207:Incorporating Sound Science in Environmental Policy & Rulemaking

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Richard B. Belzer is president of Regulatory Checkbook, a nonpartisan, non-profit organization whose mission is the inculcation of policy-neutral science and economics into regulatory policy and practice. This work includes research in a number of theoretical and applied areas including data quality, environmental economics, quantitative risk assessment, and benefit-cost analysis.

Previously, Dr. Belzer served as an economist at the U.S. Office of Management and Budget's Office of Information and Regulatory Affairs. At OMB he reviewed dozens of major proposed and draft final rulemakings, and their supporting risk and economic analyses, initiated by several agencies and executive branch departments. Subsequently, Dr. Belzer was visiting professor of public policy at Washington University in St. Louis and regulatory program manager for the Weidenbaum Center on the Economy, Business and Public Policy.

Dr. Belzer is a member of the American Economics Association (AEA) and the Society for Risk Analysis (SRA). The AEA is the premier professional society for economists, while the SRA is an interdisciplinary association of more than 2,000 professionals involved in the assessment and management of health, safety, and environmental risks. He was elected treasurer of SRA, and served on the executive committee.

Dr. Belzer earned BS and MS degrees in agricultural economics from the University of California at Davis, and the MPP from the John F. Kennedy School of Government. He also holds a doctorate in public policy from Harvard University.

James W. Conrad, Jr.

James W. Conrad, Jr. is an assistant general counsel at the American Chemistry Council in Arlington, Virginia. He has primary legal responsibility for security issues, and also provides legal and policy counsel in support of the council's regulatory, legislative, and judicial advocacy in the areas of information and science policy and enforcement. In more than a decade with the council, he has also led its advocacy regarding environmental innovation legislation and programs, governmental management of environmental information, hazardous/solid waste, and air monitoring. Mr. Conrad has also managed the association's environmental legal staff and founded the Performance Track Participants Association.

Mr. Conrad was in private practice with the Washington, DC offices of Davis, Graham & Stubbs and Cleary, Gottlieb, Steen & Hamilton, where his responsibilities encompassed regulatory advocacy, counseling, litigation, and transactional work under all the major federal environmental statutes and numerous state laws.

For most of a decade he represented conservation groups on a pro bono basis in a variety of matters involving marine mammals and bald eagles. He has chaired the City of Alexandria, Virginia environmental policy commission and served on the Bush-Cheney transition advisory committee for the EPA. He is also active in the ABA's sections on environment, energy & resources and administrative law & regulatory practice. Mr. Conrad developed and edits the *Environmental Science Deskbook.* He is a regular speaker before organizations such as the ABA, Environmental Law

Institute, ALI/ABA, Resources for the Future, Society for Risk Analysis, and ACC. Mr. Conrad's writings on environmental legal subjects have appeared regularly in journals such as ELI's *Environmental Law Reporter* and the *BNA Environment Reporter*.

He is a graduate of Haverford College and The George Washington University Law School.

Leslie J. Hushka, PhD

Dr. Leslie J. Hushka currently holds the position of issue manager for Exxon Mobil Corporation. Her responsibilities include assessing impacts of complex government programs and policies, using risk assessment methods, benefit-cost analysis, economic and legal requirements, and assisting ExxonMobil to develop scientifically sound positions on health and environmental issues. Her current areas of focus include children's health, risk assessment, chemical testing programs (e.g. REACH, TSCA), health provisions in Clean Air Act, and improvements to regulatory processes employed by the U.S. and other governments.

Prior to joining ExxonMobil (in the ExxonMobil biomedical sciences group), she held research, consulting, and program management positions with the Chemical Manufacturers Association (now the American Chemistry Council), the Naval Blood Research Laboratory, and General Electric Plastics.

Dr. Hushka serves as the treasurer for the Society for Risk Analysis (SRA) and has cochaired SRA's public policy committee, a group that sponsors Congressional briefings on emerging risk issues. She is also an active member of the Society of Toxicology (SOT) and American Association for the Advancement of Science (AAAS). She has testified before numerous science advisory boards and given frequent invited seminars at industry and academic institutions.

Dr. Hushka holds a BS from Northeastern University and a PhD in Pharmacology and Toxicology from Purdue University. She is board certified, with Diplomat status, by the American Board of Toxicology.

Jessica R. Nacheman

Jessica R. Nacheman is counsel for Exxon Mobil Corporation in Clinton Township, New Jersey. She is primarily responsible for the general legal needs of ExxonMobil Research and Engineering Company and its subsidiary, ExxonMobil Biomedical Sciences, Inc. Her areas of expertise include environmental, safety, and health, immigration, antitrust, export control, real estate, and corporate law.

Prior to joining ExxonMobil, Ms. Nacheman served as outside counsel at two New Jersey law firms, Pitney Hardin and Lowenstein Sandler where she specialized in regulatory and administrative environmental law.

Ms. Nacheman provides rotating pro-bono legal services to her house of worship as well as to the immigration community. She also provides mentoring to law and undergraduate students contemplating entering the legal field.

Ms. Nacheman received a BA from the University of Pennsylvania, a Masters of Public Health from Columbia University, and a JD from New York Law School.

