented
575 in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate,
576 reliable, and unbiased. “Integrity” refers to security, such as the protection of information from
577 unauthorized access or revision, to ensure that the information is not compromised through corruption
578 or falsification.

579 **Ensuring and Maximizing Information Quality**

580 **3.1 How does EPA ensure and maximize the quality of disseminated information?**

581 EPA ensures and maximizes the quality of information by using policies and procedures well established
582 within the Agency as appropriate to the information product. There are many tools that the Agency uses
583 such as the Quality System⁹, review by senior management, peer review process¹⁰, communications
584 product review process¹¹, the web guide¹², and the error correction process¹³. The Agency uses a
585 graded approach and uses these tools based on the intended use of the information and the resources
586 available. As part of this graded approach, EPA recognizes that some of the information it disseminates
587 includes influential scientific, financial, or statistical information, and that this category should meet a
588 higher standard of quality.

589 **3.2 How does EPA define influential information for these guidelines?**

590 “Influential,” when used in the phrase “influential scientific, financial, or statistical information,” means
591 that the Agency can reasonably determine that dissemination of the information will have or does have a
592 clear and substantial impact on important public policies or important private sector decisions. For the

⁹EPA Quality Manual for Environmental Programs 5360 A1. May 2000.
<http://www.epa.gov/quality/qs-docs/5360.pdf>

¹⁰Science Policy Council Handbook Peer Review, U.S. EPA. EPA 100-B-00-001. December 2000.
<http://www.epa.gov/osp/spc/prhandbk.pdf>

¹¹EPA's Print and Web Communications Product Review Guide. <http://www.epa.gov/dced/pdf/review.pdf>

¹²Web Guide. U.S. EPA. <http://www.epa.gov/webguide/resources/webserv.html>

¹³Integrated Error Correction Process. <http://www.epa.gov/cdx/iecp.html>

593 purposes of the EPA's Information Quality Guidelines, EPA will generally consider the following classes
594 of information to be influential, and, to the extent that they contain scientific, financial, or statistical
595 information, that information should adhere to a higher standard of quality:

- 596 • Information disseminated in support of top Agency actions (i.e., rules, substantive
597 notices, policy documents, studies, guidance) that demand the ongoing involvement of
598 the Administrator's office and extensive cross-Agency involvement; issues have the
599 potential to result in major cross-Agency or cross-media policies, are highly
600 controversial, or provide a significant opportunity to advance the Administrator's
601 priorities. May also include precedent setting or controversial science or economic
602 issues.

- 603 • Information disseminated in support of OMB Economically Significant actions: As
604 defined in Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR
605 51735, October 4, 1993), Agency actions that are likely to have an annual effect on the
606 economy of \$100 million or more or adversely affect in a material way the economy, a
607 sector of the economy, productivity, competition, jobs, the environment, public health
608 or safety, or State, local, or tribal governments or communities.

- 609 • Work Products Undergoing Peer Review: As called for under the Agency's Peer
610 Review Policy, major scientific and technical work products and economic analysis
611 used in decision making. Scientific and technical work products that are used to support
612 a regulatory program or policy position and that meet one or more of the following
613 criteria are candidates for peer review: establishes a significant precedent, model, or
614 methodology; addresses a significant controversial issue; focuses on a significant
615 emerging issue, has significant cross-Agency implications; involves a significant resource
616 investment; uses an innovative approach; or has a statutory or other legal mandate for
617 peer review. Also includes major economic analyses such as internal Agency guidance
618 for conducting economic and financial methodologies that will serve as a principal
619 method or protocol used to conduct economic analyses within a program; unique or
620 novel applications of existing economic or financial methodologies; broad-scale
621 economic assessments of regulatory programs such as those required by Congressional
622 mandates; and, new stated preference or revealed preference surveys developed to
623 assist in the economic analysis of a regulation or program.

- 624 • Case-by-case: The Agency may make determinations of what constitutes "influential
625 information" beyond those classes of information already identified on a case-by-case
626 basis for other types of disseminated information that will have or do have a clear and
627 substantial impact (i.e. change or effect) on important public policies or important
628 private sector decisions.
629

630 **3.3 How does EPA ensure and maximize the quality of “influential” information?**

631 EPA recognizes that influential scientific, financial, or statistical information should be subject to a high
632 degree of transparency about data and methods to facilitate the reproducibility of such information by
633 qualified third parties, to an acceptable degree of imprecision. It is important that analytic results have a
634 high degree of transparency regarding (1) the source of the data used, (2) the various assumptions
635 employed, (3) the analytic methods applied, and (4) the statistical procedures employed. It is also
636 important that the degree of rigor with which each of these factors is presented and discussed be scaled
637 as appropriate, and that all factors be presented and discussed. In addition, if access to data and
638 methods cannot occur due to compelling interests such as privacy, trade secrets, intellectual property,
639 and other confidentiality protections, EPA should to the extent practicable, apply robustness checks to
640 analytic results and document what checks were taken. Original and supporting data may not be
641 subject to the high and specific degree of transparency required of analytic results; however, EPA
642 should apply relevant Agency policies and procedures to achieve reproducibility to the extent
643 practicable, given ethical, feasibility, and confidentiality constraints.

