

No. 07-17388

**IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

Americans for Safe Access,

Plaintiff-Appellant

v.

United States Department of Health and Human Services, *et al.*

Defendants-Appellees.

On Appeal from the
United States District Court for the
Northern District of California
District Court No. CV-3:07-01049-WHA

ADDENDUM TO APPELLANT'S OPENING BRIEF

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Statutes

44 U.S.C. § 3516, note

44 U.S.C. § 3501

44 U.S.C. § 3504(d)(1)

44 U.S.C. § 3506(a)(1)(B)

44 U.S.C. § 3507(d)(6)

44 U.S.C. § 3516

44 U.S.C. § 3517

5 U.S.C. § 701

5 U.S.C. § 551

5 U.S.C. § 702

5 U.S.C. § 704

5 U.S.C. § 706

5 U.S.C. § 552

5 U.S.C. § 553

Regulations

66 Fed. Reg. 49718 (Sept. 28, 2001)

67 Fed. Reg. 8451 (Feb. 22, 2002)

HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility,
and Integrity of Information Disseminated to the Public

Legislative History

Reauthorization of the Paperwork Reduction Act and the Office of Information and Regulatory Affairs: Hearings Before the Legislation and National Security Subcomm. of the House Comm. on Government Operations, 101st Cong. 23 (1989)

Hearings Before the Subcomm. on the Treasury, Postal Service, and General Government Appropriations of the House Comm. on Appropriations on appropriations for fiscal year 2001, Part 3, "Executive Office of the President and Funds Appropriated to the President," 106th Cong. 477-79 (March 28, 2000)

The “Information Quality Act” (or “Data Quality Act” or “section 515”¹) -- full text

44 U.S.C. § 3516, note:

“Policy and Procedural Guidelines

Pub. L. 106-554, Sec. 1(a)(3) [title V, Sec. 515], Dec. 21, 2000, 114 Stat. 2763, 2763A-153, provided that:

“(a) In General.--The Director of the Office of Management and Budget shall, by not later than September 30, 2001, and with public and Federal agency involvement, issue guidelines under sections 3504(d)(1) and 3516 of title 44, United States Code, that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies in fulfillment of the purposes and provisions of chapter 35 of title 44, United States Code, commonly referred to as the Paperwork Reduction Act.

“(b) Content of Guidelines.--The guidelines under subsection (a) shall--

“(1) apply to the sharing by Federal agencies of, and access to, information disseminated by Federal agencies; and

“(2) require that each Federal agency to which the guidelines apply--

“(A) issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency, by not later than 1 year after the date of issuance of the guidelines under subsection (a);

“(B) establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued under subsection (a); and

“(C) report periodically to the Director--

“(i) the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency; and

¹ This enactment does not have a formal title; it is a section of the OMB portion of the Consolidated Appropriations Act for Fiscal Year 2001.

“(ii) how such complaints were handled by the agency.”

The Paperwork Reduction Act of 1995 -- relevant portions

44 U.S.C. § 3501. “Purposes

The purposes of this subchapter are to--

...

(2) ensure the greatest possible public benefit from and maximize the utility of information created, collected, maintained, used, shared and disseminated by or for the Federal Government;

....

(4) improve the quality and use of Federal information to strengthen decisionmaking, accountability, and openness in Government and society;

....

(11) improve the responsibility and accountability of the Office of Management and Budget and all other Federal agencies to Congress and to the public for implementing the information collection review process, information resources management, and related policies and guidelines established under this subchapter.

....”

44 U.S.C. § 3504(d)(1). “Authority and functions of Director

....

(d) With respect to information dissemination, the Director [of OMB] shall develop and oversee the implementation of policies, principles, standards, and guidelines to--

(1) apply to Federal agency dissemination of public information, regardless of the form or format in which such information is disseminated;. . . .”

44 U.S.C. § 3506(a)(1)(B). “Federal agency responsibilities

(a)(1) The head of each agency shall be responsible for--

....
(B) complying with the requirements of this subchapter and related policies established by the Director.

....

(b) With respect to general information resources management, each agency shall --

(1) Manage information resources to --

....

(C) improve the integrity, quality, and utility of I information to all users within and outside the agency . . .

....”

44 U.S.C. § 3507(d)(6). “Public information collection activities; submission to

Director; approval and delegation

....

(d)(1) For any proposed collection of information contained in a proposed rule--

....

(6) The decision by the Director to approve or not act upon a collection of information contained in an agency rule shall not be subject to judicial review.

....”

44 U.S.C. § 3516. “Rules and regulations

The Director shall promulgate rules, regulations, or procedures necessary to exercise the authority provided by this subchapter.”

44 U.S.C. § 3517. “Consultation with other agencies and the public

(a) In developing information resource management policies, plans, rules, regulations, procedures, and guidelines and in reviewing collections of information, the Director shall provide interested agencies and persons early and meaningful opportunity to comment.

.....”

5 U.S.C. § 701. “Application; definitions

(a) This chapter applies, according to the provisions thereof, except to the extent that --

- (1) statutes preclude judicial review; or
- (2) agency action is committed to agency discretion by law.

(b) For the purpose of this chapter --

....
(2) “person”, “rule”, “order”, “license”, “sanction”, “relief”, and “agency action” have the meanings given them by section 551 of this title.”

5 U.S.C. § 551. “Definitions

For the purpose of the subchapter --

....
(4) “rule” means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency . . .

-
- (11) “relief” includes the whole or a part of an agency --
 - (A) grant of money, assistance, license, authority, exemption, exception, privilege, or remedy;
 - (B) recognition of a claim, right, immunity, privilege, exemption, or exception; or
 - (C) taking of other action on the application or petition of, and beneficial to, a person;

....
(13) “agency action” includes the whole or a part of an agency rule, order, license sanction, relief, or the equivalent or denial thereof, or failure to act;
....”

5 U.S.C. § 702. “Right of review

A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof. An action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the ground that it is against the United States or that the United States is an indispensable party. The United States may be named as a defendant in any such action, and a judgment or decree may be entered against the United States: Provided, That any mandatory or injunctive decree shall specify the Federal officer or officers (by name or by title), and their successors in office, personally responsible for compliance. Nothing herein (1) affects other limitations on judicial review or the power or duty of the court to dismiss any action or deny relief on any other appropriate legal or equitable ground; or (2) confers authority to grant relief if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought.”

5 U.S.C. § 704. “Actions reviewable

Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority.”

5 U.S.C. § 706. “Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The review court shall --

- (1) compel agency action unlawfully withheld or unreasonably delayed; and
- (2) hold unlawful and set aside agency action, findings, and conclusions found to be --
 - (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;....”

5 U.S.C. § 552. “Public information, agency rules, opinions, orders, records, and proceedings.

(a)

- (1) Each agency shall separately state and currently publish in the Federal Register for the guidance of the public --

. . . .

- (D) substantive rules of general applicability adopted as authorized by law, and statement of general policy or interpretation of general applicability formulated and adopted by the agency; . . .
-”

5 U.S.C. § 553. “Rule making

. . . .

(b) General notice of proposed rule making shall be published in the Federal Register . . . The notice shall include --

. . . .

- (2) reference to the legal authority under which the rule is proposed;

. . . .

Except when notice or hearing is required by statute, this subsection does not apply --

- (A) to interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice; . . .
-”

OFFICE OF MANAGEMENT AND BUDGET

Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies

AGENCY: Executive Office of the President, Office of Management and Budget.

ACTION: Final guidelines, with request for comments.

SUMMARY: These guidelines implement section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554). Section 515 directs the Office of Management and Budget (OMB) to issue government-wide guidelines that "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies." Within one year after OMB issues these guidelines, agencies must issue their own implementing guidelines that include "administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency" that does not comply with the OMB guidelines. OMB is also requesting additional comment for 30 days on the "capable of being substantially reproduced" standard (paragraphs V.3.B, V.9, and V.10) which is issued on an interim final basis.

DATES: *Effective Date:* October 1, 2001.

Comment Date: Comments on the "capable of being substantially reproduced" standard in paragraphs V.3.B, V.9, and V.10 must be submitted by October 29, 2001.

ADDRESSES: Please submit comments to Brooke J. Dickson of the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. Comments can also be e-mailed to informationquality@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Brooke J. Dickson, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. Telephone (202) 395-3785.

SUPPLEMENTARY INFORMATION: In section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554; H.R. 5658), Congress directed the Office of Management and Budget (OMB) to issue, by September 30, 2001, government-wide guidelines that

"provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies * * *." Section 515(b) goes on to state that the OMB guidelines shall:

"(1) apply to the sharing by Federal agencies of, and access to, information disseminated by Federal agencies; and

"(2) require that each Federal agency to which the guidelines apply—

"(A) issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency, by not later than 1 year after the date of issuance of the guidelines under subsection (a);

"(B) establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued under subsection (a); and

"(C) report periodically to the Director—

"(i) the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency; and

"(ii) how such complaints were handled by the agency."

These guidelines are to be issued "under sections 3504(d)(1) and 3516" of the Paperwork Reduction Act of 1995; pursuant to section 3503 of that Act, the authorities of the OMB Director are carried out by the Administrator of the Office of Information and Regulatory Affairs.

Background

The focus of section 515 is on the Federal Government's information dissemination activities. Indeed, Federal agencies have disseminated information to the public for decades. Until recently, agencies have disseminated information principally by making paper copies of documents available to the public. In recent years, however, Federal information dissemination has grown due to the advent of the Internet, which has ushered in a revolution in communications. The Internet has enabled Federal agencies to disseminate an ever-increasing amount of information. Congress has strongly encouraged the Executive Branch's dissemination efforts in statutes that include particular dissemination activities and in the government-wide dissemination provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35) (the PRA). In addition, the Executive Branch's strong

support for information dissemination is reflected in the dissemination provisions of OMB Circular A-130, "Management of Federal Information Resources," as well as in the provisions in OMB Circular A-110, "Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations," related to a Freedom of Information Act request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law [64 FR 54926; October 8, 1999].

Section 515 builds upon the existing agency responsibility to ensure information quality. According to the PRA, agency Chief Information Officers (CIOs) must manage information resources to "improve the integrity, quality, and utility of information to all users within and outside the agency, including capabilities for ensuring dissemination of public information, public access to government information, and protections for privacy and security." Before an agency collects information from 10 or more persons, the agency must seek public comment "to enhance the quality, utility, and clarity of the information to be collected." The agency then must obtain OMB approval that is based upon an evaluation of the agency's need for the information, the "practical utility" of the information to be collected, and the minimization of burden that would be imposed on the public in responding to the collection. The CIO must certify to OMB that the agency, "to the maximum extent practicable, uses information technology to reduce burden and improve data quality."

In developing these guidelines to implement section 515, OMB recognized that Federal agencies disseminate many types of information in many different ways. A few examples can only begin to describe the breadth of information disseminated by the Federal government. Agencies disseminate statistical information, such as the aggregated information from the 2000 Census and the monthly and quarterly economic reports issued by the Bureau of Economic Analysis and the Bureau of Labor Statistics. Agencies disseminate information that aids members of the public in their daily activities, such as the National Weather Service's weather reports and the FAA's air travel advisories. Agencies disseminate information about health, safety, and environmental risks and information that they collect from regulated entities, such as EPA's

dissemination of Toxic Release Inventory information. Agencies also disseminate technical information that they create or obtain in the course of developing regulations, often involving scientific, engineering, and economic analysis. Agencies disseminate information when they issue reports and studies. Moreover, agencies provide the public with basic descriptions of agency authorities, activities and programs, along with the contact information for the public to interact with and access that information or those services.

Underlying Principles

In accordance with section 515, OMB has designed the guidelines to help agencies ensure and maximize the quality, utility, objectivity and integrity of the information that they disseminate (meaning to share with, or give access to, the public). It is crucial that information Federal agencies disseminate meets these guidelines. In this respect, the fact that the Internet enables agencies to communicate information quickly and easily to a wide audience not only offers great benefits to society, but also increases the potential harm that can result from the dissemination of information that does not meet basic information quality guidelines. Recognizing the wide variety of information Federal agencies disseminate and the wide variety of dissemination practices that agencies have, OMB developed the guidelines with several principles in mind.

First, OMB designed the guidelines to apply to a wide variety of government information dissemination activities that may range in importance and scope. OMB also designed the guidelines to be generic enough to fit all media, be they printed, electronic, or in other form. OMB sought to avoid the problems that would be inherent in developing detailed, prescriptive, "one-size-fits-all" government-wide guidelines that would artificially require different types of dissemination activities to be treated in the same manner. Through this flexibility, each agency will be able to incorporate the requirements of these OMB guidelines into the agency's own information resource management and administrative practices.

Second, OMB designed the guidelines so that agencies will meet basic information quality standards. Given the administrative mechanisms required by section 515 as well as the standards set forth in the PRA, it is clear that agencies should not disseminate substantive information that does not meet a basic level of quality. We recognize that some government information may need to meet higher or more specific

information quality standards than those that would apply to other types of government information. The more important the information, the higher the quality standards to which it should be held, for example, in those situations involving "influential scientific or statistical information" (a phrase defined in these guidelines). The guidelines recognize, however, that information quality comes at a cost. Accordingly, the agencies should weigh the costs (for example, including costs attributable to agency processing effort, respondent burden, maintenance of needed privacy, and assurances of suitable confidentiality) and the benefits of higher information quality in the development of information, and the level of quality to which the information disseminated will be held.

More specifically, the OMB guidelines state that "agencies shall have a basic standard of quality (including objectivity, utility, and integrity) as a performance goal * * *". We note, in the scientific context, that in 1996 the Congress, for health decisions under the Safe Drinking Water Act, has already adopted a basic standard of quality for the use of science in agency decisionmaking. Under 42 U.S.C. 300g-1(b)(3)(A), an agency is directed, "to the degree that an Agency action is based on science," to use "(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)." We also note that the OMB guidelines call for an additional level of quality "in those situations involving influential scientific or statistical information." The additional level of quality concerns a standard of care for scientific or statistical analytical results, a "capable of being substantially reproduced" standard that is discussed below.

We further note that in the 1996 amendments to the Safe Drinking Water Act the Congress adopted a basic quality standard for the dissemination of public information about risks of adverse health effects. Under 42 U.S.C. 300g-1(b)(3)(B), the agency is directed, "to ensure that the presentation of information [risk] effects is comprehensive, informative, and understandable." The agency is further directed, "in a document made available to the public in support of a regulation [to] specify, to the extent practicable— (i) each population addressed by any estimate [of applicable risk effects]; (ii) the expected risk or central estimate of

risk for the specific populations [affected]; (iii) each appropriate upper-bound or lower-bound estimate of risk; (iv) each significant uncertainty identified in the process of the assessment of [risk] effects and the studies that would assist in resolving the uncertainty; and (v) peer-reviewed studies known to the [agency] that support, are directly relevant to, or fail to support any estimate of [risk] effects and the methodology used to reconcile inconsistencies in the scientific data." We urge each agency in developing its guidelines to evaluate whether adopting or adapting these basic Congressional standards would be appropriate for judging the quality of disseminated scientific or statistical information.

Third, OMB designed the proposed guidelines so that agencies can apply them in a common-sense and workable manner. It is important that these guidelines do not impose unnecessary administrative burdens that would inhibit agencies from continuing to take advantage of the Internet and other technologies to disseminate information that can be of great benefit and value to the public. In this regard, OMB encourages agencies to incorporate the standards and procedures required by these guidelines into their existing information resources management and administrative practices rather than create new and potentially duplicative or contradictory processes. The primary example of this is that the guidelines recognize that, in accordance with OMB Circular A-130, agencies already have in place well-established information quality standards and administrative mechanisms that allow persons to seek and obtain correction of information that is maintained and disseminated by the agency. Under the OMB guidelines, agencies need only ensure that their own guidelines are consistent with these OMB guidelines, and then ensure that their administrative mechanisms satisfy the standards and procedural requirements in the new agency guidelines. Similarly, agencies may rely on their implementation of the Federal Government's computer security laws (formerly, the Computer Security Act, and now the computer security provisions of the PRA) to establish appropriate security safeguards for ensuring the "integrity" of the information that the agencies disseminate.

Summary of OMB Guidelines

These guidelines apply to Federal agencies subject to the Paperwork Reduction Act (44 U.S.C. chapter 35). Agencies are directed to develop information resources management

procedures for reviewing and substantiating (by documentation or other means selected by the agency) the quality (including the objectivity, utility, and integrity) of information before it is disseminated. In addition, agencies are to establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, correction of information disseminated by the agency that does not comply with the OMB or agency guidelines. Consistent with the underlying principles described above, these guidelines stress the importance of having agencies apply these standards and develop their administrative mechanisms so they can be implemented in a common sense and workable manner. Moreover, agencies must apply these standards flexibly, and in a manner appropriate to the nature and timeliness of the information to be disseminated, and incorporate them into existing agency information resources management and administrative practices.

Section 515 denotes four substantive terms regarding information disseminated by Federal agencies: quality, utility, objectivity, and integrity. It is not always clear how each substantive term relates—or how the four terms in aggregate relate—to the widely divergent types of information that agencies disseminate. The guidelines provide definitions that attempt to establish a clear meaning so that both the agency and the public can readily judge whether a particular type of information to be disseminated does or does not meet these attributes.

In the guidelines, OMB defines “quality” as the encompassing term, of which “utility,” “objectivity,” and “integrity” are the constituents. “Utility” refers to the usefulness of the information to the intended users. “Objectivity” focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased. “Integrity” refers to security—the protection of information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification. OMB modeled the definitions of “information,” “government information,” “information dissemination product,” and “dissemination” on the longstanding definitions of those terms in OMB Circular A-130, but tailored them to fit into the context of these guidelines.

In addition, agencies have two reporting requirements. The first report,

implemented no later than one year after the issuance of these OMB guidelines (no later than October 1, 2002), must provide the agency’s information quality guidelines that describe administrative mechanisms allowing affected persons to seek and obtain, where appropriate, correction of disseminated information that does not comply with the OMB and agency guidelines. The second report is an annual fiscal year report to OMB (to be first submitted on January 1, 2004) providing information (both quantitative and qualitative, where appropriate) on the number, nature, and resolution of complaints received by the agency regarding its perceived or confirmed failure to comply with these OMB and agency guidelines.

Public Comments and OMB Response

Section 515(a) required OMB to provide the public and the Federal agencies the opportunity to comment on these guidelines. OMB worked with Federal agencies, through a working group and through an inter-agency comment process, in the development of the proposed guidelines. The proposed guidelines were published in the *Federal Register* on June 28, 2001 (66 FR 34489) providing a public comment period of 45 days. OMB received a total of 100 comments from academic institutions (36), Federal agencies (26), individual members of the public (7), associations affiliated with academia (5), associations affiliated with medical, social science or science interests (15), associations affiliated with Federal Government interests (4), and associations affiliated with industry interests (7).

General Concerns. Many comments expressed support for the idea of government-wide quality standards for information disseminated by Federal agencies. Comments also expressed support for OMB’s commitment to creating flexible general guidelines and to minimizing the administrative costs and burdens that these guidelines will impose. The majority of comments focused on two aspects of the proposed guidelines: suggestions for placing limitations on the administrative correction mechanisms requirements of the statute; and the need to clarify specific definitions and other terms found in the guidelines.