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New tools: Information Quality and Peer Review Guidelines

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Information Quality Basics

1) **Statutory language requirements**
   [FY 2001 Consolidated Appropriations Act (Public Law 106-554)] Sec. 515. - (a) In General. – The Director of the Office of Management and Budget (OMB) shall . . . issue 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 in fulfillment of the purposes and provisions of chapter 35 of title 44, United States Code, commonly referred to as the Paperwork Reduction Act.
2) **Applies to all Federal "agencies" (as defined by the Paperwork Reduction Act)**
   a) Includes Executive branch and Federal commissions
   b) Excludes Congress and courts
3) **All information that is "used" or "disseminated"**
   a) "Used" includes all regulation and guidance
   b) "Disseminated"
      i) Anything "initiated or sponsored" by an agency
      ii) Excludes testimony, correspondence, distribution solely to employees, contractors or grantees, other Federal agencies
      iii) Watch for exceptions, exemptions, variances, provisos, as agencies seek to limit the scope of the law

What are the critical terms in information quality? Part I

1) **Affected person**
2) **Quality - Encompasses (utility, integrity, objectivity)**
   a) Utility - Refers to the usefulness of the information to the intended users; derived from the Paperwork Reduction Act.
   b) Objectivity - Focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and is substantively accurate, reliable, and unbiased.
   c) 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.

3) **Information - 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.**
   a) Government information - Information created, collected, processed, disseminated, or disposed of by or for the Federal Government. 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.
   b) 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.
4) **Dissemination -** A**gency initiated or sponsored distribution of information to the public (see 5 CFR 1320.3(d) (definition of "Conduct or Sponsor")). Does not include:**
   a) 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.
   b) Distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes.
5) **Influential - When used in the phrase "influential scientific, financial, or statistical information"**
   a) 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.
   b) 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.
6) **Reproducibility - Means that the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision.**
   a) For information judged to have more (less) important impacts, the degree of imprecision that is tolerate is reduced (increased).
   b) 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).
   c) 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.

What are the critical terms in information quality? Part II

1) **Objectivity**
   a) Objectivity involves two distinct elements, presentation and substance.
      i) Includes whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner.
      ii) full, accurate, and transparent documentation
      iii) error sources affecting data quality identified and disclosed to users
      iv) information is presented within a proper context.
   b) Basic information
      i) Publication in peer reviewed journal gets a presumption
      ii) This presumption is rebuttable
      iii) The evidentiary showing to rebut the presumption is not stated and has not been tested, but logic suggests that evidence of non-objectivity should be sufficient
   c) Influential scientific, financial, or statistical information must meet a much higher standard - Aspects of higher information quality standard include
      i) Transparency (agencies must "show their work")
      ii) Reproducibility (competent third parties must be aboe to obtain the same result with a reasonable degree of accuracy)
      iii) Together, "transparency" and "reproducibility" imply public access to data (cf. Shelby Amendment)
      iv) Where the reproducibility test is not satisfied (perhaps due to proprietary data or models), robustness checks are required (results should be insensitive to data and analytical choices)

Direct Requirements for Federal agencies

1) **Adopt a "basic" standard of quality as "performance goal"**
   a) What does this mean? Nobody seems to know
2) **Develop a process for pre-dissemination review**
   a) Objective is to prevent the need for error corrections
3) **Treat information quality as "integral to every step" of information development**
4) **Establish administrative mechanisms for affected persons to obtain timely correction**
   a) "Independent" appeal within the agency
      i) Problematic: how "independent" can an internal process really be?
   b) Agency must act on petitions and appeals
      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.
      iii) Agency shall establish an internal administrative appeal process to review the agency's initial decision, and specify appropriate time limits in which to resolve such requests for reconsideration.
5) **Effective dates**
   a) Pre-dissemination review applies to information that the agency first disseminates on or after October 1, 2002.
   b) Administrative mechanisms applies to information that the agency disseminates on or after October 1, 2002, regardless of when the agency first disseminated the information.
6) **Other requirements**
   a) 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)).

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.
c) 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.

Direct requirements on "affected parties"

1) Applies to
a) Information submitted to influence decisions
b) Petitions for error correction

2) Information submitted to influence decisions
a) Agencies must satisfy data quality guidelines if they want to use submitted data
b) However, agencies can now readily reject third-party data that they don't like if it does not satisfy data quality guidelines
c) Therefore, third parties desiring to influence agency decisions should invest in securing adherence to appropriate data quality standards prior to submission

3) Error correction petition process
a) Submit a complete, exhaustive package
   i) Meet burden of proof that information is in error
   ii) Identify relief you seek--but beware what you ask for
b) Timely appeal up the agency chain of command if:
   i) Petition is denied
   ii) Petition is accepted but relief is inadequate or inappropriate
   iii) Petition is accepted but agency fails to implement changes
   iv) Response to petition is delayed until matter is moot (covered in next presentation)
c) Is judicial review available?
   i) Information Quality Law is silent
   ii) The law appears to amend the Paperwork Reduction Act, and violations of PRA can be litigated
   iii) Do you have standing?

Peer Review Amendments to IQA

1) New amendments proposed in form of an OMB Bulletin - Goals are to:
a) Ensure that agencies conduct peer reviews of the most important scientific & technical information
b) Peer reviews are reliable, independent and transparent
c) Still under revision and public debate
   i) Summary below is based on proposed guidelines
   ii) Final product may be substantially watered down

2) Information that is Covered / Not Covered by Guidelines
a) Regulatory information means any scientific or technical study that is relevant to regulatory policy . . . used by regulatory bodies
b) Peer review undertaken by a scientific journal may be generally be presumed to be adequate
c) Concerns
   i) What if the Agency re-analyzes, summarizes, and interprets original findings?
   ii) Does establishing a rebuttable presumption for published articles free agencies from requirement to substantiate the quality of information?