644 EPA has several Agency-wide and Program- and Region-specific policies and processes which the
645 Agency applies to ensure and maximize the quality of influential information. Agency-wide processes of
646 particular importance to ensure the quality, objectivity, and transparency of influential information are
647 the Agency's Quality System, Action Development Process, Peer Review Policy, and related
648 procedures. Many influential information products may be subject to more than one of these processes.

649 **3.4 How does EPA ensure and maximize the quality of “influential” scientific risk**
650 **assessment information?**

651 In its dissemination of human health risk assessments that have been categorized as influential, EPA
652 should ensure that the risk assessment adheres to the quality principles listed below. In applying these
653 principles to human health risk assessments, the nature of the risk assessment will depend upon the
654 information available, the regulatory application of the risk information, and the resources (including
655 time) available. The level of effort and complexity of detail of a risk assessment should balance the
656 information needs for decision making and the effort needed to develop such information.

657 With respect to influential scientific information regarding human health risk assessments, EPA should
658 ensure, to the extent practicable and in conformance with Agency guidelines, the objectivity of this
659 information disseminated by the Agency by adapting the quality principles found in the SDWA
660 Amendments of 1996:

- 661 (A) The substance of the information is accurate, reliable and unbiased. This involves the use of,
662 (i) the best available, peer-reviewed science as appropriate, and supporting studies
663 conducted in accordance with sound and objective scientific practices; and
664 (ii) data collected by accepted methods or best available methods (if the reliability of the
665 method and the nature of the decision justifies the use of the data).

- 666 (B) The presentation of information on human health effects, is comprehensive, informative, and
667 understandable. In a document made available to the public, EPA should specify –
668 (i) each population addressed by any estimate of applicable human health effects;
669 (ii) the expected human health risk or central estimate of human health risk for the specific
670 populations affected;
671 (iii) each appropriate upper-bound or lower-bound estimate of human health risk;
672 (iv) each significant uncertainty identified in the process of the assessment of human health
673 effects and studies that would assist in resolving the uncertainty; and
674 (v) peer-reviewed studies known to the Administrator that support, are directly relevant to,
675 or fail to support any estimate of human health effects and the methodology used to
676 reconcile inconsistencies in the scientific data.

677 In applying these principles, "best available" refers to the availability at the time an assessment was
678 made, and that in some situations, the Agency may need to weigh the resources needed and the
679 potential delay associated with gathering additional information in comparison to the value of the new
680 information in terms of its potential to improve the substance of the assessment. In an effort to expand
681 these guidelines to apply to environmental and safety-related risk assessments, the Agency intends to
682 seek input from appropriate stakeholders and the scientific community.

683 **3.5 Does EPA ensure and maximize the quality of information from external sources?**

684 EPA recognizes that the State and other governments and third party information issue is complex and
685 requires more thought and collaboration with States, the scientific and technical community and other
686 external data providers. Consultation is needed to best ascertain and address how these guidelines may
687 apply to external sources, and to ensure the guidelines are sufficiently flexible to encourage the
688 appropriate use of external information while also ensuring and maximizing the quality of information
689 EPA disseminates. Therefore, EPA is taking and will continue to take steps to ensure that the quality
690 and transparency of data and information provided by external sources is sufficient for the intended use.

691 For information that is either voluntarily submitted to EPA in hopes of influencing a decision or that EPA
692 obtains for use in developing a policy or regulatory decision, EPA plans to work with States and other
693 governments, the scientific and technical community and other interested data providers to develop and
694 publish factors that EPA would use to assess the quality of this type of information provided by external
695 sources and used by EPA for specific purposes.

696 **Pre-dissemination Review**

697 **4.1 What are the administrative mechanisms for pre-dissemination reviews?**

698 Each EPA office and region will incorporate the information quality principles outlined in these
699 guidelines into their existing pre-dissemination review procedures as appropriate. Offices and regions
700 may develop unique and new procedures, as needed, to provide additional assurance that the
701 information disseminated by or on behalf of their organizations is consistent with these guidelines.