Many comments raised questions and concerns about how these guidelines interact with existing statutes and policies, including the Paperwork Reduction Act and the Government Performance and Results Act. We have attempted to draft these guidelines in a way that addresses the requirements of

section 515, but does not impose a completely new and untried set of standards upon Federal agencies. We encourage agencies to consider the effect of relevant existing statutes and policies in the development of their own guidelines.

Administrative Mechanisms. These guidelines require agencies to establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, correction of information maintained and disseminated by the agency that does not comply with the OMB guidelines. Many comments suggested that limits be imposed on the types of information that should be subject to these guidelines, in particular, information that is disseminated by agency libraries. OMB agrees that archival information disseminated by Federal agency libraries (for example, Internet distribution of published articles) should not be covered by these guidelines, given that libraries do not endorse the information that they disseminate. Moreover, an agency’s dissemination of public filings (for example, corporate filings with the Securities and Exchange Commission) is not covered by these guidelines. In each of these situations, the agencies have not authored these documents and have not adopted them as representing the agencies’ views. By disseminating these materials, the agencies are simply ensuring that the public can have quicker and easier access to materials that are publicly available. In developing its implementing guidelines, and in accordance with the criteria set forth in these guidelines, each agency should evaluate and identify the types of information that it disseminates that will be subject to its guidelines.

In addition, comments also raised the concern that the guidelines would apply to “preliminary” information, and they recommended that the guidelines exclude such information. OMB appreciates the concerns that these comments have raised. However, OMB does not believe that an exclusion for “preliminary” information is necessary or appropriate. It is still important that the quality of preliminary information be ensured and that preliminary information be subject to the administrative complaint-and-correction process.

A few comments stated that affected information should be limited to information used in agency rulemaking. While this has been the position of previous policies which these guidelines are not intended to modify or replace (*see, e.g.,* section __.36(d) in OMB Circular A-110), we believe the

plain meaning and intent of section 515 covers the larger government information universe.

Based on the public comments received, these guidelines allow agencies to determine the appropriate level of correction for a complaint received. Several comments suggested that agencies use disclaimers to distinguish the status of information, a practice that agencies should consider adopting as they consider their information holdings.

OMB received detailed discussion on the requirement that agencies develop administrative mechanisms allowing for affected persons to "seek and obtain correction of information that does not comply with OMB's guidelines." Members of the scientific community expressed strong concerns about the possibility of a Federal agency that would "correct" scientific information without carrying out the scientific analysis to support the correction. Comments from all fields suggested in various ways that challenging individuals should be "required to openly state his/her relationship with the data/information (familiarity/expertise) and provide information [as] to his/her interest in it."

Comments also pointed out great potential for abuse of this process. As one association summarized, "This could be seen to provide grounds for interested parties to demand access to underlying data, to compel the government to replicate research findings (at great expense and with unnecessary delay), or in other ways impede, discredit, harass or stymie research." For example, the National Oceanic and Atmospheric Administration (NOAA) explained that they receive numerous complaints from the public when they miss a weather forecast. "Does this mean that the NWS [National Weather Service] could be requested to change a forecast after the fact? Or could someone with an economic interest challenge official observational data which could affect the value of an insurance payment?" asks NOAA.

Overall, OMB does not envision administrative mechanisms that would burden agencies with frivolous claims. Instead, the correction process should serve to address the genuine and valid needs of the agency and its constituents without disrupting agency processes. Agencies, in making their determination of whether or not to correct information, may reject claims made in bad faith or without justification, and are required to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information

involved, and explain such practices in their annual fiscal year reports to OMB.

Numerous comments provided language to clarify or limit the term, "affected persons." One academic institution suggested that the term, "affected persons," reflects a criterion of "direct measurable impact with significant personal consequence." Other academic institutions suggested that "affected persons should not be permitted to challenge the substance of information without showing that a qualified scientist has found fault with its quality or integrity." Similarly, some comments argued that the ability to correct scientific information should be limited only to other scientists. Several associations suggested that OMB identify the types of information that could be challenged rather than to focus on the characteristics of a "legitimate" challenger. OMB considered these comments at length. Our conclusion is that "affected persons" are people who may benefit or be harmed by the disseminated information. This includes persons who are seeking to address information about themselves as well as persons who use information. However, each agency should consider how persons (which includes groups, organizations and corporations, as defined by the Paperwork Reduction Act) will be affected by the agency's information. Agencies should address the issue of "affected persons" in consultation with their constituents through the public comment process that agencies will provide after drafting their proposed guidelines and before submitting them for OMB review.

These guidelines require that an agency official be designated to receive and resolve complaints regarding information that does not comply with either the OMB guidelines or the agency's guidelines. In the proposed guidelines, we required, with a limited exception, that the Chief Information Officer (CIO) of the agency have this responsibility. Of the government agencies that commented on this provision, many pointed to their specific agency practices on information quality and their designation of a "quality official" who was not necessarily working under the agency CIO. Recognizing that some agencies may have specific officials in place to address quality issues, the final guidelines allow agencies to designate an appropriate official. Agencies may also designate multiple officials, i.e., based on the needs of individual agency components, as long as there is a single official with these overall responsibilities designated at the agency level. The authorized official also needs

to consult with the CIO on quality matters pertaining to information disseminated by the agency.

Agencies need to respond to complaints in a manner appropriate to the nature and extent of the complaint. Examples of appropriate responses, as suggested by comments, include personal contacts via letter or telephone, form letters, press releases or mass mailings that correct a widely disseminated error or address a frequently raised complaint. Agencies may want to utilize other methods of response under existing agency practices. For example, for agencies with a high volume of complaints, it is acceptable for the agency to describe a sample of those complaints in the annual fiscal year report to OMB. For categories of inconsequential or trivial complaints identified in the agency guidelines, an agency may decide that no response is necessary. Agencies should describe to OMB as part of the annual fiscal year report the chosen response mechanisms and how they are working.

Definitions and Other Terms. Section 515 denotes four substantive terms regarding information disseminated by Federal agencies: quality, utility, objectivity, and integrity. We have defined "quality" as an encompassing term. The organizations and individuals that submitted comments did not object to having "quality" defined as an encompassing term, but suggested that we should discuss each term separately. The principles laid out in the proposed guidelines, stated one comment, create "subjective definitions" of the four terms. This comment warned OMB that "subjective definitions of quality, objectivity, utility, and integrity could cause agencies to delay data release or disregard data for fear of challenge." Other comments expressed similar views, or as one association observed, "Science does not recognize a sliding scale of quality."

These guidelines reflect OMB's determination that "quality," "utility," "objectivity," and "integrity" are closely interrelated concepts in the context of these guidelines. Collectively, these terms address the following three aspects of the information that is to be disseminated: whether the information is useful to the intended users of the information; whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner in both presentation and as a characteristic that should be inherent to quality information; and whether the information has been protected from unauthorized access or revision.

Some comments stated that OMB was "exceeding the statutory mandate" and going beyond "Congressional intent" in specifying scientific and statistical information in these guidelines. Others felt that we should simply acknowledge that the scientific and statistical communities already have practices and standards for their information, rather than create another set of standards for these information types. OMB does not agree with those comments that said the proposed guidelines went beyond the statute in covering statistical and scientific information. Section 515 expressly states that its scope includes statistical information. Moreover, section 515 has no exclusion for scientific information, and in many respects it is very similar to (and overlaps with) statistical information. OMB, however, does appreciate the concerns that the comments raised about the guidelines not creating another set of standards for statistical and scientific information. Our guidelines do not seek to impose new standards on these communities, but to reiterate the standards that are already held in those communities.

Recognizing public interest in medical and public health information, we have specifically added a provision stating, "Agencies shall adopt specific standards of quality that are appropriate for the various categories of information they disseminate." For example, OMB encourages agencies, in crafting their agency-specific guidelines, to promote objectivity in information quality in ways that protect the confidentiality of research subjects and encourage public participation in research. These concerns are particularly salient in medical and public health research.

A number of comments regarded our discussion of ensuring that scientific information be "substantially reproducible" as requiring agencies to replicate original data and to perform independent analysis upon all scientific information disseminated by the agency. We have responded to these concerns in a number of ways. First, we make it clear that what we now refer to as the "capable of being substantially reproduced" standard applies to analytical results that are disseminated, and does not apply to the original or supporting data. Thus, replication of original data is not required. Second, the "capable of being substantially reproduced" standard is applicable only to "influential" scientific and statistical information as defined in the guidelines. Third, the guidelines call for the agency to determine that "influential" analytical results be capable of being substantially

reproducible by independent analysis. We intend this standard to say that, if appropriately qualified persons used the same or a similar methodology, they would be expected to achieve similar findings and results.

Based on the concerns expressed in the comments, we expanded upon our discussion of "capable of being substantially reproduced" in our definition of "objective," and added two explanatory definitions. We state, in paragraphs V.3.B, V.9, and V.10:

In addition, "objectivity" involves a focus on ensuring accurate, reliable, and unbiased information. In a scientific or statistical context, the original or supporting data shall be generated, and the analytical results shall be developed, using sound statistical and research methods.

i. If the results have been subject to formal, independent, external peer review, the information can generally be considered of acceptable objectivity.

ii. In those situations involving influential scientific or statistical information, the results must be capable of being substantially reproduced, if the original or supporting data are independently analyzed using the same models. Reproducibility does not mean that the original or supporting data have to be capable of being replicated through new experiments, samples or tests.

iii. Making the data and models publicly available will assist in determining whether analytical results are capable of being substantially reproduced. However, these guidelines do not alter the otherwise applicable standards and procedures for determining when and how information is disclosed. Thus, the objectivity standard does not override other compelling interests, such as privacy, trade secret, and other confidentiality protections.

"Influential" when used in the phrase "influential scientific or statistical information" means the agency expects that information in the form of analytical results will likely have an important effect on the development of domestic or international government or private sector policies or will likely have important consequences for specific technologies, substances, products or firms.

"Capable of being substantially reproduced" means that independent reanalysis of the original or supporting data using the same methods would generate similar analytical results, subject to an acceptable degree of imprecision.

As a general matter, in the scientific and research context, we regard

technical information that has been subjected to formal, independent, external peer review as presumptively objective. An example of a formal independent external peer review is the review process used by scientific journals. However, depending on the nature and timeliness of the information involved, an agency may decide that peer review is not necessary or appropriate. On the other hand, in those situations involving influential scientific or statistical information, the substantial reproducibility standard is added as a quality standard above and beyond some peer review quality standards. In the definition of "influential," when used in the phrase "influential scientific or statistical information," we note that the manner in which people perceive the scientific or statistical information can have important consequences for specific policies, technologies, substances, products, and firms.

Based on concerns with the "substantially reproducible" standard, a number of comments suggested that OMB should repropose this standard for additional public comment, rather than going final at this time. While, in deference to the statutory deadline, OMB is issuing the "capable of being substantially reproduced" standard (paragraphs V.3.B, V.9, and V.10), OMB is doing so on an interim final basis. We specifically request public comments on this standard by October 29, 2001. In addition, OMB wants to stress that the guidelines published today should be understood as a beginning of an evolutionary process that will include draft agency guidelines, public comment, final agency guidelines, development of experience with OMB and agency guidelines, and continued refinement of both OMB and agency guidelines.

OMB modeled the draft definitions of "information," "government information," "information dissemination product," and "dissemination" on the longstanding definitions of those terms in OMB Circular A-130, but tailored them to fit into the context of these guidelines. Information that is disseminated on behalf of an agency (through a contract or a grant) is considered to be sponsored by the agency and is subject to these guidelines. Consistent with the PRA concept of agency "sponsorship" of a collection of information, information is considered to be disseminated on behalf of an agency by a contractor or grantee if the dissemination is done at the agency's specific request or with the agency's specific approval. See 5 CFR 1320.3(d). Finally, it should be noted

that these guidelines focus primarily on the dissemination of substantive information (i.e. reports, studies, summaries) rather than information pertaining to basic agency operations.

We have clarified two terms for the final guidelines. The proposed guidelines included "opinions" in the definition of "information." We agree with comments that indicated agencies should not be accountable for correcting someone's opinion, but in the agency's presentation of the information, it should be clear that what is being offered is someone's opinion rather than facts or the agency's views. "Opinion" has therefore been removed from the definition of "information" in the final guidelines. The definition for "dissemination" was also revised after discussions with two Federal agencies that correspond frequently with individual members of the public regarding their participation in the agency's programs. In addition, in the definition of "dissemination," we changed the exclusion for "judicial process" to "adjudicative process" to make it clear that these guidelines do not apply to the issuance of agency adjudicative decisions.

Reporting Requirements. Agencies have two reporting requirements. The first report, taking effect no later than one year after the issuance of these OMB guidelines, must provide the agency's information quality guidelines that describe administrative mechanisms allowing affected persons to seek and obtain, where appropriate, correction of disseminated information that does not comply with these OMB guidelines. During the year that agencies have to complete their agency guidelines, agencies must publish the draft reports in the *Federal Register* for a period of public comment, and no later than nine months after the issuance of OMB's guidelines, submit their draft reports to OMB for review. Upon completion of OMB's review, final agency guidelines must be published in the *Federal Register* and made available through the agency website. The entire process must be completed by no later than one year after the issuance of the OMB guidance (no later than October 1, 2002).

The second report is an annual fiscal year report to OMB (to be first submitted on January 1, 2004) providing information on the number, nature, and resolution of complaints received by the agency regarding its perceived or confirmed failure to comply with these OMB and agency guidelines. Regarding the proposed guidelines, we received detailed comments on the required report to OMB describing the number and nature of complaints received by

the agency and how such complaints were resolved. Two Federal agencies stated that it would be burdensome to report to OMB on every single complaint they received and responded to, particularly because many of the complaints may be received in phone calls and given informal responses that address the callers' concerns. Recognizing that agencies may deal with large volumes of complaints on particular types of information disseminated by the agency, OMB's guidelines allow the agency to provide qualitative and/or quantitative descriptions of complaints received and how they were resolved (or not). OMB also recognizes that a large number of comments about a specific document may only demonstrate that the information is controversial, not that its quality is flawed.

In conclusion, issuance of these final guidelines meets the statutory requirement that section 515 imposed on OMB. As we stated earlier in this preamble, and in connection with the proposed guidelines, OMB has sought in developing these guidelines to make them flexible enough so that Federal agencies can apply them in a common sense, workable, and appropriately tailored manner to the wide variety of dissemination activities that the Federal Government undertakes. In addition, in drafting guidelines that will apply on a government-wide basis, OMB has been sensitive to the problem of unintended consequences and has tried to anticipate and address issues that could arise during the implementation of these guidelines. In this respect, the public and agency comments that we received on the proposed guidelines were very helpful and are greatly appreciated. As we explained above, we made a number of revisions to the guidelines to address the concerns raised in the comments, and we also believe that these and other concerns can be addressed as well in the implementing guidelines that each agency will develop in the coming months. In addition, OMB is issuing the "capable of being substantially reproduced" standard (paragraphs V.3.B, V.9, and V.10) on an interim final basis. We specifically request public comments on this standard over the next 30 days.

Moreover, over time as the agencies and the public gain further experience with the OMB guidelines, we would appreciate receiving any suggestions for how OMB could improve them. Just as OMB requested public comment before issuing these final guidelines, OMB will refine these guidelines as experience develops and further public comment is obtained.

Dated: September 24, 2001.

John D. Graham,
Administrator, Office of Information and Regulatory Affairs.

Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies

I. OMB Responsibilities

Section 515 of the Treasury and General Government Appropriations Act for FY2001 (Public Law 106-554) directs the Office of Management and Budget to issue government-wide guidelines that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by Federal agencies.

II. Agency Responsibilities

Section 515 directs agencies subject to the Paperwork Reduction Act (44 U.S.C. 3502(a)) to—

1. Issue their own information quality guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by the agency no later than one year after the date of issuance of the OMB guidelines;
2. Establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with these OMB guidelines; and
3. Report to the Director of OMB the number and nature of complaints received by the agency regarding agency compliance with these OMB guidelines concerning the quality, objectivity, utility, and integrity of information and how such complaints were resolved.

III. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies

1. Overall, agencies shall adopt a basic standard of quality (including objectivity, utility, and integrity) as a performance goal and should take appropriate steps to incorporate information quality criteria into agency information dissemination practices. Quality is to be ensured and established at levels appropriate to the nature and timeliness of the information to be disseminated. Agencies shall adopt specific standards of quality that are appropriate for the various categories of information they disseminate.
2. As a matter of good and effective agency information resources

management, agencies shall develop a process for reviewing the quality (including the objectivity, utility, and integrity) of information before it is disseminated. Agencies shall treat information quality as integral to every step of an agency's development of information, including creation, collection, maintenance, and dissemination. This process shall enable the agency to substantiate the quality of the information it has disseminated through documentation or other means appropriate to the information.

3. To facilitate citizen review, agencies shall establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, timely correction of information maintained and disseminated by the agency that does not comply with OMB or agency guidelines. These administrative mechanisms shall be flexible, appropriate to the nature and timeliness of the disseminated information, and incorporated into agency information resources management and administrative practices.

4. The agency's pre-dissemination review, under paragraph III.2, shall apply to information that the agency first disseminates on or after October 1, 2002. The agency's administrative mechanisms, under paragraph III.3, shall apply to information that the agency disseminates on or after October 1, 2002, regardless of when the agency first disseminated the information.

IV. Agency Reporting Requirements

1. Agencies must designate the Chief Information Officer or another official to be responsible for agency compliance with these guidelines.

2. The agency shall respond to complaints in a manner appropriate to the nature and extent of the complaint. Examples of appropriate responses include personal contacts via letter or telephone, form letters, press releases or mass mailings that correct a widely disseminated error or address a frequently raised complaint.

3. Each agency must prepare a draft report, no later than April 1, 2002, providing the agency's information quality guidelines and explaining how such guidelines will ensure and maximize the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by the agency. This report must also detail the administrative mechanisms developed by that agency to allow affected persons to seek and obtain appropriate correction of information maintained and disseminated by the agency that does

not comply with the OMB or the agency guidelines.

4. The agency must publish a notice of availability of this draft report in the **Federal Register**, and post this report on the agency's website, to provide an opportunity for public comment.

5. Upon consideration of public comment and after appropriate revision, the agency must submit this draft report to OMB for review regarding consistency with these OMB guidelines no later than July 1, 2002. Upon completion of that OMB review and completion of this report, agencies must publish notice of the availability of this report in the **Federal Register**, and post this report on the agency's web site no later than October 1, 2002.

6. On an annual fiscal-year basis, each agency must submit a report to the Director of OMB providing information (both quantitative and qualitative, where appropriate) on the number and nature of complaints received by the agency regarding agency compliance with these OMB guidelines and how such complaints were resolved. Agencies must submit these reports no later than January 1 of each following year, with the first report due January 1, 2004.

V. Definitions

1. "Quality" is an encompassing term comprising utility, objectivity, and integrity. Therefore, the guidelines sometimes refer to these four statutory terms, collectively, as "quality."

2. "Utility" refers to the usefulness of the information to its intended users, including the public. In assessing the usefulness of information that the agency disseminates to the public, the agency needs to consider the uses of the information not only from the perspective of the agency but also from the perspective of the public. As a result, when reproducibility and transparency of information are relevant for assessing the information's usefulness from the public's perspective, the agency must take care to ensure that reproducibility and transparency have been addressed in its review of the information.

3. "Objectivity" involves two distinct elements, presentation and substance.