3) **Selecting Peer Reviewers**
   a) Selected on the basis of necessary scientific and technical expertise
   b) Broad a range of expertise as is necessary
   c) Do not possess real or perceived conflicts on interest
4) **Peer Review Process**
   a) Select peer review mechanism based on the novelty and complexity of the science to be reviewed, the benefits and cost implications, and any "controversy" regarding the science
   b) Information Access and Public Comments
      i) Provide an opportunity for other interested agencies and persons to submit comments ... provided to peer reviewers
      ii) Disclose names, qualifications of peer reviewers
      iii) Include a certification explaining how agency has complied
5) **Updated Agency Guidelines**
   a) Supplement or amend IQGs to incorporate requirements
   b) Develop guidelines for entanglements that preclude an individuals
   c) Assure confidentiality in peer review

Important Caveats on Peer Review

1) **Scholarly peer review ≠ Government peer review**
   a) Including ownership, objectives, selection, procedures, interests, accountability, etc
2) **No evidence that peer review is an appropriate remedy for the "problem" government peer review is supposed to solve**
   a) Peer Review ≠ Stakeholder Dialogue
   b) Peer Review ≠ Sound science
3) **Too much attention is devoted to conflicts of interest and not enough to "coincidence of interest"**
   a) "Coincidence of interest" arises when reviewers are too cozy with the agency
   b) Conflict of Interest ≠ Bias

Lessons from experience to date

1) **Making IQ work requires work**
   a) Information quality guidelines are not self-implementing
2) **Agencies behave rationally… even when it doesn't seem like it**
   a) Agencies use substandard information when it suits their interests. They need little or no encouragement to use superior information when it suits their interests
   b) Agency behavioral change is therefore essential for success.
3) **Affected persons have advantages they have never had before**
   a) Affected persons control how they marshal resources for petitions and voluntary submissions
   b) Companies already know how to develop high-quality data
   c) Agencies do not know (and may not care) how to develop high-quality data
4) **Making best use of OMB is complex**
   a) Must deal with OMB on multiple levels
   b) OMB's and affected parties' interests are not always the same
      i) An ally where interests converge
      ii) An opponent where OMB defends agency prerogatives or Administration policy
5) **Know when you are in over your head and call for a lifeguard**
   a) Information quality gets complex fast
   b) Expertise can't be obtained off the shelf
   c) The moment you think you understand what's going on is the moment to call 911

References

1) Office of Management and Budget (OMB), Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 *Fed. Reg.* 369-378.
2) OMB, Proposed Bulletin on Peer Review and Information Quality, 68 *Fed. Reg.* 54023-54029
3) OMB, Revised Information Quality Bulletin on Peer Review, 69 *Fed. Reg.* 23230-23242

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APPLYING LESSONS ABOUT INFORMATION QUALITY: THE CASE OF PERCHLORATE

I. A BRIEF HISTORY OF THE PERCHLORATE CASE

A. What is perchlorate?

1. Anion consisting of one chlorine atom and four oxygen atoms. Copious amounts of energy are released upon combustion. Stable only as a salt compound.

2. Ammonium perchlorate:

   a. The principal oxidizer used in solid rocket motors, making it essential for space propulsion, missiles and many munitions. MIL-SPEC.

   b. Used to make road flares and to power automotive airbags.

   c. A constituent in some soils and fertilizers. Especially prominent in Chilean caliche used heavily in California agriculture during the 1900s.

3. Potassium perchlorate:

   a. The principal oxidizer in fireworks.

   b. For more than 50 years, an FDA-approved therapeutic treatment for Graves' disease (hyperthyroidism) at gram doses. Today, other treatments are preferred in the U.S. due to perchlorate's short half-life.

B. Large-scale historic releases of ammonium perchlorate resulted from aerospace and military uses.

1. Environmental effects were believed to be localized, and the culture of the day accepted routine environmental release.

2. Years later, the perchlorate anion was detected in groundwater. It has now become a *cause célèbre* among environmental activists and affiliated personal injury lawyers. Both have skillfully used the press to amplify their concerns.

3. Industry, the Department of Defense (DoD) and the National Aeronautics and Space Administration (NASA) were identified as Potentially Responsible Parties (PRPs)

under various statutes including the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA, or "Superfund").

4. Nonfederal PRPs are conducting remediation at numerous sites. Some are defense contractors that manufactured or used perchlorate for governmental purposes. Some have claims for reimbursement pending with the Federal government. Hence, these firms' financial liabilities will be shared by Federal taxpayers to an as-yet unknown degree.

5. Federal PRPs will abide by properly issued cleanup directives and standards, but they cannot be compelled to spend unappropriated funds and are exempt from bankruptcy.

    a. Active military ranges are exempt from RCRA under the Military Munitions Rule. Some States that have not adopted this rule seek to impose remediation requirements on active ranges.

    b. This rule does not apply to inactive ranges, so cleanup costs associated with base closure may be very large. Considerable attention has been devoted to sites where DoD may have had an historical presence but at which perchlorate releases by DoD have not been shown to have occurred (e.g., Rialto, California).

    c. Most pressure on DoD for cleanup has been political, not legal. See, e.g., letters from Sens. Feinstein, Boxer, Reid; Reps. Dingell and Solis.

        (i) Letters demand that DoD take action ahead of both the finalization of risk assessment and the promulgation of standards. Thy have no force of law.

        (ii) A credible explanation is that these legislators seek to elevate their States' claims against the fixed pot of funds available for remediation.

d. Sen. Boxer has pressed legislation to force EPA to expedite the promulgation of a primary drinking water standard. EPA has resisted.

(i) *The Safe Drinking Water Act (SDWA) prescribes procedures EPA must follow before deciding whether such a standard is warranted. EPA prefers to manage perchlorate within this framework rather than as an exception.*

(ii) *Given other contaminants that must compete for its regulatory affections, it is not obvious that EPA wants to regulate perchlorate under SDWA. As more States issue their own drinking water standards, the magnitude of remaining risks posed by perchlorate exposure and the degree to which it is a national phenomenon both decline.*

e. DoD seeks a remediation standard that is based on sound science and takes full account of both costs and benefits. EPA seems likely to agree fully with that language but perhaps disagree as to what it means in practice.