702 **Correction of Information**

703 **5.1 What are EPA's Administrative Mechanisms for Affected Persons to Seek and Obtain**
704 **Appropriate Correction of Information?**

705 OEI manages the administrative mechanisms which enable affected persons to seek and obtain, where
706 appropriate, correction of information maintained or disseminated by the Agency that does not comply
707 with EPA or OMB Information Quality Guidelines. Working with the program offices, regions, labs and
708 field offices, OEI will receive complaints (or copies) and distribute them to the appropriate EPA
709 information owners. "Information owners" are the responsible persons designated by management in the
710 applicable EPA program, or those who have responsibility for the quality, objectivity, utility and
711 integrity of the information product or data disseminated by EPA.

712
713 **5.2 Who may request a correction of information from the Agency?**

714 Any individual or person may request a correction of information from EPA, if that individual or person
715 is an "affected person". For the purposes of these guidelines, "affected persons" are persons who may
716 benefit or be harmed by the disseminated information.

717 **5.3 What Should be Included in a Request for Correction of Information?**

718 Persons requesting a correction of information should include the following information in their requests:

- 719 • An indication that the person is seeking correction of information disseminated by EPA
720 that the person believes does not comply with EPA or OMB Information Quality
721 Guidelines.
- 722 • Name and contact information. Organizations submitting a complaint should identify an
723 individual, to serve as a contact.
- 724 • A description of the information the person believes does not comply with EPA or
725 OMB guidelines, including specific citations, if applicable.
- 726 • An explanation of how the information does not comply with EPA or OMB guidelines
727 and, if possible, a recommendation of corrective action.

728 **5.4 Will EPA consider all requests for correction of information?**

729 EPA seeks public and stakeholder input on a wide variety of issues, including the identification and
730 resolution of discrepancies in EPA data and information. EPA will review every request for correction
731 under these guidelines and consider it for correction unless:

- 732 • The request itself is deemed "frivolous," including those made in bad faith or without

733 justification, deemed inconsequential or trivial, and for which a response would be
734 duplicative of existing processes, unnecessary, or unduly burdensome on the Agency.
735 More information on this subject may be found in the Federal Register (66 Fed. Reg. at
736 49721).

737 • It pertains to EPA actions, where a mechanism by which to submit comments to the
738 Agency is already provided. For example, EPA rulemakings include a comprehensive
739 public comment process and impose a legal obligation on EPA to respond to comments
740 on all aspects of the action. These procedural safeguards assure a thorough response to
741 comments on quality of information. EPA believes that the thorough consideration
742 required by this process meets the needs of the request for correction of information
743 process. A separate process for information that is already subject to such a public
744 comment process would be duplicative, burdensome, and disruptive to the orderly
745 conduct of the action.

746 If EPA cannot respond to a complaint in the response to comments for the action (for
747 example, because the complaint is submitted too late to be considered along with other
748 comments or because the complaint is not germane to the action), EPA will consider
749 whether a separate response to the complaint is appropriate. EPA may consider
750 frivolous any complaint which could have been submitted as a timely comment in the
751 rulemaking or other action but was submitted after the comment period.

752 • The party that submitted the complaint for EPA consideration is not an "affected
753 person." For the purposes of these guidelines, "affected persons" are persons who may
754 benefit or be harmed by the disseminated information. This includes persons who are
755 seeking to address information about themselves as well as persons who use
756 information.

757 **5.5 How will EPA respond to a request for correction of information?**

758 If a request for correction of information is deemed appropriate for consideration, EPA will make a
759 decision on the request on the basis of the information in question. If a request is approved, EPA will
760 take corrective action. Whether a request is approved or not, EPA will send an explanation to the
761 requester. EPA may elect not to correct some completed information products on a case-by-case basis
762 due to Agency priorities, time constraints, or resources. OEI will submit reports to OMB on an annual
763 basis beginning January 1, 2004 regarding the number, nature and resolution of complaints received by
764 EPA.

766 **5.6 Will EPA reconsider its decision on a request for the correction of information?**

767 If requesters of corrective actions are dissatisfied with an EPA decision regarding their request, they
768 may appeal the decision. These appeals for reconsideration should contain the following information:

769 • An indication that the person is seeking an appeal of an EPA decision on a previously
770 submitted request for a correction of information, including the date of the original
771 submission and date of EPA decision.

772 • Name and contact information. Organizations submitting an appeal should identify an
773 individual, as a contact.

774 • An explanation of why the appealing entity disagrees with the EPA decision, and, if
775 possible, a recommendation of corrective action.

776 • A copy of the original request for the correction of information.

777 **5.7 How does EPA process requests for reconsideration of EPA decisions?**

778 The requests for reconsideration of EPA decisions will be logged and tracked by OEI. These appeals
779 will be sent to the appropriate EPA program office or region, that has responsibility for the information
780 in question. Within the responsible EPA office or region, the Assistant Administrator or Regional
781 Administrator will work with OEI to form an executive panel to review the appeal. This panel will be
782 chaired by the EPA Chief Information Officer. The responsible EPA Assistant Administrator or
783 Regional Administrator, informed by the executive panel's recommendation, will make the final decision
784 on the appeal.