A. "Objectivity" includes whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner. This involves whether the information is presented within a proper context. Sometimes, in disseminating certain types of information to the public, other information must also be disseminated in order to ensure an accurate, clear, complete, and unbiased presentation.

Also, the agency needs to identify the sources of the disseminated information (to the extent possible, consistent with confidentiality protections) and, in a scientific or statistical context, the supporting data and models, so that the public can assess for itself whether there may be some reason to question the objectivity of the sources. Where appropriate, supporting data should have full, accurate, transparent documentation, and error sources affecting data quality should be identified and disclosed to users.

B. In addition, "objectivity" involves a focus on ensuring accurate, reliable, and unbiased information. In a scientific or statistical context, the original or supporting data shall be generated, and the analytical results shall be developed, using sound statistical and research methods.

i. If the results have been subject to formal, independent, external peer review, the information can generally be considered of acceptable objectivity.

ii. In those situations involving influential scientific or statistical information, the results must be capable of being substantially reproduced, if the original or supporting data are independently analyzed using the same models. Reproducibility does not mean that the original or supporting data have to be capable of being replicated through new experiments, samples or tests.

iii. Making the data and models publicly available will assist in determining whether analytical results are capable of being substantially reproduced. However, these guidelines do not alter the otherwise applicable standards and procedures for determining when and how information is disclosed. Thus, the objectivity standard does not override other compelling interests, such as privacy, trade secret, and other confidentiality protections.

4. "Integrity" refers to the security of information—protection of the information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification.

5. "Information" means any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a web page, but does not include the provision of hyperlinks to information that others disseminate. This definition does not include opinions, where the agency's presentation makes it clear that what is

being offered is someone's opinion rather than fact or the agency's views.

6. "Government information" means information created, collected, processed, disseminated, or disposed of by or for the Federal Government.

7. "Information dissemination product" means any book, paper, map, machine-readable material, audiovisual production, or other documentary material, regardless of physical form or characteristic, an agency disseminates to the public. This definition includes any electronic document, CD-ROM, or web page.

8. "Dissemination" means agency initiated or sponsored distribution of information to the public (see 5 CFR 1320.3(d) (definition of "Conduct or Sponsor"). Dissemination does not include distribution limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; and responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar law. This definition also does not include distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes.

9. "Influential" when used in the phrase "influential scientific or statistical information" means the agency expects that information in the form of analytical results will likely have an important effect on the development of domestic or international government or private sector policies or will likely have important consequences for specific technologies, substances, products or firms.

10. "Capable of being substantially reproduced" means that independent reanalysis of the original or supporting data using the same methods would generate similar analytical results, subject to an acceptable degree of imprecision.

[FR Doc. 01-24172 Filed 9-27-01; 8:45 am]
BILLING CODE 3110-01-P

PENSION BENEFIT GUARANTY CORPORATION

Submission of Information Collection for OMB Review; Comment Request; Disclosure to Participants

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of request for extension of OMB approval.

SUMMARY: The Pension Benefit Guaranty Corporation ("PBGC") is requesting that the Office of Management and Budget ("OMB") extend approval, under the Paperwork Reduction Act, of a collection of information in its regulation on Disclosure to Participants (29 CFR Part 4011) (OMB control number 1212-0050). This notice informs the public of the PBGC's request and solicits public comment on the collection of information.

DATES: Comments should be submitted by October 29, 2001.

ADDRESSES: Comments should be mailed to the Office of Information and Regulatory Affairs of the Office of Management and Budget, Attention: Desk Officer for Pension Benefit Guaranty Corporation, Washington, DC 20503. Copies of the request for extension (including the collection of information) may be obtained without charge by writing to or visiting the PBGC's Communications and Public Affairs Department, suite 240, 1200 K Street, NW., Washington, DC 20005-4026, or calling 202-326-4040. (TTY and TDD users may call 800-877-8339 and request connection to 202-326-4040). The regulation on Disclosure to Participants can be accessed on the PBGC's Web site at <http://www.pbgc.gov>.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion, Attorney, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005-4026, 202-326-4024. (For TTY and TDD, call 800-877-8339 and request connection to 202-326-4024).

SUPPLEMENTARY INFORMATION: Section 4011 of the Employee Retirement Income Security Act of 1974 requires plan administrators of certain underfunded single-employer pension plans to provide an annual notice to plan participants and beneficiaries of the plan's funding status and the limits on the PBGC's guarantee.

The PBGC's regulation implementing this provision (29 CFR Part 4011) prescribes which plans are subject to the notice requirement, who is entitled to receive the notice, and the time, form, and manner of issuance of the notice. The notice provides recipients with meaningful, understandable, and timely information that will help them become better informed about their plans and assist them in their financial planning.

The collection of information under the regulation has been approved by OMB under control number 1212-0050 (expires October 31, 2001). The PBGC is requesting that OMB extend its approval for three years. An agency may not

conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The PBGC estimates that an average of 3,331 plans per year will respond to this collection of information. The PBGC further estimates that the average annual burden of this collection of information is 2.13 hours and \$107 per plan, with an average total annual burden of 7,102 hours and \$355,200.

Issued in Washington, DC, this 24th day of September, 2001.

Stuart A. Sirkin,

Director, Corporate Policy and Research Department.

[FR Doc. 01-24372 Filed 9-27-01; 8:45 am]

BILLING CODE 7708-01-P

PENSION BENEFIT GUARANTY CORPORATION

Submission of Information Collection for OMB Review; Comment Request; Liability for Termination of Single-Employer Plans

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of request for extension of OMB approval.

SUMMARY: The Pension Benefit Guaranty Corporation ("PBGC") is requesting that the Office of Management and Budget ("OMB") extend approval, under the Paperwork Reduction Act, of a collection of information in its regulation on Employer Liability (29 CFR Part 4062) (OMB control number 1212-0017). This notice informs the public of the PBGC's request and solicits public comment on the collection of information.

DATES: Comments should be submitted by October 29, 2001.

ADDRESSES: Comments should be mailed to the Office of Information and Regulatory Affairs of the Office of Management and Budget, Attention: Desk Officer for Pension Benefit Guaranty Corporation, Washington, DC 20503. Copies of the request for extension (including the collection of information) may be obtained without charge by writing to or visiting the PBGC's Communications and Public Affairs Department, suite 240, 1200 K Street, NW., Washington, DC 20005-4026, or calling 202-326-4040. (TTY and TDD users may call 800-877-8339 and request connection to 202-326-4040). The regulation on Employer Liability can be accessed on the PBGC's Web site at <http://www.pbgc.gov>.



Federal Register

Friday,
February 22, 2002

Part IX

Office of Management and Budget

Guidelines for Ensuring and Maximizing
the Quality, Objectivity, Utility, and
Integrity of Information Disseminated by
Federal Agencies; Notice; Republication

OFFICE OF MANAGEMENT AND BUDGET

Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication

Editorial Note: Due to numerous errors, this document is being reprinted in its entirety. It was originally printed in the *Federal Register* on Thursday, January 3, 2002 at 67 FR 369-378 and was corrected on Tuesday, February 5, 2002 at 67 FR 5365.

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Final guidelines.

SUMMARY: These final guidelines implement section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554; H.R. 5658). Section 515 directs the Office of Management and Budget (OMB) to issue government-wide guidelines that "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies." By October 1, 2002, agencies must issue their own implementing guidelines that include "administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency" that does not comply with the OMB guidelines. These final guidelines also reflect the changes OMB made to the guidelines issued September 28, 2001, as a result of receiving additional comment on the "capable of being substantially reproduced" standard (paragraphs V.3.B, V.9, and V.10), which OMB previously issued on September 28, 2001, on an interim final basis.

DATES: *Effective Date:* January 3, 2002.

FOR FURTHER INFORMATION CONTACT: Brooke J. Dickson, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. Telephone (202) 395-3785 or by e-mail to informationquality@omb.eop.gov.

SUPPLEMENTARY INFORMATION: In section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554; H.R. 5658), Congress directed the Office of Management and Budget (OMB) to issue, by September 30, 2001, government-wide guidelines that "provide policy and procedural

guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies * * * Section 515(b) goes on to state that the OMB guidelines shall:

"(1) apply to the sharing by Federal agencies of, and access to, information disseminated by Federal agencies; and
 "(2) require that each Federal agency to which the guidelines apply—

"(A) issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency, by not later than 1 year after the date of issuance of the guidelines under subsection (a);

"(B) establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued under subsection (a); and
 "(C) report periodically to the Director—

"(i) the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency and;

"(ii) how such complaints were handled by the agency."

Proposed guidelines were published in the *Federal Register* on June 28, 2001 (66 FR 34489). Final guidelines were published in the *Federal Register* on September 28, 2001 (66 FR 49718). The Supplementary Information to the final guidelines published in September 2001 provides background, the underlying principles OMB followed in issuing the final guidelines, and statements of intent concerning detailed provisions in the final guidelines.

In the final guidelines published in September 2001, OMB also requested additional comment on the "capable of being substantially reproduced" standard and the related definition of "influential scientific or statistical information" (paragraphs V.3.B, V.9, and V.10), which were issued on an interim final basis. The final guidelines published today discuss the public comments OMB received, the OMB response, and amendments to the final guidelines published in September 2001.

In developing agency-specific guidelines, agencies should refer both to the Supplementary Information to the final guidelines published in the *Federal Register* on September 28, 2001 (66 FR 49718), and also to the Supplementary Information published today. We stress that the three "Underlying Principles" that OMB

followed in drafting the guidelines that we published on September 28, 2001 (66 FR 49719), are also applicable to the amended guidelines that we publish today.

In accordance with section 515, OMB has designed the guidelines to help agencies ensure and maximize the quality, utility, objectivity and integrity of the information that they disseminate (meaning to share with, or give access to, the public). It is crucial that information Federal agencies disseminate meets these guidelines. In this respect, the fact that the Internet enables agencies to communicate information quickly and easily to a wide audience not only offers great benefits to society, but also increases the potential harm that can result from the dissemination of information that does not meet basic information quality guidelines. Recognizing the wide variety of information Federal agencies disseminate and the wide variety of dissemination practices that agencies have, OMB developed the guidelines with several principles in mind.

First, OMB designed the guidelines to apply to a wide variety of government information dissemination activities that may range in importance and scope. OMB also designed the guidelines to be generic enough to fit all media, be they printed, electronic, or in other form. OMB sought to avoid the problems that would be inherent in developing detailed, prescriptive, "one-size-fits-all" government-wide guidelines that would artificially require different types of dissemination activities to be treated in the same manner. Through this flexibility, each agency will be able to incorporate the requirements of these OMB guidelines into the agency's own information resource management and administrative practices.

Second, OMB designed the guidelines so that agencies will meet basic information quality standards. Given the administrative mechanisms required by section 515 as well as the standards set forth in the Paperwork Reduction Act, it is clear that agencies should not disseminate substantive information that does not meet a basic level of quality. We recognize that some government information may need to meet higher or more specific information quality standards than those that would apply to other types of government information. The more important the information, the higher the quality standards to which it should be held, for example, in those situations involving "influential scientific, financial, or statistical information" (a phrase defined in these guidelines). The guidelines recognize, however, that

information quality comes at a cost. Accordingly, the agencies should weigh the costs (for example, including costs attributable to agency processing effort, respondent burden, maintenance of needed privacy, and assurances of suitable confidentiality) and the benefits of higher information quality in the development of information, and the level of quality to which the information disseminated will be held.

Third, OMB designed the guidelines so that agencies can apply them in a common-sense and workable manner. It is important that these guidelines do not impose unnecessary administrative burdens that would inhibit agencies from continuing to take advantage of the Internet and other technologies to disseminate information that can be of great benefit and value to the public. In this regard, OMB encourages agencies to incorporate the standards and procedures required by these guidelines into their existing information resources management and administrative practices rather than create new and potentially duplicative or contradictory processes. The primary example of this is that the guidelines recognize that, in accordance with OMB Circular A-130, agencies already have in place well-established information quality standards and administrative mechanisms that allow persons to seek and obtain correction of information that is maintained and disseminated by the agency. Under the OMB guidelines, agencies need only ensure that their own guidelines are consistent with these OMB guidelines, and then ensure that their administrative mechanisms satisfy the standards and procedural requirements in the new agency guidelines. Similarly, agencies may rely on their implementation of the Federal Government's computer security laws (formerly, the Computer Security Act, and now the computer security provisions of the Paperwork Reduction Act) to establish appropriate security safeguards for ensuring the "integrity" of the information that the agencies disseminate.

In addition, in response to concerns expressed by some of the agencies, we want to emphasize that OMB recognizes that Federal agencies provide a wide variety of data and information. Accordingly, OMB understands that the guidelines discussed below cannot be implemented in the same way by each agency. In some cases, for example, the data disseminated by an agency are not collected by that agency; rather, the information the agency must provide in a timely manner is compiled from a variety of sources that are constantly updated and revised and may be

confidential. In such cases, while agencies' implementation of the guidelines may differ, the essence of the guidelines will apply. That is, these agencies must make their methods transparent by providing documentation, ensure quality by reviewing the underlying methods used in developing the data and consulting (as appropriate) with experts and users, and keep users informed about corrections and revisions.

Summary of OMB Guidelines

These guidelines apply to Federal agencies subject to the Paperwork Reduction Act (44 U.S.C. chapter 35). Agencies are directed to develop information resources management procedures for reviewing and substantiating (by documentation or other means selected by the agency) the quality (including the objectivity, utility, and integrity) of information before it is disseminated. In addition, agencies are to establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, correction of information disseminated by the agency that does not comply with the OMB or agency guidelines. Consistent with the underlying principles described above, these guidelines stress the importance of having agencies apply these standards and develop their administrative mechanisms so they can be implemented in a common sense and workable manner. Moreover, agencies must apply these standards flexibly, and in a manner appropriate to the nature and timeliness of the information to be disseminated, and incorporate them into existing agency information resources management and administrative practices.

Section 515 denotes four substantive terms regarding information disseminated by Federal agencies: quality, utility, objectivity, and integrity. It is not always clear how each substantive term relates—or how the four terms in aggregate relate—to the widely divergent types of information that agencies disseminate. The guidelines provide definitions that attempt to establish a clear meaning so that both the agency and the public can readily judge whether a particular type of information to be disseminated does or does not meet these attributes.

In the guidelines, OMB defines "quality" as the encompassing term, of which "utility," "objectivity," and "integrity" are the constituents. "Utility" refers to the usefulness of the information to the intended users. "Objectivity" focuses on whether the disseminated information is being

presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased. "Integrity" refers to security—the protection of information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification. OMB modeled the definitions of "information," "government information," "information dissemination product," and "dissemination" on the longstanding definitions of those terms in OMB Circular A-130, but tailored them to fit into the context of these guidelines.

In addition, Section 515 imposes two reporting requirements on the agencies. The first report, to be promulgated no later than October 1, 2002, must provide the agency's information quality guidelines that describe administrative mechanisms allowing affected persons to seek and obtain, where appropriate, correction of disseminated information that does not comply with the OMB and agency guidelines. The second report is an annual fiscal year report to OMB (to be first submitted on January 1, 2004) providing information (both quantitative and qualitative, where appropriate) on the number, nature, and resolution of complaints received by the agency regarding its perceived or confirmed failure to comply with these OMB and agency guidelines.

Public Comments and OMB Response

Applicability of Guidelines. Some comments raised concerns about the applicability of these guidelines, particularly in the context of scientific research conducted by Federally employed scientists or Federal grantees who publish and communicate their research findings in the same manner as their academic colleagues. OMB believes that information generated and disseminated in these contexts is not covered by these guidelines unless the agency represents the information as, or uses the information in support of, an official position of the agency.

As a general matter, these guidelines apply to "information" that is "disseminated" by agencies subject to the Paperwork Reduction Act (44 U.S.C. 3502(1)). See paragraphs II, V.5 and V.8. The definitions of "information" and "dissemination" establish the scope of the applicability of these guidelines. "Information" means "any communication or representation of knowledge such as facts or data * * *". This definition of information in paragraph V.5 does "not include opinions, where the agency's presentation makes it clear that what is

being offered is someone's opinion rather than fact or the agency's views."

"Dissemination" is defined to mean "agency initiated or sponsored distribution of information to the public." As used in paragraph V.8, "agency INITIATED * * * distribution of information to the public" refers to information that the agency disseminates, e.g., a risk assessment prepared by the agency to inform the agency's formulation of possible regulatory or other action. In addition, if an agency, as an institution, disseminates information prepared by an outside party in a manner that reasonably suggests that the agency agrees with the information, this appearance of having the information represent agency views makes agency dissemination of the information subject to these guidelines. By contrast, an agency does not "initiate" the dissemination of information when a Federally employed scientist or Federal grantee or contractor publishes and communicates his or her research findings in the same manner as his or her academic colleagues, even if the Federal agency retains ownership or other intellectual property rights because the Federal government paid for the research. To avoid confusion regarding whether the agency agrees with the information (and is therefore disseminating it through the employee or grantee), the researcher should include an appropriate disclaimer in the publication or speech to the effect that the "views are mine, and do not necessarily reflect the view" of the agency.

Similarly, as used in paragraph V.8., "agency * * * SPONSORED distribution of information to the public" refers to situations where an agency has directed a third-party to disseminate information, or where the agency has the authority to review and approve the information before release. Therefore, for example, if an agency through a procurement contract or a grant provides for a person to conduct research, and then the agency directs the person to disseminate the results (or the agency reviews and approves the results before they may be disseminated), then the agency has "sponsored" the dissemination of this information. By contrast, if the agency simply provides funding to support research, and it the researcher (not the agency) who decides whether to disseminate the results and—if the results are to be released—who determines the content and presentation of the dissemination, then the agency has not "sponsored" the dissemination even though it has funded the research

and even if the Federal agency retains ownership or other intellectual property rights because the Federal government paid for the research. To avoid confusion regarding whether the agency is sponsoring the dissemination, the researcher should include an appropriate disclaimer in the publication or speech to the effect that the "views are mine, and do not necessarily reflect the view" of the agency. On the other hand, subsequent agency dissemination of such information requires that the information adhere to the agency's information quality guidelines. In sum, these guidelines govern an agency's dissemination of information, but generally do not govern a third-party's dissemination of information (the exception being where the agency is essentially using the third-party to disseminate information on the agency's behalf). Agencies, particularly those that fund scientific research, are encouraged to clarify the applicability of these guidelines to the various types of information they and their employees and grantees disseminate.

Paragraph V.8 also states that the definition of "dissemination" does not include "* * * distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes." The exemption from the definition of "dissemination" for "adjudicative processes" is intended to exclude, from the scope of these guidelines, the findings and determinations that an agency makes in the course of adjudications involving specific parties. There are well-established procedural safeguards and rights to address the quality of adjudicatory decisions and to provide persons with an opportunity to contest decisions. These guidelines do not impose any additional requirements on agencies during adjudicative proceedings and do not provide parties to such adjudicative proceedings any additional rights of challenge or appeal.

The Presumption Favoring Peer-Reviewed Information. As a general matter, in the scientific and research context, we regard technical information that has been subjected to formal, independent, external peer review as presumptively objective. As the guidelines state in paragraph V.3.b.i: "If data and analytic results have been subjected to formal, independent, external peer review, the information may generally be presumed to be of acceptable objectivity." An example of a formal, independent, external peer review is the review process used by scientific journals.