C. In a 1992 letter to EPA Region IX, EPA's Superfund Health Risk Technical Support Center in Cincinnati established a "provisional" Reference Dose (RfD) of 0.0001 milligrams per kilogram per day (mg/kg-day). This corresponds to a drinking water equivalent level (DWEL) of 4 parts per billion (ppb).

1. What is a Reference Dose (RfD)?

a. Defined by EPA, not by Federal law or regulation, as follows:

"An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." (See http://www.epa.gov/iris/gloss8.htm#r.)

b. While there is some scientific content in this definition, lawyers can clearly observe the nonscientific elements that drive the definition. Examples:

(i) *"Uncertainty spanning perhaps an order of magnitude" [10x]*

(ii) *Where is the (nominal) 10x span located—above the RfD, below the RfD, on both sides of the RfD, or bisected by the RfD?*

(iii) *What is a "sensitive subpopulation"? How large must a group be to be so identified? Must it be identifiable in fact or just in theory? What does "sensitive" mean?*

(iv) *How much risk is an "appreciable" risk?*

(v) *What is a "deleterious" effect?*

2. Science facts about the 1992 "provisional" RfD:

    a. It was based on 1952 study of 12 Graves' disease patients], eight of whom were treated with perchlorate at gram doses (i.e., more than 100,000 times the levels found in drinking water).

    b. It incorporates a 1000-fold "uncertainty factor" given limited scientific knowledge about low-level impacts in 1992.

    c. The "point of departure" from which this 1000-fold factor begins was substantial reduction in thyroid hormone levels—the therapeutic purpose of perchlorate administration in Graves' disease patients.

3. Procedural facts about the 1992 "provisional" RfD:

    a. It was an internal "issue paper" sent to EPA Region IX. There was no notice and comment.

    b. The document is silent with respect to how it ought to be used. ("There's nobody here but us chickens.")

4. Practical effects of the 1992 "provisional" RfD:

    a. The document does not establish a legally enforceable remediation standard. However, it invites others to set such a standard using the document as the scientific basis.

    b. Under CERCLA and RCRA, EPA has extremely broad authority to establish cleanup standards. Under CERCLA, it is very difficult for PRPs to challenge these standards.

c. For PRP-lead cleanups governed by a consent decree, there is no judicial review available. For Fund-lead cleanups, PRPs are liable unless they can prove that the remedy was "inconsistent" with the National Contingency Plan (NCP). The NCP was written to maximize EPA's interpretative discretion, so proving inconsistency is a very tall order.

d. The document provides an adequate scientific basis for a cleanup standard given the constrained legal procedures available under CERCLA.

5. Federal and private PRPs drew the following conclusions:

   a. The source of their problem was scientific uncertainty; EPA justified its 1000-fold "uncertainty factor" on the fact that much was not known about the risks of perchlorate at low levels. The solution of this problem was to fund and perform scientific research that would reduce scientific uncertainty, thereby enabling EPA to dramatically reduce its "uncertainty" factor and raise the RfD.

   b. Federal and private PRPs also shared the same policy objective: a rational balancing of costs and benefits in risk management decision making. Balancing costs and benefits required sound science and economic analysis, both of which were lacking.

   c. EPA may have been interested in reducing scientific uncertainty, but apparently was not so interested as to be willing to fund scientific research. Therefore, the PRPs inferred that if they did not fund this research themselves, no one would do so and risk management decisions would be based on the "provisional" RfD.

   d. Accordingly, the PRPs agreed to fund a battery of studies and to adhere to EPA demands concerning the nature of the data it said it needed to reduce its 1000-fold "uncertainty" factor.

6. Most of these conclusions proved incorrect because the premises which underlie them were false. (More about this below.)

D. The 1995 revised "provisional" RfD.

1. In 1995, industry PRPs provided EPA new scientific information and asked the Agency to reduce the "uncertainty" factor.

2. EPA continued to rely on the 1952 clinical study. EPA agreed that the 1000-fold "uncertainty" factor might be overly precautionary. EPA modified the "provisional" RfD to 0.0001—0.0005 mg/kg-day, 4-18 ppb DWEL. The revised "provisional" RfD uses an "uncertainty" factor range of 300—1000.

3. The 1995 "provisional" RfD is still in place. Both EPA Regions and States use it as the basis for site-specific remediation standards. Some States use it as the basis for provisional drinking water standards.

E. 1997-98: With great fanfare, the "Public-Private Partnership" including industry, DoD, EPA, various California agencies, and others, is formed.

1. Peer consultation including all stakeholders says RfD cannot be derived based on limited information available. EPA asks DoD to fund new studies in accordance with EPA protocols.

2. Second peer consultation including representatives from DoD, EPA, and Cal/EPA to set funding priorities.

3. Studies are performed to inform risk assessment.

4. Eight high-priority studies identified; DoD agrees to fund.

5. Federal Interagency Perchlorate Steering Committee (IPSC) formed to coordinate. Public meetings held, collaboration sought with other stakeholders.

F. EPA's 1998 draft health risk assessment.

1. EPA treated a certain histological phenomenon (hypertrophy) as equivalent to a pre-cancerous condition (hyperplasia).

2. EPA proposed a reference dose of 0.0009 mg/kg-day, 32 ppb DWEL. The composite uncertainty factor was 100.

3. 1999 EPA-funded external peer review.

    a. Little or no controversy arises over the procedures. EPA contractor consults with stakeholders to ensure balance. Procedures allow for active stakeholder participation in the peer review.

    b. Panel critical of both EPA's scientific rationale and the proposed RfD. Panel says hypertrophy is an adaptive cellular response and not an adverse effect, as stated by EPA. Panel says EPA's proposed RfD is very likely to be overly precautionary, and could be increased substantially if certain studies were performed or repeated.