REQUEST FOR PUBLIC COMMENTS

EPA requests public comment and input on the following questions. EPA appreciates your input on these and other aspects of the draft EPA guidelines that are not listed below. Please visit <http://www.epa.gov/oei/qualityguideline> to learn more about how to submit your comments to EPA. At that web page you may also submit your comments online and view other comments that will be submitted to EPA during the 30-day public comment period throughout May 2002. There is also an opportunity for you to share your comments with EPA orally at the EPA public meeting in May. Please visit that web page to register by May 3, 2002. EPA thanks you for providing your input on these draft guidelines.

Influential Information

“Influential,” when used in the phrase “influential scientific, financial, or statistical information,” means that the Agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions. Consistent with OMB’s guidance, EPA has chosen to identify influential information in terms of specific classes of information that are developed and reviewed through Agency-wide processes.

- Is this an appropriate approach?
- Is the scope of information too broad?
- Are there other classes of information that should be included?

EPA intends to develop experience implementing its definition of influential information over the first year, and then potentially broaden it to incorporate other classes of information disseminated by EPA.

- Is this an appropriate approach and consistent with the goal to continually improve Agency information?

Reproducibility

Influential scientific, financial, or statistical information generally has a higher degree of quality, in particular, transparency that facilitates the reproducibility of the information by qualified third parties.

- What comments do you have on the Agency’s approach to facilitating the reproducibility of influential information?
- Is it appropriate for the influential scientific, financial, and statistical information EPA disseminates?
- What types of original and supporting data do you believe should or should not be subject to a reproducibility requirement given ethical, feasibility, or confidentiality constraints?
- What suggestions do you have for performing and reporting robustness checks of influential analytic results in cases where public access to data and methods will not occur due to other compelling interests such as privacy, trade secrets, intellectual property, and other

- confidentiality protections?
- In particular, how might such robustness checks be applied to third party data that are used in analyses included in influential scientific, financial, and statistical information disseminated by EPA?

Influential risk assessment

EPA has adapted the SDWA quality principles for influential scientific risk assessments regarding human health risks and would like to hear from you on this issue.

- What suggestions do you have with respect to the EPA adaptation of the SDWA principles for influential scientific risk assessments regarding human health risks?
- Do you think that an adaptation of the SDWA quality principles is appropriate for most influential scientific risk assessments regarding human health risks disseminated by EPA?

EPA has decided to adapt the SDWA quality principles in the future for environmental and safety risk assessments. This will enable EPA to inform its decisions on how to best address this issue based on public input.

- What suggestions do you have for how EPA should address environmental and safety risk assessments?
- How do you think EPA should adapt the SDWA principles to accommodate these different risk assessments?
- Or, if you do not believe that EPA should adapt these principles, how would you suggest EPA address environmental and safety risk assessments in its quality guidelines?

Sources of Information Disseminated by EPA

During the development of these guidelines, EPA considered how to address information that is not generated by the Agency, but is later disseminated by EPA in a publication or through a regulatory or policy decision. Although this information may not be covered by these guidelines when it is first generated by outside sources, it may be covered by the guidelines if the Agency subsequently decided to use the information in a publication or policy decision.

- EPA would like you to suggest specific assessment factors that the Agency should consider using when assessing specific kinds of information submitted to EPA by outside sources, or information EPA obtains from outside sources.
- EPA also requests your input on how it should properly consult with the scientific and technical community in establishing these assessment factors.

Complaint Resolution

EPA has developed a complaint resolution process. That is, your initial complaint would be heard by

what EPA calls the "information owner". That "information owner" is the EPA person designated by management in the EPA program, or who has the responsibility for the quality, objectivity, utility and integrity of the information disseminated by EPA. Next, should you appeal the initial decision, your appeal would be heard by the Assistant Administrator (AA) or Regional Administrator (RA) for that program or region. The AA and RA are the highest ranking official for those organizations. They are political appointees. That appeal would be decided in collaboration with a standing panel. That panel would consist of other AAs and RAs to ensure that your appeal is taken to a most senior level right away. The EPA Chief Information Officer would chair that panel. There are many more details that EPA has yet to decide and the Agency encourages your input as it develops this proposal.

- Specifically, what suggestions do you have regarding the receipt of the initial complaint through the Office of Environmental Information? Do you think a central point of entry is useful or problematic?
- What are appropriate time periods for this process?
- Once an appeal is submitted it would be decided by a top EPA official in collaboration with an executive panel. Do you think this is sufficiently objective and efficient to ensure a timely and appropriate response to an appeal?