Most comments approved of the prominent role that peer review plays in the OMB guidelines. Some comments contended that peer review was not accepted as a universal standard that incorporates an established, practiced, and sufficient level of objectivity. Other comments stated that the guidelines would be better clarified by making peer review one of several factors that an agency should consider in assessing the objectivity (and quality in general) of original research. In addition, several comments noted that peer review does not establish whether analytic results are capable of being substantially reproduced. In light of the comments, the final guidelines in new paragraph V.3.b.i qualify the presumption in favor of peer-reviewed information as follows: "However, this presumption is rebuttable based on a persuasive showing by the petitioner in a particular instance."

We believe that transparency is important for peer review, and these guidelines set minimum standards for the transparency of agency-sponsored peer review. As we state in new paragraph V.3.b.i: "If data and analytic results have been subjected to formal, independent, external peer review, the information may generally be presumed to be of acceptable objectivity. However, this presumption is rebuttable based on a persuasive showing by the petitioner in a particular instance. If agency-sponsored peer review is employed to help satisfy the objectivity standard, the review process employed shall meet the general criteria for competent and credible peer review recommended by OMB-OIRA to the President's Management Council (9/20/01) (http://www.whitehouse.gov/omb/infocoreg/oira_review-process.html), namely, "that (a) peer reviewers be selected primarily on the basis of necessary technical expertise, (b) peer reviewers be expected to disclose to agencies prior technical/policy positions they may have taken on the issues at hand, (c) peer reviewers be expected to disclose to agencies their sources of personal and institutional funding (private or public sector), and (d) peer reviews be conducted in an open and rigorous manner."

The importance of these general criteria for competent and credible peer review has been supported by a number of expert bodies. For example, "the work of fully competent peer-review panels can be undermined by allegations of conflict of interest and bias. Therefore, the best interests of the Board are served by effective policies and procedures regarding potential conflicts of interest, impartiality, and panel balance." (*EPA's Science Advisory*

Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance, GAO-01-536, General Accounting Office, Washington, DC, June 2001, page 19.) As another example, "risk analyses should be peer-reviewed and accessible—both physically and intellectually—so that decision-makers at all levels will be able to respond critically to risk characterizations. The intensity of the peer reviews should be commensurate with the significance of the risk or its management implications." (*Setting Priorities, Getting Results: A New Direction for EPA*, Summary Report, National Academy of Public Administration, Washington, DC, April 1995, page 23.)

These criteria for peer reviewers are generally consistent with the practices now followed by the National Research Council of the National Academy of Sciences. In considering these criteria for peer reviewers, we note that there are many types of peer reviews and that agency guidelines concerning the use of peer review should tailor the rigor of peer review to the importance of the information involved. More generally, agencies should define their peer-review standards in appropriate ways, given the nature and importance of the information they disseminate.

Is Journal Peer Review Always Sufficient? Some comments argued that journal peer review should be adequate to demonstrate quality, even for influential information that can be expected to have major effects on public policy. OMB believes that this position overstates the effectiveness of journal peer review as a quality-control mechanism.

Although journal peer review is clearly valuable, there are cases where flawed science has been published in respected journals. For example, the NIH Office of Research Integrity recently reported the following case regarding environmental health research:

"Based on the report of an investigation conducted by [XX] University, dated July 16, 1999, and additional analysis conducted by ORI in its oversight review, the US Public Health Service found that Dr. [X] engaged in scientific misconduct. Dr. [X] committed scientific misconduct by intentionally falsifying the research results published in the journal *SCIENCE* and by providing falsified and fabricated materials to investigating officials at [XX] University in response to a request for original data to support the research results and conclusions report in the *SCIENCE* paper. In addition, PHS finds that there is no original data or other corroborating evidence to support the research results and conclusions reported in the *SCIENCE* paper as a whole." (66 FR 52137, October 12, 2001).

Although such cases of falsification are presumably rare, there is a significant scholarly literature documenting quality problems with articles published in peer-reviewed research. "In a [peer-reviewed] meta-analysis that surprised many—and some doubt—researchers found little evidence that peer review actually improves the quality of research papers." (See, e.g., *Science*, Vol. 293, page 2187 (September 21, 2001.)) In part for this reason, many agencies have already adopted peer review and science advisory practices that go beyond journal peer review. See, e.g., Sheila Jasanoff, *The Fifth Branch: Science Advisers as Policy Makers*, Cambridge, MA, Harvard University Press, 1990; Mark R. Powell, *Science at EPA: Information in the Regulatory Process*. Resources for the Future, Washington, DC, 1999, pages 138–139; 151–153; *Implementation of the Environmental Protection Agency's Peer Review Program: An SAB Evaluation of Three Reviews*, EPA-SAB-RSAC-01-009, A Review of the Research Strategies Advisory Committee (RSAC) of the EPA Science Advisory Board (SAB), Washington, DC, September 26, 2001. For information likely to have an important public policy or private sector impact, OMB believes that additional quality checks beyond peer review are appropriate.

Definition of "Influential". OMB guidelines apply stricter quality standards to the dissemination of information that is considered "influential." Comments noted that the breadth of the definition of "influential" in interim final paragraph V.9 requires much speculation on the part of agencies.

We believe that this criticism has merit and have therefore narrowed the definition. In this narrower definition, "influential", when used in the phrase "influential scientific, financial, or statistical information", is amended to mean 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." The intent of the new phrase "clear and substantial" is to reduce the need for speculation on the part of agencies. We added the present tense—"or does have"—to this narrower definition because on occasion, an information dissemination may occur simultaneously with a particular policy change. In response to a public comment, we added an explicit reference to "financial" information as consistent with our original intent.

Given the differences in the many Federal agencies covered by these

guidelines, and the differences in the nature of the information they disseminate, we also believe it will be helpful if agencies elaborate on this definition of "influential" in the context of their missions and duties, with due consideration of the nature of the information they disseminate. As we state in amended paragraph V.9, "Each agency is authorized to define 'influential' in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible."

Reproducibility. As we state in new paragraph V.3.b.ii: "If an agency is responsible for disseminating influential scientific, financial, or statistical information, agency guidelines shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties." OMB believes that a reproducibility standard is practical and appropriate for information that is considered "influential", as defined in paragraph V.9—that "will have or does have a clear and substantial impact on important public policies or important private sector decisions." The reproducibility standard applicable to influential scientific, financial, or statistical information is intended to ensure that information disseminated by agencies is sufficiently transparent in terms of data and methods of analysis that it would be feasible for a replication to be conducted. The fact that the use of original and supporting data and analytic results have been deemed "defensible" by peer-review procedures does not necessarily imply that the results are transparent and replicable.

Reproducibility of Original and Supporting Data. Several of the comments objected to the exclusion of original and supporting data from the reproducibility requirements. Comments instead suggested that OMB should apply the reproducibility standard to original data, and that OMB should provide flexibility to the agencies in determining what constitutes "original and supporting" data. OMB agrees and asks that agencies consider, in developing their own guidelines, which categories of original and supporting data should be subject to the reproducibility standard and which should not. To help in resolving this issue, we also ask agencies to consult directly with relevant scientific and technical communities on the feasibility of having the selected categories of original and supporting data subject to the reproducibility standard. Agencies are encouraged to address ethical, feasibility, and confidentiality issues

with care. As we state in new paragraph V.3.b.ii.A, "Agencies may identify, in consultation with the relevant scientific and technical communities, those particular types of data that can practicably be subjected to a reproducibility requirement, given ethical, feasibility, or confidentiality constraints." Further, as we state in our expanded definition of "reproducibility" in paragraph V.10, "If agencies apply the reproducibility test to specific types of original or supporting data, the associated guidelines shall provide relevant definitions of reproducibility (e.g., standards for replication of laboratory data)." OMB urges caution in the treatment of original and supporting data because it may often be impractical or even impermissible or unethical to apply the reproducibility standard to such data. For example, it may not be ethical to repeat a "negative" (ineffective) clinical (therapeutic) experiment and it may not be feasible to replicate the radiation exposures studied after the Chernobyl accident. When agencies submit their draft agency guidelines for OMB review, agencies should include a description of the extent to which the reproducibility standard is applicable and reflect consultations with relevant scientific and technical communities that were used in developing guidelines related to applicability of the reproducibility standard to original and supporting data.

It is also important to emphasize that the reproducibility standard does not apply to all original and supporting data disseminated by agencies. As we state in new paragraph V.3.b.ii.A, "With regard to original and supporting data related [to influential scientific, financial, or statistical information], agency guidelines shall not require that all disseminated data be subjected to a reproducibility requirement." In addition, we encourage agencies to address how greater transparency can be achieved regarding original and supporting data. As we also state in new paragraph V.3.b.ii.A, "It is understood that reproducibility of data is an indication of transparency about research design and methods and thus a replication exercise (i.e., a new experiment, test, or sample) shall not be required prior to each dissemination." Agency guidelines need to achieve a high degree of transparency about data even when reproducibility is not required.

Reproducibility of Analytic Results. Many public comments were critical of the reproducibility standard and expressed concern that agencies would

be required to reproduce each analytical result before it is disseminated. While several comments commended OMB for establishing an appropriate balance in the "capable of being substantially reproduced" standard, others considered this standard to be inherently subjective. There were also comments that suggested the standard would cause more burden for agencies.

It is not OMB's intent that each agency must reproduce each analytic result before it is disseminated. The purpose of the reproducibility standard is to cultivate a consistent agency commitment to transparency about how analytic results are generated: the specific data used, the various assumptions employed, the specific analytic methods applied, and the statistical procedures employed. If sufficient transparency is achieved on each of these matters, then an analytic result should meet the "capable of being substantially reproduced" standard.

While there is much variation in types of analytic results, OMB believes that reproducibility is a practical standard to apply to most types of analytic results. As we state in new paragraph V.3.b.ii.B, "With regard to analytic results related [to influential scientific, financial, or statistical information], agency guidelines shall generally require sufficient transparency about data and methods that an independent reanalysis could be undertaken by a qualified member of the public. These transparency standards apply to agency analysis of data from a single study as well as to analyses that combine information from multiple studies." We elaborate upon this principle in our expanded definition of "reproducibility" in paragraph V.10: "With respect to analytic results, 'capable of being substantially reproduced' means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error."

Even in a situation where the original and supporting data are protected by confidentiality concerns, or the analytic computer models or other research methods may be kept confidential to protect intellectual property, it may still be feasible to have the analytic results subject to the reproducibility standard. For example, a qualified party, operating under the same confidentiality protections as the original analysts, may be asked to use the same data, computer model or statistical methods to replicate the analytic results reported in the original study. See, e.g., "Reanalysis of the

Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality," A Special Report of the Health Effects Institute's Particle Epidemiology Reanalysis Project, Cambridge, MA, 2000.

The primary benefit of public transparency is not necessarily that errors in analytic results will be detected, although error correction is clearly valuable. The more important benefit of transparency is that the public will be able to assess how much an agency's analytic result hinges on the specific analytic choices made by the agency. Concreteness about analytic choices allows, for example, the implications of alternative technical choices to be readily assessed. This type of sensitivity analysis is widely regarded as an essential feature of high-quality analysis, yet sensitivity analysis cannot be undertaken by outside parties unless a high degree of transparency is achieved. The OMB guidelines do not compel such sensitivity analysis as a necessary dimension of quality, but the transparency achieved by reproducibility will allow the public to undertake sensitivity studies of interest.

We acknowledge that confidentiality concerns will sometimes preclude public access as an approach to reproducibility. In response to public comment, we have clarified that such concerns do include interests in "intellectual property." To ensure that the OMB guidelines have sufficient flexibility with regard to analytic transparency, OMB has, in new paragraph V.3.b.ii.B.i, provided agencies an alternative approach for classes or types of analytic results that cannot practically be subject to the reproducibility standard. "[In those situations involving influential scientific, financial, or statistical information * * *] making the data and methods publicly available will assist in determining whether analytic results are reproducible. However, the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections." Specifically, in cases where reproducibility will not occur due to other compelling interests, we expect agencies (1) to perform robustness checks appropriate to the importance of the information involved, e.g., determining whether a specific statistic is sensitive to the choice of analytic method, and, accompanying the information disseminated, to document their efforts to assure the needed robustness in information quality, and (2) address in their guidelines the

degree to which they anticipate the opportunity for reproducibility to be limited by the confidentiality of underlying data. As we state in new paragraph V.3.b.ii.B.ii, "In situations where public access to data and methods will not occur due to other compelling interests, agencies shall apply especially rigorous robustness checks to analytic results and document what checks were undertaken. Agency guidelines shall, however, in all cases, require a disclosure of the specific data sources that have been used and the specific quantitative methods and assumptions that have been employed."

Given the differences in the many Federal agencies covered by these guidelines, and the differences in robustness checks and the level of detail for documentation thereof that might be appropriate for different agencies, we also believe it will be helpful if agencies elaborate on these matters in the context of their missions and duties, with due consideration of the nature of the information they disseminate. As we state in new paragraph V.3.b.ii.B.ii, "Each agency is authorized to define the type of robustness checks, and the level of detail for documentation thereof, in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible."

We leave the determination of the appropriate degree of rigor to the discretion of agencies and the relevant scientific and technical communities that work with the agencies. We do, however, establish a general standard for the appropriate degree of rigor in our expanded definition of "reproducibility" in paragraph V.10: "Reproducibility means that the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision. For information judged to have more (less) important impacts, the degree of imprecision that is tolerated is reduced (increased)." OMB will review each agency's treatment of this issue when reviewing the agency guidelines as a whole.

Comments also expressed concerns regarding interim final paragraph V.3.B.iii, "making the data and models publicly available will assist in determining whether analytic results are capable of being substantially reproduced," and whether it could be interpreted to constitute public dissemination of these materials, rendering moot the reproducibility test. (For the equivalent provision, see new paragraph V.3.b.ii.B.i.) The OMB guidelines do not require agencies to reproduce each disseminated analytic result by independent reanalysis. Thus,

public dissemination of data and models *per se* does not mean that the analytic result has been reproduced. It means only that the result should be CAPABLE of being reproduced. The transparency associated with this capability of reproduction is what the OMB guidelines are designed to achieve.

We also want to build on a general observation that we made in our final guidelines published in September 2001. In those guidelines we stated: "... in those situations involving influential scientific, financial, or statistical information, the substantial reproducibility standard is added as a quality standard above and beyond some peer review quality standards" (66 FR 49722 (September 28, 2001)). A hypothetical example may serve to illustrate this point. Assume that two Federal agencies initiated or sponsored the dissemination of five scientific studies after October 1, 2002 (see paragraph III.4) that were, before dissemination, subjected to formal, independent, external peer review, i.e., that met the presumptive standard for "objectivity" under paragraph V.3.b.i. Further assume, at the time of dissemination, that neither agency reasonably expected that the dissemination of any of these studies would have "a clear and substantial impact" on important public policies, i.e., that these studies were not considered "influential" under paragraph V.9, and thus not subject to the reproducibility standards in paragraphs V.3.b.ii.A or B. Then assume, two years later, in 2005, that one of the agencies decides to issue an important and far-reaching regulation based clearly and substantially on the agency's evaluation of the analytic results set forth in these five studies and that such agency reliance on these five studies as published in the agency's notice of proposed rulemaking would constitute dissemination of these five studies. These guidelines would require the rulemaking agency, prior to publishing the notice of proposed rulemaking, to evaluate these five studies to determine if the analytic results stated therein would meet the "capable of being substantially reproduced" standards in paragraph V.3.b.ii.B and, if necessary, related standards governing original and supporting data in paragraph V.3.b.ii.A. If the agency were to decide that any of the five studies would not meet the reproducibility standard, the agency may still rely on them but only if they satisfy the transparency standard and—as applicable—the disclosure of

robustness checks required by these guidelines. Otherwise, the agency should not disseminate any of the studies that did not meet the applicable standards in the guidelines at the time it publishes the notice of proposed rulemaking.

Some comments suggested that OMB consider replacing the reproducibility standard with a standard concerning "confirmation" of results for influential scientific and statistical information. Although we encourage agencies to consider "confirmation" as a relevant standard—at least in some cases—for assessing the objectivity of original and supporting data, we believe that "confirmation" is too stringent a standard to apply to analytic results. Often the regulatory impact analysis prepared by an agency for a major rule, for example, will be the only formal analysis of an important subject. It would be unlikely that the results of the regulatory impact analysis had already been confirmed by other analyses. The "capable of being substantially reproduced" standard is less stringent than a "confirmation" standard because it simply requires that an agency's analysis be sufficiently transparent that another qualified party could replicate it through reanalysis.

Health, Safety, and Environmental Information. We note, in the scientific context, that in 1996 the Congress, for health decisions under the Safe Drinking Water Act, adopted a basic standard of quality for the use of science in agency decisionmaking. Under 42 U.S.C. 300g-1(b)(3)(A), an agency is directed, "to the degree that an Agency action is based on science," to use "(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)."

We further note that in the 1996 amendments to the Safe Drinking Water Act, Congress adopted a basic quality standard for the dissemination of public information about risks of adverse health effects. Under 42 U.S.C. 300g-1(b)(3)(B), the agency is directed, "to ensure that the presentation of information [risk] effects is comprehensive, informative, and understandable." The agency is further directed, "in a document made available to the public in support of a regulation [to] specify, to the extent practicable— (i) each population addressed by any estimate [of applicable risk effects]; (ii) the expected risk or central estimate of

risk for the specific populations [affected]; (iii) each appropriate upper-bound or lower-bound estimate of risk; (iv) each significant uncertainty identified in the process of the assessment of [risk] effects and the studies that would assist in resolving the uncertainty; and (v) peer-reviewed studies known to the [agency] that support, are directly relevant to, or fail to support any estimate of [risk] effects and the methodology used to reconcile inconsistencies in the scientific data."

As suggested in several comments, we have included these congressional standards directly in new paragraph V.3.b.ii.C, and made them applicable to the information disseminated by all the agencies subject to these guidelines: "With regard to analysis of risks to human health, safety and the environment maintained or disseminated by the agencies, agencies shall either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (42 U.S.C. 300g-1(b)(3)(A) & (B))." The word "adapt" is intended to provide agencies flexibility in applying these principles to various types of risk assessment.

Comments also argued that the continued flow of vital information from agencies responsible for disseminating health and medical information to medical providers, patients, and the public may be disrupted due to these peer review and reproducibility standards. OMB responded by adding to new paragraph V.3.b.ii.C: "Agencies responsible for dissemination of vital health and medical information shall interpret the reproducibility and peer-review standards in a manner appropriate to assuring the timely flow of vital information from agencies to medical providers, patients, health agencies, and the public. Information quality standards may be waived temporarily by agencies under urgent situations (e.g., imminent threats to public health or homeland security) in accordance with the latitude specified in agency-specific guidelines."

Administrative Correction Mechanisms. In addition to commenting on the substantive standards in these guidelines, many of the comments noted that the OMB guidelines on the administrative correction of information do not specify a time period in which the agency investigation and response must be made. OMB has added the following new paragraph III.3.i to direct agencies to specify appropriate time periods in which the investigation and response need to be made. "Agencies shall specify appropriate time periods

for agency decisions on whether and how to correct the information, and agencies shall notify the affected persons of the corrections made."