G. EPA's 1999 "Interim Assessment Guidance".

1. Pressure has been mounting on EPA to set enforceable standards.

    a. Industry expects EPA to increase the "provisional" RfD to 32 ppb DWEL pending completion of new studies, second risk assessment and subsequent peer review.

    b. EPA Regions demand guidance from HQ.

2. EPA's Office of Research and Development (ORD) issued this "Interim Assessment Guidance" via a memorandum to Regional Administrators. EPA acknowledges the 1999 peer review but does not reveal or comment upon the panel's conclusions. EPA uses "uncertainty" to justify leaving the "provisional" RfD unchanged.

    a. "Because ORD is committed to bringing the latest available science to bear on the human and ecotoxicology assessments, ORD is recommending that … EPA risk assessors and risk managers follow the attached interim guidance" (emphasis added).

    b. "The Office of Research and Development (ORD) recommends that Agency risk assessors and risk managers continue to use the standing provisional RfD range of 0.0001 to 0.0005 mg/kg-day for perchlorate-related assessment activities" (emphasis added).

c. "The standing provisional RfD range is the more conservative of the estimates available at this time and, therefore, more likely to be public health protective in the face of this uncertainty."

d. "This document provides guidance to EPA Regions concerning Agency activities related to perchlorate. It also provides guidance to the public and the regulated community on how EPA intends to exercise its discretion in carrying out these activities. The guidance is designed to implement national policy on these issues. The document does not, however, substitute for EPA statutes [sic] and regulations; nor is it a regulation itself. Thus, it cannot impose legally binding requirements on EPA or the regulated community, and may not apply to a particular situation based upon the circumstances. EPA decisionmakers retain the discretion to adopt approaches on a case-by-case basis that differ from this guidance where appropriate. EPA may change this guidance in the future."

H. Perchlorate Study Group (PSG) is formed. PSG is an unincorporated alliance of manufacturers and aerospace users. PSG agrees to fund new studies recommended by the 1999 external peer review panel in hopes that EPA will raise the RfD.

I. Results of new studies, as reported by their authors, led federal and industry PRPs to believe that EPA's revised risk assessment would conclude that environmental levels of perchlorate posed no human health risk and that a much higher RfD was scientifically appropriate.

1. No neurodevelopmental effects were detected in animals.

2. No behavioral effects were detected in animals.

3. No evidence of carcinogenicity, immunotoxicity, or other effects was found.

J. EPA's 2001 draft health risk assessment differed substantially from these expectations.

1. EPA subjected the animal data to *post hoc* statistical analysis and found what it characterized as adverse effects at the lowest doses tested. (These effects consisted

of differences in the thickness of certain brain structures in rat pups.)

2. EPA concluded that ecological studies in California and Arizona which claimed adverse effects at low doses strongly supported its conclusions. (Both studies were subsequently refuted.)

3. EPA proposed an RfD of 0.00003 mg/kg-day, 1 ppb DWEL. EPA's composite "uncertainty" factor was 300, the same as the lower bound of the range from 1995.

4. The point of departure from which EPA applied this factor was iodide uptake inhibition (IUI) at the sodium iodide symporter (NIS), a protein "gate" through which iodine is taken into the thyroid gland.

    a. IUI is biochemically mundane, and occurs routinely due to a host of factors including diet.

    b. IUI occurs at exposure levels thousands of times below any change in thyroid hormone levels.

    c. The half-life of perchlorate is about 8 hours and is fully excreted without metabolism. This means that exposures on $day_{(t)}$ are essentially absent by $day_{(t+2)}$. Therefore, exposure must be virtually continuous to sustain any biochemical or biological effect, and risk cannot be modeled as a function of cumulative exposure.

    d. Substantial and persistent perchlorate exposure is needed to reduce thyroid hormones. Occupational exposures as high as 17,500 ppb DWEL over several years had failed to do so.

    e. A substantial and sustained decrease in thyroid hormones, at very specific times during gestation, is needed to create potential neurodevelopmental risk in the fetus. There are no data suggesting that this has ever happened.

    f. EPA's selected endpoint of concern is "subtle neurodevelopmental impairment"—i.e., effects too small to be detected.

5. EPA scheduled an external peer review 60 days after release of draft health risk assessment, which ran for 500+ pages plus included thousands of pages of supporting documentation. EPA did not disclose the California ecological study.

K. The Public-Private Partnership disintegrates.

1. Potential consequences were staggering: Site remediation costs estimated in $ billions; vast reaches of So Cal (e.g., all of the Colorado River from Lake Mead south) would require treatment.

2. Federal agency PRPs were particularly angry given previously collegial relationship with a sister federal agency, and they strenuously objected to the peer review.

a. The schedule was too fast, implying falsely that a public health crisis existed.

b. The composition of the panel was suspect in certain respects.

c. EPA sought comments on its risk assessment but excluded the review of these comments from the Charge to peer reviewers.

d. The rules of procedure denied all stakeholders save EPA a meaningful opportunity to participate.

3. What could explain EPA's behavior?

a. Genuine disagreement about the science.

b. Predetermined policy bias rather than science (i.e., preference for risk management decisions based on a low RfD).

c. Institutional incapacity to raise an RfD (i.e., make it less "protective") irrespective of the scientific evidence.

d. Others?

L. What Went Wrong.

1. The Public-Private Partnership was based on false premises.

a. "EPA and PRPs share the same goals and objectives."

(i) For PRPs, perchlorate cleanup is not their core business.