Several comments stated that the OMB guidelines needed to direct agencies to consider incorporating an administrative appeal process into their administrative mechanisms for the correction of information. OMB agreed, and added the following new paragraph III.3.ii: "If the person who requested the correction does not agree with the agency's decision (including the corrective action, if any), the person may file for reconsideration within the agency. The agency shall establish an administrative appeal process to review the agency's initial decision, and specify appropriate time limits in which to resolve such requests for reconsideration." Recognizing that many agencies already have a process in place to respond to public concerns, it is not necessarily OMB's intent to require these agencies to establish a new or different process. Rather, our intent is to ensure that agency guidelines specify an objective administrative appeal process that, upon further complaint by the affected person, reviews an agency's decision to disagree with the correction request. An objective process will ensure that the office that originally disseminates the information does not have responsibility for both the initial response and resolution of a disagreement. In addition, the agency guidelines should specify that if the agency believes other agencies may have an interest in the resolution of any administrative appeal, the agency should consult with those other agencies about their possible interest.

Overall, OMB does not envision administrative mechanisms that would burden agencies with frivolous claims. Instead, the correction process should serve to address the genuine and valid needs of the agency and its constituents without disrupting agency processes. Agencies, in making their determination of whether or not to correct information, may reject claims made in bad faith or without justification, and are required to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information involved, and explain such practices in their annual fiscal year reports to OMB.

OMB's issuance of these final guidelines is the beginning of an evolutionary process that will include draft agency guidelines, public comment, final agency guidelines, development of experience with OMB and agency guidelines, and continued refinement of both OMB and agency guidelines. Just as OMB requested

public comment before issuing these final guidelines, OMB will refine these guidelines as experience develops and further public comment is obtained.

Dated: December 21, 2001.

John D. Graham,
Administrator, Office of Information and Regulatory Affairs.

Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies

I. OMB Responsibilities

Section 515 of the Treasury and General Government Appropriations Act for FY2001 (Public Law 106-554) directs the Office of Management and Budget to issue government-wide guidelines that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by Federal agencies.

II. Agency Responsibilities

Section 515 directs agencies subject to the Paperwork Reduction Act (44 U.S.C. 3502(1)) to—

1. Issue their own information quality guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by the agency no later than one year after the date of issuance of the OMB guidelines;

2. Establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with these OMB guidelines; and

3. Report to the Director of OMB the number and nature of complaints received by the agency regarding agency compliance with these OMB guidelines concerning the quality, objectivity, utility, and integrity of information and how such complaints were resolved.

III. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies

1. Overall, agencies shall adopt a basic standard of quality (including objectivity, utility, and integrity) as a performance goal and should take appropriate steps to incorporate information quality criteria into agency information dissemination practices. Quality is to be ensured and established at levels appropriate to the nature and timeliness of the information to be disseminated. Agencies shall adopt

specific standards of quality that are appropriate for the various categories of information they disseminate.

2. As a matter of good and effective agency information resources management, agencies shall develop a process for reviewing the quality (including the objectivity, utility, and integrity) of information before it is disseminated. Agencies shall treat information quality as integral to every step of an agency's development of information, including creation, collection, maintenance, and dissemination. This process shall enable the agency to substantiate the quality of the information it has disseminated through documentation or other means appropriate to the information.

3. To facilitate public review, agencies shall establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, timely correction of information maintained and disseminated by the agency that does not comply with OMB or agency guidelines. These administrative mechanisms shall be flexible, appropriate to the nature and timeliness of the disseminated information, and incorporated into agency information resources management and administrative practices.

i. Agencies shall specify appropriate time periods for agency decisions on whether and how to correct the information, and agencies shall notify the affected persons of the corrections made.

ii. If the person who requested the correction does not agree with the agency's decision (including the corrective action, if any), the person may file for reconsideration within the agency. The agency shall establish an administrative appeal process to review the agency's initial decision, and specify appropriate time limits in which to resolve such requests for reconsideration.

4. The agency's pre-dissemination review, under paragraph III.2, shall apply to information that the agency first disseminates on or after October 1, 2002. The agency's administrative mechanisms, under paragraph III.3., shall apply to information that the agency disseminates on or after October 1, 2002, regardless of when the agency first disseminated the information.

IV. Agency Reporting Requirements

1. Agencies must designate the Chief Information Officer or another official to be responsible for agency compliance with these guidelines.

2. The agency shall respond to complaints in a manner appropriate to

the nature and extent of the complaint. Examples of appropriate responses include personal contacts via letter or telephone, form letters, press releases or mass mailings that correct a widely disseminated error or address a frequently raised complaint.

3. Each agency must prepare a draft report, no later than April 1, 2002, providing the agency's information quality guidelines and explaining how such guidelines will ensure and maximize the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by the agency. This report must also detail the administrative mechanisms developed by that agency to allow affected persons to seek and obtain appropriate correction of information maintained and disseminated by the agency that does not comply with the OMB or the agency guidelines.

4. The agency must publish a notice of availability of this draft report in the **Federal Register**, and post this report on the agency's website, to provide an opportunity for public comment.

5. Upon consideration of public comment and after appropriate revision, the agency must submit this draft report to OMB for review regarding consistency with these OMB guidelines no later than July 1, 2002. Upon completion of that OMB review and completion of this report, agencies must publish notice of the availability of this report in its final form in the **Federal Register**, and post this report on the agency's web site no later than October 1, 2002.

6. On an annual fiscal-year basis, each agency must submit a report to the Director of OMB providing information (both quantitative and qualitative, where appropriate) on the number and nature of complaints received by the agency regarding agency compliance with these OMB guidelines and how such complaints were resolved. Agencies must submit these reports no later than January 1 of each following year, with the first report due January 1, 2004.

V. Definitions

1. "Quality" is an encompassing term comprising utility, objectivity, and integrity. Therefore, the guidelines sometimes refer to these four statutory terms, collectively, as "quality."

2. "Utility" refers to the usefulness of the information to its intended users, including the public. In assessing the usefulness of information that the agency disseminates to the public, the agency needs to consider the uses of the information not only from the

perspective of the agency but also from the perspective of the public. As a result, when transparency of information is relevant for assessing the information's usefulness from the public's perspective, the agency must take care to ensure that transparency has been addressed in its review of the information.

3. "Objectivity" involves two distinct elements, presentation and substance.

a. "Objectivity" includes whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner. This involves whether the information is presented within a proper context. Sometimes, in disseminating certain types of information to the public, other information must also be disseminated in order to ensure an accurate, clear, complete, and unbiased presentation. Also, the agency needs to identify the sources of the disseminated information (to the extent possible, consistent with confidentiality protections) and, in a scientific, financial, or statistical context, the supporting data and models, so that the public can assess for itself whether there may be some reason to question the objectivity of the sources. Where appropriate, data should have full, accurate, transparent documentation, and error sources affecting data quality should be identified and disclosed to users.

b. In addition, "objectivity" involves a focus on ensuring accurate, reliable, and unbiased information. In a scientific, financial, or statistical context, the original and supporting data shall be generated, and the analytic results shall be developed, using sound statistical and research methods.

i. If data and analytic results have been subjected to formal, independent, external peer review, the information may generally be presumed to be of acceptable objectivity. However, this presumption is rebuttable based on a persuasive showing by the petitioner in a particular instance. If agency-sponsored peer review is employed to help satisfy the objectivity standard, the review process employed shall meet the general criteria for competent and credible peer review recommended by OMB-OIRA to the President's Management Council (9/20/01) (http://www.whitehouse.gov/omb/inforeg/oira_review-process.html), namely, "that (a) peer reviewers be selected primarily on the basis of necessary technical expertise, (b) peer reviewers be expected to disclose to agencies prior technical/policy positions they may have taken on the issues at hand, (c) peer reviewers be expected to disclose to agencies their sources of personal and

institutional funding (private or public sector), and (d) peer reviews be conducted in an open and rigorous manner.”

ii. If an agency is responsible for disseminating influential scientific, financial, or statistical information, agency guidelines shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties.

A. With regard to original and supporting data related thereto, agency guidelines shall not require that all disseminated data be subjected to a reproducibility requirement. Agencies may identify, in consultation with the relevant scientific and technical communities, those particular types of data that can practicably be subjected to a reproducibility requirement, given ethical, feasibility, or confidentiality constraints. It is understood that reproducibility of data is an indication of transparency about research design and methods and thus a replication exercise (i.e., a new experiment, test, or sample) shall not be required prior to each dissemination.

B. With regard to analytic results related thereto, agency guidelines shall generally require sufficient transparency about data and methods that an independent reanalysis could be undertaken by a qualified member of the public. These transparency standards apply to agency analysis of data from a single study as well as to analyses that combine information from multiple studies.

i. Making the data and methods publicly available will assist in determining whether analytic results are reproducible. However, the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections.

ii. In situations where public access to data and methods will not occur due to other compelling interests, agencies shall apply especially rigorous robustness checks to analytic results and document what checks were undertaken. Agency guidelines shall, however, in all cases, require a disclosure of the specific data sources that have been used and the specific quantitative methods and assumptions that have been employed. Each agency is authorized to define the type of robustness checks, and the level of

detail for documentation thereof, in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible.

C. With regard to analysis of risks to human health, safety and the environment maintained or disseminated by the agencies, agencies shall either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (42 U.S.C. 300g-1(b)(3)(A) & (B)). Agencies responsible for dissemination of vital health and medical information shall interpret the reproducibility and peer-review standards in a manner appropriate to assuring the timely flow of vital information from agencies to medical providers, patients, health agencies, and the public. Information quality standards may be waived temporarily by agencies under urgent situations (e.g., imminent threats to public health or homeland security) in accordance with the latitude specified in agency-specific guidelines.

4. “Integrity” refers to the security of information—protection of the information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification.

5. “Information” means any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a web page, but does not include the provision of hyperlinks to information that others disseminate. This definition does not include opinions, where the agency’s presentation makes it clear that what is being offered is someone’s opinion rather than fact or the agency’s views.

6. “Government information” means information created, collected, processed, disseminated, or disposed of by or for the Federal Government.

7. “Information dissemination product” means any books, paper, map, machine-readable material, audiovisual production, or other documentary material, regardless of physical form or characteristic, an agency disseminates to the public. This definition includes any electronic document, CD-ROM, or web page.

8. “Dissemination” means agency initiated or sponsored distribution of

information to the public (see 5 CFR 1320.3(d) (definition of “Conduct or Sponsor”). Dissemination does not include distribution limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; and responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar law. This definition also does not include distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes.

9. “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. Each agency is authorized to define “influential” in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible.

10. “Reproducibility” means that the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision. For information judged to have more (less) important impacts, the degree of imprecision that is tolerated is reduced (increased). If agencies apply the reproducibility test to specific types of original or supporting data, the associated guidelines shall provide relevant definitions of reproducibility (e.g., standards for replication of laboratory data). With respect to analytic results, “capable of being substantially reproduced” means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error.

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HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public

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A. Summary

The U.S. Department of Health and Human Services (HHS) developed these guidelines to implement Office of Management and Budget (OMB) January 2002 requirement that all federal agencies issue guidelines for ensuring the quality of the information that they disseminate to the public. The Department of Health and Human Services is the United States government's principal agency for protecting the health of all Americans and providing essential human services, especially to those who are least able to help themselves. The Department includes more than 300 programs, covering a wide spectrum of activities.

In the course of carrying out program missions, agencies and staff offices within HHS disseminate a wide variety of information to the public, ranging from research and statistical reports to authoritative health and medical information. Many of these information dissemination activities and products rank among the highest quality scientific, statistical and programmatic information among federal agencies, and in many cases set the national and international standard for quality.

HHS is committed to disseminating information that meets the standards of quality set forth in OMB and in the guidelines discussed in this document. It is HHS's goal to ensure and maximize the quality, objectivity, utility, and integrity of information that it disseminates to the public. We strive to provide information that is accurate, reliable, clear, complete, unbiased, and useful. We are committed to integrating the principle of information quality into every phase of information development, including creation, collection, maintenance, and dissemination. The guidelines that follow describe the quality assurance policies and practices that support information dissemination activities in HHS.

Following an overview of the OMB Guidelines and HHS guidelines, the quality assurance policies of each of the major operating agencies and staff offices of HHS are described. Each set of agency guidelines includes a description of a) the mission of the agency, b) the scope and applicability of the guidelines within the agency, c) the types of information that the agency disseminates, d) the dissemination methods employed by the agency, e) the policies, standards and practices that the agency employs to ensure the quality of the information it disseminates, and f) an administrative mechanism and contact points for each agency so that individuals may seek correction of any information that is believed not to meet the OMB, HHS, or agency-specific guidelines along with an administrative appeals process.

B. OMB Guidelines

On September 28, 2001, and as amended on February 22, 2002, OMB issued final Guidelines to implement section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554). The statute directs OMB to "issue government wide guidelines that provide policy and procedural guidance to federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by federal agencies." By October 1, 2002, agencies must issue their own implementing guidelines. The guidelines only apply to information that is disseminated on or after October 1, 2002. The administrative mechanism for correction applies to information that the agency disseminates on or after October 1, 2002, regardless of when the agency first disseminated the information.

In general, the OMB Guidelines require agencies to adopt a basic standard of quality as a performance goal and take appropriate steps to incorporate information quality criteria into agency information dissemination practices. Quality is to be ensured and established at levels appropriate to the nature and timeliness of the information to be disseminated, and specific standards may be adopted that are appropriate to the various categories of information that is disseminated. Agencies are to develop a process for reviewing the quality of information before it is disseminated. Further, information quality is to be treated as an integral step in every aspect of the information development process.

In issuing the Guidelines, OMB outlined several guiding principles. First, OMB designed the Guidelines to apply to a wide variety of government dissemination activities that may range in importance and scope. OMB also designed the Guidelines to be generic enough to fit all media, whether printed or electronic. OMB specifically sought to avoid the problems inherent in developing detailed, prescriptive, "one size fits all" guidelines that would artificially require all

types of dissemination activities to be treated in the same manner. Second, OMB designed the Guidelines so that agencies will meet basic information quality standards. The Guidelines recognize that some government information may need to meet higher or more specific standards than others, depending on their purpose and scope. The more important the information, the higher the quality standards to which it might be held, for example, "influential scientific, financial or statistical information" described below. At the same time, OMB recognizes that information quality comes at a cost. Accordingly, agencies are encouraged to weigh the costs and benefits of higher information quality in the development of information, and the level of quality to which it will be held.

Third, OMB designed the Guidelines so that agencies can apply them in a common sense, workable manner. OMB expects agencies to use existing processes rather than create new and potentially duplicative or contradictory processes. Finally, OMB recognizes that the Guidelines cannot be implemented in the same way by all agencies. While the implementation may differ, the essence of the Guidelines will apply. The agencies must make their methods transparent by providing documentation, ensure quality by reviewing the underlying methods used, by consulting as needed with both experts and users, and by keeping users notified about corrections and revisions. These underlying principles apply equally well across the diversity of HHS agencies and information dissemination activities, and they have been adopted in the approach to the HHS Guidelines described below.

C. HHS Responsibilities

In accordance with the OMB Guidelines, agencies subject to the Paperwork Reduction Act (44USC 3502(1)) are required to:

Issue their own information quality guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency not later than one year after the issuance of the OMB Guidelines;

Establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines. Agencies also are to specify appropriate time periods for agency decisions on whether and how to correct the information, and are to notify the affected persons of the action taken. If the person who requested the correction does not agree with the agency's decision (including the corrective action, if any), that person may file for reconsideration within the agency. The agency is to establish an administrative appeal process to review the initial decision, and specify appropriate time limits in which to resolve such requests for reconsideration.

Report periodically to the OMB Director on the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency and how such complaints were resolved by the agency.

The HHS guidelines described in this plan incorporate the underlying principles that OMB used in designing their government-wide guidelines. First, the HHS guidelines apply to a wide range of

government information dissemination activities across HHS and are generic enough to fit all types of media, including print, electronic, and other forms within HHS. Second, the HHS guidelines are intended to assure that all the information that is disseminated meets a basic level of quality and that more important information meets a more rigorous quality standard. Third, the HHS guidelines explicitly recognize the very different types of information that various HHS agencies disseminate depending on their missions, including the need for flexibility in implementation and avoidance of a "one size fits all" approach. Fourth, the statement of HHS information quality policies and procedures are issued in the form of guidelines and not a regulation.

HHS itself encompasses a broad and diverse range of health and human services programs which, while unified in their pursuit of broad goals, are themselves very diverse, encompassing the nation's largest health insurance plan, the nation's preeminent biomedical research agency, as well as most of the nation's federal capacity for public health protection and preparedness and income assistance to needy families. Accordingly, the HHS approach to implementation of the OMB Guidelines is designed to allow HHS agencies and offices to use existing agency quality assurance mechanisms, and apply the guidelines in a flexible manner that recognizes the mission of the agency, the wide range of data that is disseminated and the frequent reliance on third party sources.

D. Framework for HHS Guidelines

1. Purpose

These Guidelines describe the policies and procedures that HHS agencies employ to ensure the quality of the information they disseminate and the administrative complaint mechanisms that HHS agencies make available to the public. The Guidelines provide policy and procedural guidance to HHS staff and are intended to inform the public about agency quality assurance policies and procedures.

HHS views the guidelines as an evolving document and process. HHS will continually review the performance of the guidelines in the context of agency statutes and missions and will make revisions to the guidelines as necessary.

2. Definitions

- a. "Quality" is an encompassing term comprising utility, objectivity, and Integrity. Therefore, the Guidelines sometimes refer to these four statutory terms, collectively, as "quality."
- b. "Utility" refers to the usefulness of the information to its intended users, including the public. In assessing the usefulness of information that the agency disseminates to the public, the agency needs to consider the uses of the information not only from the perspective of the agency but also from the perspective of the public. As a result, when transparency of information is relevant for assessing the information's usefulness from the public's perspective, the agency must take care to ensure that transparency has been addressed in its review of the information.
- c. "Objectivity" involves two distinct elements, presentation and substance.

"Objectivity" includes whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner. This involves whether the information is presented within a proper context. Sometimes, in disseminating certain types of information to the public, other information must also be disseminated in order to ensure an accurate, clear, complete, and unbiased presentation. Also, the agency needs to identify the sources of the disseminated information (to the extent possible, consistent with confidentiality protections) and, in a scientific, financial, or statistical context, the supporting data and models, so that the public can assess for itself whether there may be some reason to question the objectivity of the sources. Where appropriate, data should have full, accurate, transparent documentation, and error sources affecting data quality should be identified and disclosed to users.

In addition, "objectivity" involves a focus on ensuring accurate, reliable, and unbiased information. In a scientific, financial or statistical context, the original and supporting data shall be generated, and the analytic results shall be developed, using sound statistical and research methods.

1. If data and analytic results have been subjected to formal, independent, external peer review, the information may generally be presumed to be of acceptable objectivity. However, this presumption is rebuttable based on a persuasive showing by the petitioner in a particular instance. If agency-sponsored peer review is employed to help satisfy the objectivity standard, the review process employed shall meet the general criteria for competent and credible peer review recommended by OMB-OIRA to the President's Management Council (9/20/01) (www.whitehouse.gov/omb/inforeg/oira_review-process.html), namely, that (a) peer reviewers be selected primarily on the basis of necessary technical expertise, (b) peer reviewers be expected to disclose to agencies prior technical/policy positions they may have taken on the issues at hand, (c) peer reviewers be expected to disclose agencies their sources of personal and institutional funding (private or public sector), and (d) peer reviews be conducted in an open and rigorous manner."
2. If an agency is responsible for disseminating influential scientific, financial, or statistical information, agency guidelines shall include a high degree of transparency about the data and methods to facilitate the reproducibility of such information by qualified third parties.