(a) Pollution is an expected "cost of doing business", so its cleanup is an expected burden.

(b) They are inclined to defer to EPA on cleanup standards and focus attention only on the least-cost method to comply.

(c) This deference can be self-defeating, as EPA often sets standards based on whatever they believe regulated entities can afford to pay.

(ii) For EPA, its core business is to identify potential harms, however remote, and order others to clean them up or prevent them from occurring.

(a) Public health and environmental benefits are hard to measure and fraught with controversy.

(b) Punitive costs borne by others serve as a political "biomarker" of EPA effectiveness ("Cost Theory of Benefit")

(iii) Imposing costly remedies supports the core business by reinforcing public perception that the problems EPA addresses are" important (e.g., is ppb-level perchlorate worse than "brown water" in the Berkshires?).

(a) EPA often bears significant institutional and political costs from failing to over-regulate

(b) EPA usually bears little or no institutional and political costs from excess regulation.

(c) But see "brown water" in Berkshires as an example of public backlash, albeit directed at Massachusetts Department of Environmental Protection, which relied on EPA risk assessment for its policy choices.

b. "If they were left alone to decide, EPA and PRP would identify essentially the same data gaps and design the same studies to fill those gaps."

   (i) For the PRPs, the reduction of scientific uncertainty was key to increasing the RfD. Thus, the PRPs identified gaps in scientific knowledge and sought to plug them, expecting that EPA would gain greater confidence that a higher RfD would be "safe".

   (ii) For EPA, scientific uncertainty is essential to preserve and maximize its decision making discretion. Thus, EPA was not interested in resolving scientific uncertainties; rather, EPA sought any evidence justifying its concern about potential risk at very low doses. EPA's choice of endpoint is crucial to understanding: subtle neurodevelopmental could never be proved not to occur, so the potential for such risks could never be ruled out.

c. "EPA risk assessments are policy-neutral (i.e., they do not have strong policy defaults embedded within them)."

   (i) This is known to be untrue by virtually all risk assessment practitioners.

   (ii) EPA asserts that, as a matter of both law and policy, it is inappropriate for its risk assessments to be policy-neutral. Hence, policy-neutrality is an undesirable attribute in a risk assessment.

d. "EPA risk management is a separate activity from risk assessment."

   (i) At EPA, risk management has never been convincingly shown to be a separate activity from risk assessment.

   (ii) EPA resists making the policy content of its risk assessments transparent so that others can tell where science ends and policy begins.

e. "EPA risk management decisions strike a rational balance among competing objectives, including cost."

(i) EPA has occasionally asserted that this is true, but documents the case only where social benefits vastly exceed social costs.

(ii) In any case where social costs exceed social benefits, EPA invokes other principles for risk management decision-making such as concern about uncertainty, needs for precaution, etc.

2. Based on these false premises, the PRPs agreed to fund studies based on EPA specifications and delegate the task of risk assessment to EPA.

a. EPA determined what data were needed. EPA selected the research protocols. EPA selected the contractors to perform the research. EPA reserved to itself sole authority to interpret the data.

b. Exceptions to (a) above prove the rule; the following studies were funded and performed without EPA control, and EPA has found them nettlesome:

(i) Greer et al. 2001: This clinical study showed no effects at all (much less <u>adverse</u> effects) healthy adults below 200 ppb. (EPA participated in developing the protocol and used some of the data in its risk assessment. Therefore, the Agency cannot dismiss the study's relevance.)

(ii) Lamm et al. 2000: This occupational study of perchlorate workers showed no measurable effects at exposures as high as 17,500 ppb drinking water equivalent. (EPA has asserted that the absence of adverse effects is attributable to weekend "recovery" that would necessarily occur in the drinking water context. That the magnitudes of the exposures in question are so high is not discussed.)

(iii) Crump et al. 2000: This epidemiological study of children in Chile showed no effects at exposure of 110 ppb. (This study is known to be confounded by high iodine intake, and EPA attributes the absence of adverse effects to excess iodine. EPA also has implicitly argued that Chilean children are too different from American children to be representative.)

3. Inadequate attention was paid to ensuring that the data used in the risk assessment meet appropriate data quality standards.

    a. After the fact, material errors were discovered in the design of the principal animal study the PRPs had funded (i.e., coronal v. sagittal sectioning; soy diets).

    b. After the fact, material errors were discovered in laboratory practices (i.e., errors in actual sectioning of brain tissue, causing biased measurements).

    c. Positive ecological studies that EPA judged supportive of their conclusions were shown to be suspect.

        (i) The ecological study in Arizona failed to control for the age of neonatal testing.

        (ii) Ecological study in California was a master's thesis dependent on undisclosed and non-reproducible data.

M. At several points, federal PRPs have appealed to the White House to intervene. Areas of concern include:

1. Science: EPA's characterization of the science is highly controversial.

2. Science policy: EPA's longstanding practice of embedding hidden policy judgments into ostensibly scientific work products takes away the authority of political officials to make policy decisions—in this case, make informed tradeoffs between environmental protection and national security, military readiness, and the space program (both manned and unmanned).

3. Regulatory policy: EPA's "assessment" guidance and "provisional" RfD are used as the scientific basis for selecting cleanup levels. More disturbingly, some EPA Regions and States rely on the EPA 2002 external peer review draft risk assessment as the basis for drinking water and cleanup standards.