Original and supporting data must be subject to commonly accepted scientific, financial, and statistical standards related thereto. However, agency guidelines shall not require that all disseminated data be subjected to a reproducibility requirement. Agencies may identify, in consultation with the relevant scientific and technical communities, those particular types of data that can practicably be subjected to a reproducibility requirement, given ethical, feasibility, or confidentiality constraints. It is understood that reproducibility of data is an indication of transparency about research design

and methods and thus a replication exercise (i.e., a new experiment, test, or sample) shall not be required prior to each dissemination.

With regard to analytic results, agency guidelines shall generally require sufficient transparency about data and methods that an independent reanalysis could be undertaken by a qualified member of the public. These transparency standards apply to agency analysis of data from a single study as well as to analyses that combine information from multiple studies.

Making the data and methods publicly available will assist in determining whether analytic results are reproducible. However, the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections.

In situations where public access to data and methods will not occur due to other compelling interests, agencies shall apply especially rigorous robustness checks to analytic results and document what checks were undertaken. However, agency guidelines, in all cases, shall require a disclosure of the specific data sources that have been used and the specific quantitative methods and assumptions that have been employed. Each agency is authorized to define the type of robustness checks, and level of detail for documentation thereof, in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible.

With regard to analysis of risks to human health, safety and the environment maintained or disseminated by the agencies, agencies shall either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (42 U.S.C. 300g-1(b)(3)(A) & (B)). Agencies responsible for dissemination of vital health and medical information shall interpret the reproducibility and peer-review standards in a manner appropriate to assuring the timely flow of vital information from agencies to medical providers, patients, health agencies, and the public. Information quality standards may be waived temporarily by agencies under urgent situations (e.g., imminent threats to public health or homeland security) in accordance with the latitude specified in agency-specific guidelines.

- d. "Integrity" refers to the security of information -- protection of the information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification.
- e. "Information" means any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a web page, but does not include the provision of hyperlinks to information that others disseminate. This definition does not include

- opinions, where the agency's presentation makes it clear that what is being offered is someone's opinion rather than fact or the agency's views.
- f. "Government information" means information created, collected, processed, disseminated, or disposed of by or for the Federal Government.
 - g. "Information dissemination product" means any book, paper, map, machine-readable material, audiovisual production, or other documentary material, regardless of physical form or characteristic, an agency disseminates to the public. This definition includes any electronic document, CD-ROM, or web page.
 - h. "Dissemination" means agency initiated or sponsored distribution of information to the public (see 5 C.F.R. 1320.3(d) (definition of "Conduct or Sponsor"). Dissemination does not include distribution intended to be limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; and responses to request for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar law. This definition also does not include distribution limited to correspondence with individuals or persons, archival records, public filings, subpoenas or adjudicative processes.
 - i. "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. Each agency is authorized to define "influential" in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible.
 - j. "Reproducibility" means that the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision. For information judged to have more (less) important impacts, the degree of imprecision that is tolerated is reduced (increased). If agencies apply the reproducibility test to specific types of original or supporting data, the associated guidelines shall provide relevant definitions of reproducibility (e.g., standards for replication of laboratory data). With respect to analytic results, "capable of being substantially reproduced" means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error.

3. Scope and Applicability of the Guidelines

The HHS guidelines described in this implementation plan apply to substantive information dissemination activities that are initiated or sponsored by HHS agencies. The pre-dissemination review described in the guidelines only applies to information that is disseminated on or after October 1, 2002. The administrative mechanism for correction applies to information that the agency disseminates on or after October 1, 2002, regardless of when the agency first disseminated the information. The guidelines do not apply to the large proportion of extramural scientific research activity supported by HHS whose dissemination is the sole responsibility of the academic researcher rather than HHS. The guidelines do apply to the dissemination of information by federal intramural researchers if the dissemination is agency-initiated or sponsored. Otherwise, appropriate disclaimers are to be included in the report or speech to distinguish the research from agency views and

positions. The guidelines do not apply to distribution of information limited to correspondence with individuals or persons, press releases that support the announcement or give public notice of information that the agency disseminates elsewhere, archival material, public filings, subpoenas or adjudicative processes. Nor do they apply to opinions, when the agency's presentation makes clear that what is disseminated is someone's opinion rather than fact or agency views.

4. **Overview of HHS Information Dissemination and Quality Assurance**

a. ***The HHS Mission***

The Department of Health and Human Services is the United States government's principal agency for protecting the health of all Americans and providing essential human services, especially to those who are least able to help themselves. The Department includes more than 300 programs, covering a wide spectrum of activities. Program responsibilities include:

- Ensuring a safe and healthy America
- Conducting and supporting medical and social science research
- Preventing outbreaks of infectious diseases
- Assuring the safety of foods and drugs
- Administering the Medicare and Medicaid programs
- Providing financial assistance for low income families
- Improving maternal and child health
- Administering the Head Start program
- Preventing child abuse and domestic violence
- Providing assistance to States for substance abuse treatment and prevention
- Providing services for older Americans
- Assuring comprehensive health services for Native Americans

b. ***Categories of Information Disseminated***

The development and dissemination of timely and high quality data and information is a critical component of the missions of many HHS programs, as well as those of HHS partners in the health and human services communities. As a result, HHS plays a major role in information dissemination, as a producer and user of high quality data and information, as a collaborator with partners in the health and human services communities, and as a national leader in health and human services information policy.

In carrying out their diverse statutes and missions, HHS agencies develop and support the dissemination of the following types of substantive information:

- Scientific research studies (the results of biomedical, behavioral, services research and social science research)
- Statistical and analytic studies (the results of surveys, statistical systems as well as analytical and modeling studies and public use data files)

- Programmatic, administrative and regulatory information, including program evaluations
- Authoritative health, medical and human services information aimed at consumers and health and human services professionals.
- Public health surveillance, epidemiology and risk assessment studies and information

c. *Types of Dissemination Mechanisms*

HHS agencies disseminate information through a wide range of methods and print and electronic media. These include publication in peer reviewed literature, published reports, periodicals, newsletters, brochures, clearinghouses, websites, CD-ROM and other electronic media.

d. *Overview of Quality Assurance Policies and Practices in HHS*

Depending upon their specific statutes and missions and the nature of the information they disseminate to the public, HHS agencies currently use a variety of quality assurance methods and procedures. These methods and procedures are designed to maximize the quality of HHS information, including the objectivity, utility, and integrity.

Objectivity involves a focus on ensuring that information is accurate, reliable and unbiased and that information products are presented in an accurate, clear, complete and unbiased manner. Objectivity is achieved by using reliable data sources and sound analytical techniques, and carefully reviewing information products prepared by qualified people using proven methods.

Utility involves the usefulness of the information to its intended users. Utility is achieved by staying informed of information needs and developing new data, and information products where appropriate. Based on internal analyses of information requirements, convening and attending conferences, working with advisory committees and stakeholders, sponsoring outreach activities, and where appropriate, testing publications with targeted audiences to ensure relevance, clarity, and comprehensiveness, HHS agencies keeps abreast of information needs.

Integrity refers to the security of information from unauthorized access or revision to ensure that the information is not compromised through corruption or falsification. HHS agencies have in place rigorous controls to ensure the integrity of its administrative information. Three distinct objectives are pursued in protecting the integrity of information: ensuring that there is no deliberate or accidental improper disclosure of sensitive automated information; protecting against deliberate or accidental corruption of automated information; and protecting against deliberate or accidental actions that cause automated information resources to be unavailable to users

when needed. Information is accorded protection against disclosure, alteration, loss, or destruction based on the degree of sensitivity.

In addition, HHS agencies use appropriate safeguards to protect data from improper disclosure by backing up critical data periodically, and, if a security incident occurs, by following proper incident response procedures. Managers are responsible for ensuring that employees, both Government and contractors, observe all security requirements, and that employees receive appropriate security training. HHS also is instituting an enterprise-wide structured management control review process that applies throughout the system life cycle. As part of this process, risk analyses are conducted to establish a balance between an acceptable level of risk and the costs associated with safeguards.

In addition, HHS is subject to a number of statutory requirements that protect the sensitive information it gathers and maintains on individuals. Among these are:

- Health Insurance Portability and Accountability Act of 1996
- Privacy Act of 1974
- Computer Security Act of 1987
- Office of Management and Budget (OMB) Circulars A-123, A-127, and A-130
- Government Information Security Reform Act
- Federal Managers' Financial Integrity Act (FMFIA) of 1982

e. ***HHS Information Quality Goals***

The development of data and information within HHS is generally undertaken within the context of two overarching goals:

- attention to information quality as a total and continuing process, and
- commitment to making data and information supported with public funds available to the public, consistent with confidentiality concerns and resource availability.

Further, when HHS agencies prepare a Paperwork Reduction Act (PRA) clearance submission, they strive to engage in a data development effort that will result in information that will be collected, maintained, and used in a way that is consistent with OMB, HHS, and agency-specific information quality guidelines. As a general policy, HHS views data and information quality as a continuing process that begins at the inception of the information development process with project conceptualization and carries through all phases of data planning, design and execution, including information dissemination activities. Further, HHS agencies that support or sponsor research and statistical activities are encouraged to not only describe the methods and data sources in a clear and transparent manner in the reports they release, but also to make the data used for the report available to the public through public use data files, restricted access research files, research data

centers, data archives and other mechanisms consistent with confidentiality, legal and proprietary restrictions.

In addition, HHS agencies review the quality (including the objectivity, utility, and integrity) of information before it is disseminated and treat information quality as integral to every step of the development of information, including its creation, collection, maintenance and dissemination. The quality assurance processes that are used to ensure the quality of specific categories of information are described below.

Research and scientific studies disseminated by HHS are subject to an external, objective peer review process at both the inception stage and the pre-dissemination stage as a part of the publication process in peer reviewed journals. In addition, the quality of all of the intramural research programs of HHS agencies is continually reviewed and monitored by advisory committees and boards of scientific advisors. In accordance with widely accepted scientific research practice in the U.S., research reports disseminated by HHS agencies describe the methods, data sources, analytical techniques, measures, assumptions and limitations of the research, so that the study could be substantially reproduced. If original data are employed, it is the policy of HHS to make every effort to make the data available to the public in de-identified form consistent with confidentiality requirements, proprietary restrictions and resource availability.

Statistical activities of HHS agencies are based on reliable data sources and are carried out in accordance with modern statistical theory and practice, including scientific sampling, statistical inference and analytical techniques and practices. All statistical programs employ or have access to experts in statistics and research design. HHS houses the National Center for Health Statistics, the federal government's designated general purpose statistical agency for health statistics, as well as programmatic and special purpose statistical activities. All proposals for original data collection activities in HHS undergo a rigorous and exacting review process in connection with the Paperwork Reduction Act, which also provides opportunity for public comment in the design of the information collection. Frequent meetings with user groups are common, and individual surveys and statistical systems often employ project specific technical advisory groups. Substantive reports from HHS statistical activities undergo a quality review process within their organizations before they are released, including expert review by supervisors, internal peer review by qualified scientists and statisticians, and in some cases external peer review as well as expert review by other offices prior to dissemination.

Programmatic and administrative information -- A significant amount of substantive information is disseminated by HHS agencies in connection with and as a byproduct of the administration of programs. Often the programmatic and administrative information disseminated is obtained from

third parties, such as States, grantees, health plan contractors or intermediaries, or community-based organizations. In their stewardship function, agencies often collect, compile, standardize, analyze and disseminate such programmatic information. While the reliance on third parties places limits on the federal quality assurance authorities, a variety of techniques are employed to promote the accuracy, completeness and timeliness of the information. These include use of generally accepted accounting and financial management procedures and principles, internal controls, legal certifications and assurances on the part of the organizations supplying the information, audited financial reports and statements, as well as sample audits and site visits, and checks for completeness and consistency with trends and external controls. Programmatic reports are typically subject to supervisory review before release.

Program evaluation studies are often undertaken by HHS agencies to assess program functioning and identify opportunities for improvement. Agencies employ quality assurance procedures in the choice and development of evaluation projects. Proposals for evaluation activities in HHS agencies are usually reviewed by agency management for suitability, utility and methodology in accordance with sound evaluation design and standards of evaluation practice. Many evaluation projects have specific technical advisory committees that oversee the design and conduct of the evaluation in accordance with standard evaluation theory and practice, and they often provide an expert review of the final report. Results of evaluation activities are released to the public only after agency management has completed a review of the quality, accuracy and completeness of the report.

Regulatory information -- A variety of information is used in support of regulatory development and decision-making. Regulatory activity undertaken by HHS agencies closely tracks statutory authorities and program responsibilities. Scientific, financial, and statistical information used in support of regulatory decision-making is subject to a quality review process within the agency involving appropriate experts depending upon the nature of the information. In addition, all significant proposed regulations are reviewed by OMB prior to issuance for public comment, and all proposed regulatory actions provide for extensive public comment.

Authoritative health, scientific and consumer information -- Several HHS agencies develop and disseminate authoritative health and human services information intended for consumers and the professional community. In some instances, the agency simply provides a link to information developed by other authoritative organizations. In other instances, the agency develops its own consumer and professional practice information. In the latter case, the information is reviewed for scientific and medical accuracy and completeness by experts within the agency before it is disseminated. In a number of instances the information also is reviewed by scientific and medical advisory

bodies before dissemination as well, depending on the nature of the information.

Public health surveillance and epidemiological information -- Several HHS agencies compile, analyze and disseminate information from public health surveillance systems and epidemiological activities. In many surveillance systems, the primary information is developed by State and local government agencies, clinical laboratories and other health care entities and reported to CDC for national aggregation and analysis. Data quality is assured through use of reliable data sources, appropriate statistical techniques, agreement on national reporting standards, quality control procedures, standard case definitions and reports, adherence to professional practices and standards for public health reporting in the U.S., and frequent consultation with the user community. Before such information is disseminated, it is reviewed for medical, scientific and public health accuracy, soundness and utility by agency experts. Comment and feedback is encouraged on such information, and HHS agencies work closely with the relevant professional and public health organizations.

f. ***Influential Scientific, Financial and Statistical Information***

From time to time, HHS agencies disseminate influential scientific, financial and statistical information as defined in the OMB Guidelines. In such instances, care is taken to ensure that the information is substantially reproducible and replicable. This goal is accomplished by using reliable data sources and sound analytical techniques, and by employing a high degree of transparency about the data, sources, methods, measures, assumptions and limitations used to develop the information in order to facilitate reproducibility by qualified third parties. In the case of original or supporting data, most major epidemiological and statistical activities sponsored by HHS agencies have well developed public use data dissemination programs that make much of the data available to the public in standardized, de-identified micro-data files.

Because of confidentiality, ethical and feasibility constraints and legal obligations to third parties supplying the information, there may be instances where original or supporting data may not be available to the public, but HHS agencies typically will work with qualified third parties to facilitate understanding, and transparency in data sources and methods will be emphasized in the report or in reference documents. In the case of analytical studies, HHS agencies will make provisions for sufficient transparency about data and methods so that an independent reanalysis could be undertaken by a qualified member of the public.

g. ***Health, Safety and Environmental Information***

Several HHS agencies have science-based missions and use such information in decision making. These agencies **adapt** the quality standards discussed in the Safe

Drinking Water Act Amendments of 1996 (SDWA) (42 U.S.C. 300g-1(b)(3)(A) and (B)). The adaptation involves the commitment of these agencies to use: a.) the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including peer reviewed studies when available and b.) data collected by accepted methods (if reliability of the method and the nature of the decision justify use of the data.) Additional detail relating to the standards employed by individual agencies is described in Part II, the individual agency section of these guidelines.

h. ***Urgent Public Health and Safety Information***

Several HHS agencies are responsible for dissemination of authoritative health, medical and safety information on a real time basis in order to protect the health of the public against urgent and emerging threats. Accordingly, nothing in these guidelines relating to reproducibility or peer review shall be construed to limit or delay the timely flow of vital information from agencies to medical providers, patients, health agencies, and the public. HHS reserves the right to waive information quality standards temporarily for agencies addressing urgent situations (e.g., imminent threats to public health or homeland security) in accordance with the latitude described in both the OMB and agency specific guidelines.

E. Overview of HHS Agency Complaint Procedures

The OMB Guidelines require all agencies to establish administrative mechanisms allowing affected persons to seek and obtain correction of information disseminated by the agency that does not comply with OMB, HHS or agency-specific guidelines. Agencies also are to specify appropriate time periods for agency decisions on whether and how to correct the information, and are to notify the affected persons of the action taken. If the person who requested the correction does not agree with the agency's decision (including the corrective action, if any), that person may file for reconsideration within the agency. The agency is to establish an administrative appeal process to review the initial decision, and specify appropriate time limits in which to resolve such requests for reconsideration. The agency need not respond substantively to information not covered by the guidelines or to frivolous or repetitive requests for correction.

Requests for correction of information quality pursuant to Section 515 are to be directed to the respective agency. A common format for complaints has been developed across HHS. The approach is described below. **To accompany the actual implementation of the Guidelines in October 2002, HHS has created a department-wide website describing in user friendly terms the procedures and contact persons for submitting requests for corrections. The web site can be accessed at www.hhs.gov/infoquality.**

Responsibility of the Complainant

In general, to seek an information quality request for correction of information disseminated by any HHS agency, individuals should follow the procedures described below. Requests for correction that are specific and provide evidence to support the need for correction will

enable the agency to provide a satisfactory response. Complainants should be aware that they bear the "burden of proof" with respect to the necessity for correction as well as with respect to the type of correction they seek.

A complaint or request for correction of information must be in written hard copy or electronic form, be sent to the agency designated address by mail or electronic-mail (e-mail); and state that an information quality request for correction is being submitted. In terms of content, the complaint letter must contain:

- a detailed description of the specific material that needs to be corrected including where the material is located, i.e. the publication title, date, and publication number, if any, or the website and web page address (url), or the speech title, presenter, date and place of delivery;
- the specific reasons for believing the information does not comply with OMB, HHS, or agency-specific guidelines and is in error and supporting documentation, if any;
- the specific recommendations for correcting the information;
- a description of how the person submitting the complaint is affected by the information error; and
- the name, mailing address, telephone number, e-mail address, and organizational affiliation, if any, of the individual making the complaint.

Responsibility of the Agency

Based on a review of the information provided, the agency will determine whether a correction is warranted and if, so what action to take. The agency will respond to the requestor by letter or e-mail. The agency's response will explain the findings of the review and the actions that the agency will take, if any. The response will consider the nature and timeliness of the information involved and such factors as the significance of the correction on the use of the information, the magnitude of the correction and the resource requirements for the correction. The response will describe how the complainant may request reconsideration. The agency will respond to all requests for correction within 60 calendar days of receipt. If the request requires more than 60 calendar days to resolve, the agency will inform the complainant that more time is required and indicate the reason why and an estimated decision date.

Appeals for Reconsideration

If the individual submitting the complaint does not agree with the agency's decision (including the corrective action), the complainant may send a written hard copy or electronic request for reconsideration within 30 days of receipt of the agency's decision. The appeal shall state the reasons why the agency response is insufficient or inadequate. Complainants shall attach a copy of their original request and the agency response to it, clearly mark the appeal with the words, "Information Quality Appeal," and send the appeal to the specific agency appeals address.

The agency official who handles the original complaint will not have responsibility for resolving the appeal. The agency will respond to all requests for appeals within 60 calendar days of receipt. If the request requires more than 60 calendar days to resolve, the agency will inform the complainant that more time is required and indicate the reason why and an estimated decision date.

Rulemakings and Other Public Comment Procedures

Existing public comment procedures for rule-makings and other formal agency actions already provide well established procedural safeguards that allow affected persons to raise information quality issues on a timely basis. Accordingly, agencies will use these existing procedures to respond to information quality complaints that arise in this process.

In cases where the agency disseminates a study, analysis, or other information prior to the final agency action or information product, requests for correction will be considered prior to the final agency action or information product in those cases where in the agency's judgment issuing an earlier response would not unduly delay issuance of the agency action or information product and the complainant has shown a reasonable likelihood of suffering actual harm from the agency's dissemination if the agency does not resolve the complaint prior to the final agency action or information product.

Last revised: November 13, 2003

REAUTHORIZATION OF THE PAPERWORK REDUC-
TION ACT AND THE OFFICE OF INFORMATION
AND REGULATORY AFFAIRS

United States

HEARINGS

BEFORE THE

LEGISLATION AND NATIONAL
SECURITY SUBCOMMITTEE

OF THE

COMMITTEE ON
GOVERNMENT OPERATIONS
HOUSE OF REPRESENTATIVES

ONE HUNDRED FIRST CONGRESS

FIRST SESSION

JULY 25, 27; AUGUST 1 AND 2, 1989

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Testimony of

REP. BOB WISE (D-WV)

Chairman, Government Information, Justice,
and Agriculture Subcommittee

before the

LEGISLATION AND NATIONAL SECURITY SUBCOMMITTEE

of the

HOUSE COMMITTEE ON GOVERNMENT OPERATIONS

on

THE PAPERWORK REDUCTION ACT REAUTHORIZATION

Tuesday, July 25, 1989

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Mr. Chairman, I want to thank you and the members of the Subcommittee for allowing me to appear here today. Let me state at the beginning that I support the Paperwork Reduction Act. I do not, however, support all of the actions taken by the Office of Information and Regulatory Affairs during the last eight years. I think that the reauthorization process provides the Congress with an excellent opportunity to redirect OMB policies into more fruitful directions.

I want to limit my comments today to the information dissemination policy issues that Congress needs to address in the reauthorization legislation. In my role as Chairman of the Government Information, Justice, and Agriculture Subcommittee, I have a special interest in information issues.

Two months ago, I introduced H.R. 2381, the Information Policy Act of 1989. H.R. 2381 was intended to reform, refine, and restrict the information dissemination policy functions of the Director of the Office of Management and Budget. In drafting this bill, I worked closely with you, Mr. Chairman, and with your staff. I hope that the principles set out in H.R. 2381 can be included in any legislation that the Committee produces.

The flow of information from the federal government to its citizens is essential to the successful functioning of the democratic process and to the proper operation of the economy. In fact, the federal government is the largest single producer, consumer, and disseminator of information in the United States.

There are many segments of American society that need government information in order to function. These include the federal government itself, every type of business and industry, libraries and schools, newspapers and television, state and local governments, and ordinary citizens.

Government data is used in many different ways. Voters may use any type of federal information to help make political decisions. Federal, State and local agencies use federal statistical and economic data to make management decisions. Corporations rely on census information to make strategic business decisions. People doing business with the federal government need information to know what products and services are being purchased. Everyone relies on information from the National Weather Service to know if it will rain tomorrow.

Federal information is also a valuable economic commodity. There is a large and growing private information industry that functions in part by taking public government data, adding value to it, and reselling it to others. There are thousands of information products and services that are based in whole or in part on government information.

Because government information is so important, the policies and practices that regulate the dissemination of government information are also important. Over the last few years, the Office of Information and Regulatory Affairs at OMB has become the central information policy maker for the federal government.

At the end of 1985, OMB issued Circular A-130 on the management of federal information resources. The most important part of the circular sets out policies that apply to the collection and dissemination of federal agency information. A draft supplement to the circular was published for comment earlier this year.

Existing and proposed OMB information policies have been controversial. Some object that OMB takes an accountant's view of the value of government information; that OMB is too concerned about cost-effectiveness and cost recovery, and that OMB has not put sufficient emphasis on meeting government's obligations to make information available to the public in a useful way.

Another complaint is that OMB policies are too heavily tilted toward the private sector. OMB wants to prevent agencies from offering an information product if the private sector might offer a similar product. Here too, the complaint is that OMB places too high a priority on the interests of the private information industry and too little weight on meeting the information needs of the public.

In January of this year, OMB proposed further policy guidance on information dissemination issues. This draft statement also became the center of controversy. Many people objected to the language that agencies should avoid disseminating any value-added electronic information products.

The draft OMB guidance included an example of the application of this principle using CD-ROM. CD-ROM stands for "Compact Disc Read Only Memory". This technology -- which is very similar to the audio compact discs now used in place of phonograph records -- has the ability to store and retrieve very large amounts of data on a small, inexpensive disc.

OMB suggested that agencies planning to release databases on CD-ROMs should not include on the discs the search and retrieval software necessary to access the database. According to OMB, this would be a prohibited value-added service.

CD-ROM may well be an excellent way of making information available in a useful electronic format. We may need to encourage wider use of CD-ROM by federal agencies. But releasing massive amounts of data without adequate indexes and software tools that permit people to make effective use of the data is worthless. OMB's artificial restrictions on value-added services would mean that government CD-ROM discs would have no value at all.

ation is so important, the policies of dissemination of government information. Over the last few years, the Regulatory Affairs at OMB has become a major maker for the federal government.

OMB issued Circular A-130 on the dissemination of information resources. The most important policies that apply to the dissemination of federal agency information. A draft was published for comment.

Information policies have been established at OMB takes an accountant's view of dissemination; that OMB is too concerned with cost recovery, and that OMB has not recognized government's obligations to the public in a useful way.

OMB policies are too heavily oriented. OMB wants to prevent agencies to produce if the private sector might do it too, the complaint is that OMB does not take the interests of the private sector into little weight on meeting the needs of the public.

OMB proposed further policy changes on dissemination issues. This draft has caused a great deal of controversy. Many people believe that agencies should avoid disseminating information products.

OMB included an example of the use of CD-ROM. CD-ROM stands for "compact disc read-only memory". This technology -- which is used for compact discs now used in place of floppy discs -- has the ability to store and retrieve very large amounts of information in a small, inexpensive disc.

OMB is planning to release databases on compact discs. The search and retrieval of the database. According to OMB, this is a value-added service.

OMB's excellent way of making information available in compact disc format. We may need to encourage federal agencies. But releasing information without adequate indexes and software to make effective use of the data is a waste. Restrictions on value-added services on compact discs would have no value at all.

On June 15, 1989, OMB issued a second notice of further policy development on dissemination of information. OMB withdrew its January notice and said that its dissemination policies had not been "well communicated". In essence, OMB came as close as any agency can to admitting that its policies were wrong.

While I think that this is a very positive development, I remain cautious. I think that OMB is now headed in the right direction, but I will reserve judgment. In the absence of continued pressure from the Congress and from others, it is possible that OMB could slip back into its old ways.

Whether or not you like the information policies that OMB has established, their importance is undeniable. OMB's policies have become the focus of debate on these issues. Ten years ago, the Freedom of Information Act was at the center of federal dissemination policies. The FOIA still retains its importance today and will continue to be an essential tool in the future.

But the FOIA has been joined by other information distribution mechanisms. New technology is forcing us to reconsider how the federal government provides information to its citizens. The federal government needs to modernize its information apparatus, and the Congress needs to modernize information policy laws.

OMB's policy guidance was issued under the authority of the Paperwork Reduction Act. But that Act contains few specifics on dissemination issues. Congress has not provided any clear direction for OMB's policy making efforts on information dissemination. We should use the paperwork reauthorization to define, direct, and limit the information dissemination policy functions of OMB.

Congress needs to act because changes in technology are making our information dissemination laws obsolete. Most of our statutes were written in an era when all information was on paper. Today, more information is kept in electronic formats, and this raises new problems that existing laws do not resolve.

I support the use of information technology to modernize the government's information activities. But I want to be sure that the benefits of that technology will be fully shared with the public. I want to be sure that agencies will not use technology to exercise monopoly control over public information. I want to be sure that fees for electronic information will be reasonable.

The federal government needs effective, efficient, and equitable information dissemination policies. That should be our objective. We must limit OMB's authority to issue guidance that is inconsistent with congressionally determined goals. The information provisions of H.R. 2381 would require OMB to issue revised guidance that would:

-- recognize that the flow of information from the federal government to citizens is essential to the proper operation of the United States as a democratic society;

-- require that electronic databases maintained by agencies be available to the public in useful electronic formats with adequate software, indexes and other tools;

-- prohibit the maintenance of monopoly control over public information;

-- supplement and not replace the information disclosure requirements of the Freedom of Information Act;

-- require agencies to use marginal cost pricing and to provide for fee waivers for public interest disclosures; and

-- require agencies to make public information products, including products in electronic formats, available to depository libraries.

In addition, the legislation requires OMB to develop oversight and enforcement procedures; provide for the development and maintenance of an index of public databases maintained by federal agencies; and establish an advisory committee on information policy issues.

Another provision requires the preparation of uniform technical standards for government produced CD-ROM discs. CD-ROM clearly has a lot of potential for making data widely available at low costs. We may need to encourage -- but not direct -- the use of CD-ROM by federal agencies. If the government can develop uniform procedures for indexing, data formatting, and search software, then government CD-ROM discs will be easier for everyone to use. Standards for other electronic information technologies are also authorized.

The setting of standards is a complex task. The wrong standards can inhibit rather than promote progress. Uniformity can be a curse at times rather than a blessing. We need to allow those who develop standards enough latitude to decide what types of standards will be helpful.

Finally, there are a number of miscellaneous changes to other records laws. Among other things, these changes would increase oversight of Privacy Act systems of records notices and give the Archivist of the United States authority to determine what constitutes a record under the Federal Records Act.

The general idea is to establish basic principles in statute and let OMB issue uniform policy guidance. Decisions about the dissemination of specific information products and services will be left to the agencies.

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I don't think that the Congress can or should micromanage
agency information activities. I certainly don't want OMB to
control all information in the federal government. Nevertheless,
every agency must operate under uniform and consistent rules and
procedures. I want to expressly limit OMB's role to policy
making.

Another pitfall to avoid is the prescription of any specific
technology in statute. It is apparent that information policy is
being driven today by technological developments. But in shaping
new policies, we need technology-neutral principles that can be
equally applied to floppy disks, magnetic tapes, CD-ROM, or
whatever else the computer industry develops. I want to
encourage the use of any information technology that will make
government data more valuable. At the same time, I don't want a
statute directing the use of a specific technology.

Some concerns have been expressed about the effect of this
legislation on the printing laws and on the Government Printing
Office. I do not view any of the information policy principles
in the legislation as inconsistent with existing printing laws.
I do not think that anything in the legislation undermines the
central role of the Government Printing Office as the
government's printer or central source of publications. GPO has
a role to play in the dissemination of electronic as well as
printed information products. If the legislation raises
ambiguities, I am confident that we can amend the bill to address
any legitimate concerns.

In closing, I want to emphasize the importance of
congressional action on information policy. OMB is now operating
in a vacuum. If we don't pass legislation, then OMB will
continue to do whatever it wants, without restriction. OMB says
it wants to do the right thing. But if Congress doesn't act, OMB
might just reaffirm its old, erroneous policies. We need
legislation to make sure that OMB guidance will change direction
and that future guidance will be consistent with information
policy goals established by statute.

Mr. Chairman, I look forward to working with you, with Mr.
Horton, and with the other members of the Subcommittee on this
important legislation.

TREASURY, POSTAL SERVICE, AND GENERAL
GOVERNMENT APPROPRIATIONS FOR
FISCAL YEAR 2001

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE
COMMITTEE ON APPROPRIATIONS
HOUSE OF REPRESENTATIVES
ONE HUNDRED SIXTH CONGRESS
SECOND SESSION

Mar. 28, 2000

SUBCOMMITTEE ON THE TREASURY, POSTAL SERVICE, AND GENERAL
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NOTE: Under Committee Rules, Mr. Young, as Chairman of the Full Committee, and Mr. Obey, as Ranking
Minority Member of the Full Committee, are authorized to sit as Members of all Subcommittees.

MICHELLE MRDEZA, JEFF ASHFORD, KURT DODD, and TAMMY HUGHES,
Staff Assistants

PART 3

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TUESDAY, MARCH 28, 2000.

OFFICE OF MANAGEMENT AND BUDGET

WITNESS

JACOB J. LEW, DIRECTOR

Mr. KOLBE. The subcommittee on Treasury, Postal Service and General Government will come to order. We are very pleased this morning to welcome the Director of the Office of Management and Budget, Jack Lew.

Mr. Lew, we have had a chance to review your appropriation request for fiscal year 2001 and want to commend you and your staff for the level of detail you have provided us. I guess, actually, we should expect that coming from OMB for their own budget. More specifically, I commend the careful way in which you have addressed the specific Subcommittee concerns regarding OMB staff training and the strategic role played by OMB's communication office.

This is the first time in 8 years that OMB has requested an increase in their, full-time employment levels. Given the potential spending allocation this subcommittee is likely to get this year, this may have not been the right time to have asked for that increase, but nonetheless, I am certainly receptive to hearing more about the request and specifically how this additional staff is going to help OMB meet its statutory obligations.

Before we begin, I want to make one general observation. Mr. Director, over the years we have had a number of interesting hearings with you, not so much focused on the OMB appropriation request, but rather on priorities that this Administration establishes as it relates to Treasury law enforcement and Federal law enforcement.

In the past, when I have asked you why Treasury law enforcement has not fared as well as enforcement efforts that come under the Justice Department in the President's budget request, you have, at least in a general way, I think, responded by saying that the recommendations reflect the Administration's priorities and that you have always said you believe the numbers are adequate to allow the agencies within Treasury to do their job.

Obviously, I have not agreed with you on this point. Actually the Subcommittee has not really agreed on this point and we have fought fairly furiously for additional funding.

There continues to be some serious gaps in both funding and personnel, particularly as it relates to the U.S. Customs Service and I don't think the requests have been adequate. Now, I know you would be very disappointed if I didn't have some charts for this hearing to reflect some of that. So I have got a couple of charts here to show what I once again am talking about. This first one

would be happy to take a look at it. I take these things very seriously. They come to me. They don't always come to me the day they are issued. There are hundreds and hundreds of GAO reports, so they do take a little bit of time to make their way to my office. I would be happy to take a look at it.

Mrs. NORTHUP. Let me ask you. I know that—I assume as I look at rulemaking, my thought about OMB is that you all are supposed to judge whether the regulation is one, legally sound, economically sensitive as well as necessary, that it is meaningful, that it is useful. Would you agree with that evaluation that your agency does on rulemaking?

Mr. LEW. We have a number of functions that we play in reviewing rules. Obviously, the law requires rules. Part of our function is make sure the rules get implemented in a timely manner. In cases where agencies are undertaking policies, we have the responsibility to work with them to make sure they have done the kind of analysis to make sure that they have considered the views, both of other agencies, of other parties outside of the government, and the analysis in terms of—in case of major rules, the cost and benefits.

Mrs. NORTHUP. Do you also, though, judge a rule by whether or not it is legally sound?

Mr. LEW. We do review whether there is a legal basis. That is one of many factors that we consider. I think that it is always our intention to make sure that we are doing things that are mandated by law or within the authorities we have under the law. That is not typically the area of greatest controversy. The area of greatest controversy is usually whether they are in the least burdensome way possible or whether or not they have taken account of cost as well we benefits, and we have very active processes on major rules in that area.

Mrs. NORTHUP. I'm going to submit the rest of my questions but I would be very eager, as we go through this process, to have your response as to what sort of the level, what sort of rules you have, apply those criteria to and some specific questions. Thank you.

Mr. KOLBE. Thank you, Mrs. Northup. If you are able to remain, there will be time for a second round of questioning.

Mrs. Emerson.

IMPROVING DATA QUALITY

Mrs. EMERSON. Thanks, Mr. Chairman. Director Lew, I want to ask you, if I could, about some action that was urged by this Congress in the FY 1999 Omnibus Appropriations Act, specifically as it related to regulations for data quality. We had stated that the Committee expected OMB to issue rules by September 30, 1999, with regard to data quality, and as far as I can tell, you all haven't done anything to date. Do you have any idea when these data quality regs might be issued?

Mr. LEW. My recollection is that it was something that was in the House report, but we worked with the Committee over the conference period on it. I am not aware of a requirement.

Mr. KOLBE. If the gentlelady would yield, the language does say "urge," but we certainly urge very strongly.

Mrs. EMERSON. And if I may just say in the joint explanatory statement, it did, in fact, say something to that effect. You are

right, Mr. Chairman, urging very strongly. So can I take it then because we only urged and didn't mandate that you all have not gotten around to doing that yet?

Mr. LEW. Let me, if I may, respond on the substance of the matter and our concern. We have been concerned in the discussion of this policy that right now there are private rights of action in cases where there are consequences. We are concerned about a change of policy that would create rights of action where there aren't consequences. That is a tremendous expansion of potential litigation. It is the kind of issue we have worked with the Congress on over the years when we discussed regulatory reform generally, and it is a very, very serious matter. I don't want to suggest that this is a small issue. There may be real differences between us. I was just handed a letter that we received on March 27, which I haven't had a chance to read yet, where you have asked questions on this. I would be happy to read this and respond to it.

Mrs. EMERSON. My reason for asking this isn't to trick you or to get caught up in anything, but rather a lot of the information if, in fact, the public goes to the website of the EPA just, for example, they would see EPA's take on a particular policy as opposed to oftentimes perhaps a more objective viewpoint or the other side not having an opportunity to respond. So it is not the legal action part I am concerned about; it is the ability to get the straight skinny on things, if you will.

Mr. LEW. The problem is—and this is not unique to this particular proposal—there are many proposals where when you change the administrative process to create rights. There are also opportunities for review and delay. I don't think we disagree on the basic premise that rules should be based on the best quality of information. That is not an issue we disagree on. The question on what constitutes the right quality, who makes the determination how, those are obviously very complicated questions. I would be happy to pursue this with you and have John Spotila, the head of our Office of Information and Regulatory Affairs, work with you on it. I don't want to suggest we don't have very serious concerns.

Mrs. EMERSON. I appreciate that and I know that the Center for Regulatory Effectiveness, which I believe is composed of a lot of ex-OMB officials, they put together some sort of a suggested policy that I would appreciate your at least taking a look at it and getting back to me about that.

Mr. LEW. Be happy to.

[The information follows:]

Federal Government Data Quality

OMB is committed to helping the Federal government provide the public with high quality information. We work with the agencies in several ways to improve the quality of such information. Under the Paperwork Reduction Act, we review information collection proposals to ensure that they have maximum "practical utility." We coordinate and review the development and use of federal statistics. OMB Circular A-130 describes the best practices that agencies should follow to collect and use timely and appropriate information. It also establishes the criteria for agency budget requests to ensure that proposed information management investments are appropriate, efficient, and effective.