N. The White House Interagency Working Group (IWG) on Perchlorate.

1. The IWG was established to address issues raised by Federal PRPs.

2. Procedural problems afflicted the IWG from the outset.

a. The IWG has been co-managed by competing loci of power within the White House—the Office of Management and Budget, the Council on Environmental Quality, the Office of Science and Technology Policy.

b. No charter was established for how the group would operate.

c. EPA owns the science and regulatory policy defaults. Overcoming these defaults usually requires consensus. Therefore, EPA benefits from procedural ambiguity, delay, and the inherent difficulties of collective decision-making.

d. No set of procedures governs its actions. Informal procedures were followed, and EPA has repeatedly violated them without penalty.

3. Products of the IWG process are important but limited.

    a. Science issues were referred to an ad hoc committee of the National Academies. NAS is one of few institutions capable of overruling EPA once it has made a (tentative) decision. Critical issues in any NAS review include:

        (i) The Charge.

        (ii) The experts.

        (iii) The staff.

b. Many science issues delegated to NAS could have been resolved with early attention to data quality.

c. Review of science policy and regulatory policy concerns have been delayed until conclusion of the NAS review.

II. WHAT ARE THE CRITICAL DATA QUALITY DECISION POINTS?

A. Durable prior agreement (DPA) must be secured on all salient issues before new scientific information is collected.

1. Why this matters: DPAs are like regulatory pre-nups—they protect assets the parties bring to the relationship and deter post-agreement mischief.

a. Are all parties with capacity to veto rational decisions included or neutralized? Often, entities not party to a DPA can kill it later.

b. In the case of perchlorate, some parties were not (or never could be) party to the agreement, but later they identified themselves as "essential" (e.g., environmental activists; personal injury attorneys; beneficiaries of the perception that perchlorate poses a high risk, such as purveyors of remediation and drinking water treatment technologies).

c. PRPs believed they had reached agreement, but this agreement was not made enforceable through a contract, consent decree or other device.

B. Contents of a durable prior agreement.

1. Agreement on a common objective.

a. Why this matters: Regulatory agencies generally have different objectives than those they regulate, even if the language they use is the same. Ambiguity invites conflicting interpretation.

(i) Example: "Sound science." Will anyone admit to preferring unsound science?

(ii) Example from the perchlorate Public-Private Partnership): "Credible science for credible decisions." Will anyone admit to preferring non-credible science, or incredible decisions?

b. Fundamental differences in EPA's mission (environmental protection) and DoD's mission (national security) made conflict inevitable.

2. Agreement on which questions are to be resolved by science and which questions are to be resolved by policy makers.

   a. Why this matters: Science and policy are non-transparently commingled in EPA risk assessment practices. EPA has a record of making policy decisions through ostensibly scientific analysis. Policy officials sometimes prefer the façade of science to avoid having to bear responsibility ("The scientists made me do it!")

   b. EPA science policy defaults often drive how scientific information will be interpreted such that high-quality science should not be funded. Example:

      (i) EPA policy on developmental and neurotoxicological (DNT) endpoints is that any change in any direction irrespective of dose-dependency is presumptively adverse.

      (ii) High-quality studies will show effects that, under EPA's policy, are presumptively adverse.

3. Agreement on the science policy defaults and what evidentiary standard is needed.

   a. Why this matters: Science policy defaults serve conflicting purposes:

      (i) Placeholders for scientific ignorance or uncertainty to be removed once ignorance or uncertainty is reduced.

      (ii) Placeholders for agency policy preferences.

b. Under (i) above, science policy defaults are temporary pending new scientific information superior to what the default was based on.

c. Under (ii) above, science policy defaults are permanent and immovable.

4. Agreement on the procedures that will be followed to determine whether the evidentiary standard has been met.

   a. Why this matters: Process is policy.

   b. Critical questions include:

      (i) Who decides?

      (ii) What criteria will be used?

      (iii) Does precedent matter? Who decides what precedents are applicable?

5. Agreement concerning how data will be collected, analyzed and interpreted?

    a. Why this matters: Scientific protocols determine what results are discoverable. The choice of statistical methods determines what results are discovered. The interpretative framework for data determines what the results mean.

    b. The funding partners did not consider this, and assumed EPA would follow best scientific practices.

6. Agreement on what constitutes an adequate answer such that no additional research would be required?

    a. Why this matters: Without clarity, there is no end to EPA's informational demands. There is always a chance that one more study will find a problem, or at least raise "concerns". EPA's discretion is maximized by uncertainty.

    b. The critical stopping point to define is, "What constitutes sufficient evidence of the absence of risk at exposure levels of interest?" Beware of irrelevancies, such as evidence of risk at unrealistically high exposure levels or under bizarre scenarios (e.g., trespassing subsistence infants).

7. Vigilant oversight of agency adherence to the DPA is essential.

    a. Why this matters: Trust is foolishness. Neither mistakes nor chicanery can be corrected after the fact.

    b. In theory, both the Administrative Procedure Act and new data quality procedures provide a means of disciplining misbehaving agencies. The courts give agencies great deference under the APA, so the utility of this appellate device is limited.

    c. Data quality procedures may be able to discipline agency misbehavior, though it is too new to draw conclusions.

C. If a DPA cannot be achieved, develop a strategic plan for the generation and use of scientific information combined with

vigorous oversight of EPA information via Paperwork Reduction Act and data quality procedures.

1. Rebuttable presumptions to guide your strategic plan:

    a. EPA will attempt to use its regulatory authorities (and if that fails, its permitting and/or enforcement authorities) to compel you to produce the information it wants.

    b. EPA will try to use against you any information you voluntarily generate and provide in the hope that it will persuade them of the correctness of your position.

    c. Secure all available legal protections to permit the candid expression of views, and establish appropriate communication methods from the outset.

        (i) Email is convenient, efficient, effective and dangerous.

        (ii) Email communications involving government agencies (including state universities) are permanent public records subject to FOIA.