The FY1999 House Report language urged OMB to establish government-wide rules for ensuring the quality of federally-disseminated information. We appreciate the need for ensuring such quality and are sensitive to the possibility that OMB Circular A-130 might need to be updated or supplemented to deal with concerns in this area. OMB Circular A-130 already establishes complaint resolution procedures for perceived violations of data quality and other requirements in the Circular. Section 9(a)10 of the Circular contains a requirement that each agency CIO must:

"monitor agency compliance with the policies, procedures, and guidance in this Circular. Acting as an ombudsman, the [CIO] shall consider alleged instances of agency failure to comply with this Circular and recommend or take corrective action as appropriate."

The Circular also contains a specific requirement for agencies to report to OMB any alleged violations and their resolution:

"The [CIO] shall report annually, not later than February 1st of each year, to the Director those instances of alleged failure to comply with this Circular and their resolution."

Last summer, OMB canvassed the agency Chief Information Officers (CIOs) about data quality. They indicated to us that they have not been hearing complaints about the quality of federally-disseminated information. None expressed a need for further guidance in this area. Based on our canvass of the CIOs and OMB's own experience, there does not currently appear to be a significant problem in this area. We are monitoring CIO activities and will be alert to any widespread complaints about publicly-disseminated information.

At the present time, OMB is not convinced that new "one-size-fits-all" rules will add much to existing OMB guidance and oversight activity and the procedures followed by individual agencies. We are reluctant to issue more regulations without a clear sense that they would be useful in promoting data quality. We are also concerned that new regulations might prove counterproductive to the goal of increasing data quality. The Report suggests that agencies be required to establish a new "petition" process under which persons could file formal "complaints" over the quality of information. These administrative requirements could consume significant agency resources. An adversarial petition process also might discourage the type of free and open dialogue between the agency and the public that is crucial for identifying and addressing data quality issues.

**QUESTIONS FOR THE RECORD SUBMITTED BY THE COMMITTEE
OFFICE OF MANAGEMENT AND BUDGET**

Government-wide Rescission

Question: What were the specific instructions given to agencies in the application of the across the board rescission? Were identical instructions given to all agencies or was there latitude in the application of the cuts?

Answer: OMB Bulletin No. 00-01 provided the following guidance to all Executive departments and agencies on the criteria to be used in applying the rescission:

1. Reductions should be taken from the least critical funding available to the agency.
2. Reductions should be considered from enacted funding above the President's request.
3. Reductions in earmarked, or other project funding should be applied to categories of spending, not targeted on specific member initiatives.
4. Wherever possible, no reductions should be taken that would require - reductions-in-force.
5. Agencies are encouraged not to use an across-the-board funding cut allocation method.

Agencies had the latitude to propose whatever allocations best fit their needs, so long as they met the legal requirements of the law and were consistent with the criteria in the Bulletin.

Question: In total, how much is included in the President's budget for restoration of funds associated with these rescissions? For the record, provide the total amount requested to be restored in FY 2001 by account and amount.

Answer: There were no funds specifically included in the FY 2001 President's budget request to restore funds rescinded in FY 2000. There was one FY 2000 supplemental request totaling \$150,000 for OPM salaries and expenses related to cyber security.

Information Technology Architecture

Question: OMB is requesting \$1,030,000 in FY 2001 and a total of \$8,460,000 over the FY 2001-2005 time period to upgrade its information technology systems. In OMB's October, 1996 memorandum to agencies regarding "Funding Information Systems Investments," OMB defined "a major information systems" as one that requires special management attention because of its importance to an agency mission; its high development operating, or

D.C. and National Parks Service: For FY 2001, \$1.8 million is requested in the Department of Interior's National Parks Service budget and \$6.2 million in the District of Columbia's budget for inauguration activities.

Defense: For FY 2001, \$1 million is requested in the Department of Defense budget for inauguration activities.

In addition, transition costs for the White House Office, Office of the Vice President, and Executive Residence are estimated to be \$2.3 million, which includes personnel unemployment, terminal leave, temporary personnel support, and other operational expenses associated with transition.

For other agencies, we estimate that the net impact of personnel turnover due to the transition is zero, with terminal leave and other costs of departing personnel being offset by FTE lapses caused by delays in filling senior positions.

Question: What guidance will OMB provide to agencies in the preparation of the FY 2002 President's budget prior to the change in Administrations?

Answer: The Budget Act directs the President to submit a budget to Congress by the first Monday in February. Therefore, the FY 2002 Budget will be submitted by the next President. However, in order to lay the groundwork for the incoming administration's budget and to facilitate development of that budget during the transition, OMB will shortly send agencies guidance for the development of budget materials.

Data Quality

Question: Over the past several years, this Committee has been very interested in the areas of public access to data and the quality of publicly disseminated information. Regarding the issue of data quality, the Subcommittee understands that OMB has been working with agency Chief Information Officers to assess their views regarding the nature and extent of information quality and reliability. What is the status of this assessment? How many CIOs have you met with and which agencies do they represent?

Answer: OMB sent a data call to the CIO Council in May 1999. OMB received 15 timely responses.

The data call posed three questions:

- 1) Has the agency recently received complaints regarding data quality or related issues?

2) Does the agency have a centralized complaint resolution process in which the CIO, acting as an ombudsman for the agency, considers and acts upon complaints about any alleged violation of the Paperwork Reduction Act or OMB Circular A-130 (beyond the narrow issue of data quality)?

3) Have the procedures resolved any complaints which may have been received?

Analysis of Responses:

- Three agencies described specifically complaints that they have received:

EPA stated that there have been "specific data inaccuracies and areas where data do not meet stakeholders needs." On April 1, 1999, EPA adopted a "Data Quality Strategic Plan," and the Administrator has created a new Office of Information as a central organization responsible for ensuring the agency's rational collection and management of quality information.

Justice stated that it had received specific data quality complaints in the past, and provided a recent example where the accuracy of crime statistics for a particular State contained in an issue of the Uniform Crime Reports was claimed to be inaccurate. Justice corrected the mistake and reissued the Report.

Commerce stated that it had received a complaint that the price for a particular Patent and Trademark Office cd-rom product exceeded the cost of dissemination standard of the PRA and A-130. An analysis of the pricing methodology disclosed that the price was not excessive. (Note: this was not a data quality complaint.)

- Ten agencies (Agriculture, Defense, Education, HHS, HUD, State, GSA, NASA, NARA, NSF) stated that they have not recently received specific complaints but have a centralized process in place to handle any complaints which may be received.
- Two agencies (Energy and Interior) reported that they do not have a centralized complaint resolution process and that any complaint would be the responsibility of the specific agency component.

Question: As a result of this assessment: Do you anticipate issuing regulations regarding the quality, objectivity, utility and integrity of data and information used, generated or disseminated by federal agencies?

Answer: Based on our experience over the years as well as a canvass of agency Chief of Information Officers in 1999 (see above), we do not believe there is a government-wide problem that would require new regulations. We are not aware that either Congress or the Executive Branch has received any widespread or frequent complaints about publicly-disseminated information. The language in the previous Committee Report seems to be a response to one or two isolated instances which apparently were not taken up under the existing procedures.

In addition, such rules would also be counter-productive to the goal of increasing quality. Under the Committee Report, all agencies would be required to promulgate their own implementing regulations, and agencies would have to establish a new "petition" process under which persons could file formal "complaints" over the quality of information. These administrative requirements would consume significant agency resources, and the petition process would introduce an adversarial approach that is simply inappropriate here. Agencies want to hear public concerns about the quality of information. However, requiring agencies to establish a litigation-type process would not encourage the free and open dialogue between the agency and the public that is crucial for identifying and addressing any problems that exist.

Finally, under the Committee Report, OMB's regulations would extend not only to Federal agencies, but also to non-Federal entities that disseminate information with Federal financial support -- such as contractors, State and local governments, and non-profit grantees. The Report language would therefore impose new unfunded Federal mandates and, contrary to the spirit of the First Amendment, would represent a significant Federal intrusion into how non-Federal entities communicate with the public on public matters.

Question: Do you anticipate issuing a report regarding your findings on the quality of publicly disseminated data?

Answer: We do not plan to issue a separate report. We have discussed this issue extensively in the attached letters to Representatives Emerson and Bliley.

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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

May 25, 1999

THE DIRECTOR

The Honorable Jo Ann Emerson
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Emerson:

Thank you for your letter of May 6, 1999, seeking our views about language contained in House Report 105-592, accompanying the Fiscal Year 1999 Omnibus Appropriation concerning the "Reliability and Dissemination of Information." (Pages 49-50).

The goal of the report language is to maximize the quality of publicly-disseminated information. Federal agencies have for decades released a vast array of public information on a variety of subjects, ranging from economic statistics to weather reports, from agricultural forecasts to public health advisories. Agencies have been and are committed to ensuring timely and accurate information dissemination as part of their basic missions, as well as part of their responsibilities under the Paperwork Reduction Act (PRA). Over the years, OMB and the agencies have worked to ensure the utility and accuracy of public information through the rigorous PRA review of regulations, surveys, and forms which collect the information that is subsequently disseminated.

We are following up on the concerns outlined in the House report by consulting with agency Chief Information Officers to assess their views regarding the nature and extent of information quality and reliability and are reviewing current practices in the area to determine what changes if any are necessary. In addition, we are reviewing the report prepared by the Center for Regulatory Effectiveness to which you refer. Because it focuses on a specific Environmental Protection Agency program, we are discussing this matter with EPA to better understand the issues raised by the report.

Thank you for your interest in this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Jacob J. Lew".

Jacob J. Lew
Director

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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

July 12, 1999

THE DIRECTOR

The Honorable Tom Bliley
Chairman
Committee on Commerce
U.S. House of Representatives
Washington, DC 20515-6115

Dear Mr. Chairman:

Thank you for your letter of May 20, 1999, regarding improving the scientific basis for Federal regulatory decision making, particularly at the Environmental Protection Agency (EPA), and improving the quality of data and information used and disseminated by Federal agencies. You also ask about language contained in House Report 105-592, accompanying the Fiscal Year 1999 Omnibus Appropriation concerning the "Reliability and Dissemination of Information." (Pages 49-50).

The Administration has a demonstrated commitment to using the best available data and information in making decisions involving risk assessment and management. For example, Executive Order No. 12866, *Regulatory Planning and Review*, directs regulatory agencies to adhere to a set of twelve principles, including "...(4) In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction," and "...(7) Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation." [EO 12866, Section 1(b).] The latter provision is mirrored closely in the 1997 Report by the Commission on Risk Assessment and Risk Management referenced in your letter. The Executive Order also requires that economically significant regulatory actions be accompanied by an analysis of costs and benefits, including, to the extent feasible, a quantification of benefits such as risk reduction. [EO 12866, Section 6(a)(C).]

In 1996, OMB, in consultation with an interagency work group, issued a set of "best practices" for conducting analyses of regulations under EO 12866. This document includes a detailed treatment of risk assessment, including issues related to data quality. It states, for example:

"The assessment of outcomes associated with regulatory actions to address risks to health, safety, and the environment raises a number of scientific difficulties. Key issues involve the quality and reliability of the data, models, assumptions, scientific inferences, and other information used in risk analyses...The treatment of uncertainty in developing risk, benefit, and cost information also must be guided by the principles of *full-disclosure* and *transparency* [emphasis in the original], as with other elements of the Economic Analysis. Data, models, and their implications for risk assessment should be identified in the risk characterization. Inferences and assumptions should be identified and evaluated explicitly, together with adequate justification of choices made, and assessments of the effects of these choices on the analysis." [*Economic Analysis of Federal Regulations Under Executive Order 12866*, p 16.]

You specifically note provisions in the Safe Drinking Water Act (SDWA) Amendments of 1996 related to improving the quality of data and enhancing the scientific basis for regulatory decisions. The SDWA Amendments require EPA to use the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices in developing new drinking water regulations. It further directs EPA to prepare Health Risk Reduction and Cost Analyses that include assessments of quantifiable and nonquantifiable health risk reduction benefits, quantifiable and nonquantifiable costs, incremental costs and benefits associated with each alternative standard considered, effects on both the general population and sensitive subpopulations, potential increased health risks associated with co-occurring contaminants, and other relevant factors, including data quality and uncertainty. [*SDWA, Section 1412(b)(3)(C).*] In February of this year, EPA published its first analysis under the new statutory provisions, relating to radon in drinking water.

The SDWA Amendments also direct EPA to establish a monitoring program for unregulated contaminants in drinking water in order to provide high quality data to determine if there is a need for future regulations, and to maintain this data in a publicly-accessible National Contaminant Occurrence Database (NCOD). In April, EPA proposed regulations governing this monitoring, including a primary list of eleven contaminants for which full-scale monitoring will be conducted, and a supplemental list of about 20 contaminants for which pilot-scale monitoring will be conducted as analytical methods are refined. And in June, EPA launched the NCOD, which has been developed over the past three years with extensive public input.

Regarding the status of OMB activities related to the Conference Report language, OMB has been working with agency Chief Information Officers (CIOs) to determine what issues related to data quality may need to be addressed, and what activities agencies already have underway to deal with them. As an example of such activities, EPA announced last fall that it would be creating a new Information Office with a broad mandate to manage and improve the quality of information used both by the agency and distributed to the public. In March, EPA announced that one component of this office would be a new Data Quality Board charged with assuring data quality and performing oversight of all data collected at the agency. In April, the agency adopted a Data Quality Management Plan, which was developed with substantial public

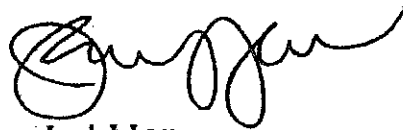
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input, to facilitate review of a broad range of factors that influence the overall quality of environmental data, including timeliness, accessibility, contextual relevance, adequate coverage, scientific and technical precision, and accuracy.

Thank you again for your interest in the Administration's activities in the area of assuring data quality.

Sincerely,

A handwritten signature in black ink, appearing to read "Jacob J. Lew". The signature is fluid and cursive, with a large initial "J" and "L".

Jacob J. Lew
Director

cc: The Honorable C.W. Bill Young
The Honorable Jim Kolbe
The Honorable Steny Hoyer
The Honorable David Obey

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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

April 18, 2000

The Honorable Jo Ann Emerson
US House of Representatives
Washington, DC 20515

Dear Representative Emerson:

Thank you for your letter of March 20, in which you ask about the Office of Management and Budget (OMB) response to the language in the FY 1999 Omnibus Appropriations Act conference report (House Report 105-592), which concerned the quality of information that Federal agencies disseminate to the public.

OMB is committed to helping the Federal government provide the public with high quality information. We work with the agencies in several ways to improve the quality of such information. Under the Paperwork Reduction Act, we review information collection proposals to ensure that they have maximum "practical utility." We coordinate and review the development and use of federal statistics. OMB Circular A-130 describes the best practices that agencies should follow to collect and use timely and appropriate information. It also establishes the criteria for agency budget requests to ensure that proposed information management investments are appropriate, efficient, and effective.

The FY1999 House Report language urged OMB to establish government-wide rules for ensuring the quality of federally-disseminated information. We appreciate the need for ensuring such quality and are sensitive to the possibility that OMB Circular A-130 might need to be updated or supplemented to deal with concerns in this area. OMB Circular A-130 already establishes complaint resolution procedures for perceived violations of data quality and other requirements in the Circular. Section 9(a)10 of the Circular contains a requirement that each agency CIO must:

"monitor agency compliance with the policies, procedures, and guidance in this Circular. Acting as an ombudsman, the [CIO] shall consider alleged instances of agency failure to comply with this Circular and recommend or take corrective action as appropriate."

The Circular also contains a specific requirement for agencies to report to OMB any alleged violations and their resolution:

"The [CIO] shall report annually, not later than February 1st of each year, to the Director those instances of alleged failure to comply with this Circular and their resolution."

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Last summer, OMB canvassed the agency Chief Information Officers (CIOs) about data quality. They indicated to us that they have not been hearing complaints about the quality of federally-disseminated information. None expressed a need for further guidance in this area. Based on our canvass of the CIOs and OMB's own experience, there does not currently appear to be a significant problem in this area. We are monitoring CIO activities and will be alert to any widespread complaints about publicly-disseminated information.

At the present time, OMB is not convinced that new "one-size-fits-all" rules will add much to existing OMB guidance and oversight activity and the procedures followed by individual agencies. We are reluctant to issue more regulations without a clear sense that they would be useful in promoting data quality. We are also concerned that new regulations might prove counterproductive to the goal of increasing data quality. The Report suggests that agencies be required to establish a new "petition" process under which persons could file formal "complaints" over the quality of information. These administrative requirements could consume significant agency resources. An adversarial petition process also might discourage the type of free and open dialogue between the agency and the public that is crucial for identifying and addressing data quality issues.

We also note that the House Report suggests that any new regulations extend not only to Federal agencies, but also to non-Federal entities that disseminate information with Federal financial support, such as contractors, State and local governments, and non-profit grantees. This might lead to new unfunded Federal mandates and an intrusion into how non-Federal entities communicate with the public on public matters.

We are very much interested in exploring other ways to improve data quality. We believe it important to have interagency cooperation in this regard and to enlist the public in an ongoing dialogue aimed at improving such quality. Data quality is one of many considerations of agency information management activity. In that regard, we are launching this month an initiative to work with select agencies (HCFA, EPA, DOT, HHS, OSHA, IRS, and SBA) and the public on how we can collect information more effectively, with improved efficiency and data quality. We expect these discussions to identify agency best information management practices as well as recommendations for improving specific information collection and management activities.

We appreciate your strong interest in information quality and would welcome any further thoughts you might have on this subject.

Sincerely,



John T. Spotila
Administrator

**QUESTIONS FOR THE RECORD FROM
CONGRESSWOMAN JO ANN EMERSON****Data Quality**

Question: Would OMB be willing to seek public comment on Data Quality to help clarify some of the issues, such as defining exactly what is "quality," that you raised during the hearing?

Answer: OMB is very concerned about ensuring the quality of the information that the Federal Government disseminates to the public. The Federal agencies that disseminate information take seriously their responsibility to ensure its quality. OMB works with the agencies to ensure the quality of Federally-disseminated information in several ways, including:


- reviewing federal collections of information under the Paperwork Reduction Act (to ensure that collections have the maximum "practical utility"),
- coordinating and reviewing federal statistical activities, and
- setting general policy for information dissemination through OMB Circular A-130.

As mentioned above, OMB is launching an initiative to examine how the Federal government can collect information more effectively and efficiently. This initiative is public, is being announced in the Federal Register, and will begin with a public forum on April 27. Through this initiative, we are soliciting public comment on how to improve federal information collection and management activities generally and specifically. If we conclude that further public comment on data quality is desirable after the conclusion of this initiative, we will consider steps to obtain it.

CERTIFICATE OF SERVICE

I hereby certify that two copies of the foregoing were served, via second day Federal Express mail, upon Alisa Klein, Mark Stern, Department of Justice, Civil Division, Appellate Staff, Room 7235, 950 Pennsylvania Ave., N.W., Washington, D.C. 20004, this seventh day of April, 2008.

I hereby certify that an original and fifteen copies of the foregoing were served, via Federal Express ground transportation, upon the Clerk, U.S. Court of Appeals for the Ninth Circuit, 95 Seventh St., San Francisco, CA 94103, this seventh day of April, 2008.



Joseph D. Elford