2. Secure early, effective and genuinely independent scientific peer review.

    a. Why this matters: Peer review is the default mechanism for demonstrating "quality", but it cannot serve this purpose without genuine independence.

    b. By the time EPA seeks peer review, the Agency usually has reached at least a tentative conclusion. In such cases, Agency wants peer review to affirm its work, not to inform it. EPA's typical response to a critical peer review is to back-burner the issue for a new peer review panel.

    c. How EPA tries to control the peer review process:

        (i) EPA decides which among several peer review models to apply.

        (ii) EPA controls the Charge (i.e., instructions) to the reviewers.

(iii) EPA decides what expertise is needed, and can effectively include sympathetic reviewers by careful crafting of expertise requirements (e.g., expertise in "children's health").

(iv) EPA seeks peer reviewers who share the Agency's policy views and agenda; are willing to defer to EPA on science policy matters; or who benefit greatly from the access and prestige associated with service as a peer reviewer.

(v) EPA either selects the reviewers directly (e.g., Science Advisory Board) or hires the contractor that selects the reviewers. Contractors that select reviewers EPA doesn't like risk not being rehired.

(vi) EPA will behave defensively if peer reviewers behave too independently, acting in ways that encourage a favorable review and discourage an unfavorable one.

d. Critical issues that must be addressed for peer review to be genuinely independent:

(i) The peer review model.

(a) Review of the agency's work product for "adequacy". This is the default, and the default answer is that the work product is "adequate".

(b) Review of the underlying science on which the agency's work product depends. This model focuses on data quality, and prior to the 2003 UNMC Perchlorate State of the Science Symposium had never been attempted before.

(c) EPA hires contractors to avoid having to comply with the Federal Advisory Committee Act (FACA); see Byrd v. United States EPA, 174 F.3d 239 (D.C. Cir., 1999).

(d) Through its contracts, EPA has substantial influence over the procedures the contractor will follow without triggering the "management and control" test in Byrd.

(ii) The Charge. Issues include:

(a) Is the Charge overly broad? As the breadth of the Charge increases, the expertise of any panel thins out such that only 1 or 2 panelists have expertise in any specific area.

(b) Does the Charge direct the panel to review science or the Agency's derivative risk assessment?

(c) Does the Charge ask the panel to judge whether a derivative secondary document is correct, or only if it is "adequate"?

(d) Does the Charge ask or invite the panel to make policy judgments, or to affirm those made by EPA?

(iii) The experts. Issues include:

(a) Who selects them?

(b) What expertise do they have, or lack?

(c) Conflicts of interest. (See OMB's 2003 draft peer review bulletin.)

(d) Coincidence of interest. Do they see the world through the Agency's lens?

(iv) The staff.

(a) Who does the real work?

(b) On whom do they rely for assistance? The Agency?

(v) What does the Charge to peer reviewers include and exclude?

(a) Underlying, primary science?

(b) Derivative, secondary science?

(c) Science policy?

(d) Regulatory policy?

(vi) What procedures will be followed during the review?

(a) Active stakeholder participation? (e.g., 1999 EPA peer review)

(b) Agency domination with token stakeholder participation? (e.g., 2002 EPA peer review)

(c) Open participation? (e.g., 2003 UNMC Perchlorate State of the Science Symposium)

(vii) How does the agency respond to the peer review report?

(a) Neither law nor regulation specifies how EPA must respond.

(b) In no case is an agency required to defer to a peer review report; such deference would be an unconstitutional delegation of decision making authority.

(c) Peer review reports are committee work products, so they often contain mixed messages and/or internal inconsistencies. EPA excels in cherry-picking favorable comments and ignoring others.

3. Lessons from EPA peer review practices.

    a. Do not assume EPA peer reviews will be genuinely independent of focused on the most important issues.

    b. Do not assume that EPA will adequately respond to critical comments.

    c. Active engagement in the process is necessary (but not sufficient).

    d. The best strategy is to organize peer reviews of primary scientific studies before EPA does (e.g., 2003 UNMC Perchlorate State of the Science Symposium).

4. Aggressively use peer review to enhance the credibility of your own science.

    a. EPA can ignore your scientific information if it has not been peer reviewed.

    b. Peer review can create momentum in favor of your science that is hard for EPA to stop.

III. USING INFORMATION QUALITY STRATEGICALLY

A. Take stock of the available options.

1. Is it likely you can achieve a DPA, when so many before you have failed?

2. If not, develop a strategic plan for the vigorous oversight of information collected by EPA, and the generation of scientific information beneficial to your case.

B. Vigorously review the information EPA relies upon for risk assessment.

1. Use the data quality petition process to force EPA to disclose certain critical information.

    a. Transparency is the only universally accepted data quality principle.

    b. Information EPA did not disclose is essential to its case.

c. If a competent third-party cannot reproduce EPA's work, it cannot satisfy the data quality standard of "objectivity". "Influential" scientific information must satisfy this standard in order to be *potentially* objective.

2. Obtain genuinely independent review of the science EPA relies on. Refuse to allow EPA to control the process.

   a. Focus on primary science, not secondary agency risk assessments or policy issues.

   b. Apply consistent scientific standards to all data.

   c. Conduct the review in public with maximum public participation.

3. Communicate results to appropriate audiences.

   a. Results of independent review were presented to the NAS and were well received.

   b. Publication in a peer reviewed journal is planned.

C. Use the information quality petition process to force withdrawal of disseminated information that does not meet applicable data quality standards (especially for "influential" scientific information).

1. Where justified, use the data quality petition process to show that EPA science products are not credible.

2. No not use the data quality petition process to fight policy battles.

   a. Matters of scientific interpretation are very difficult to challenge this way.

   b. Policy matters are impossible to challenge this way.

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Additional Resources

General information

Government	http://www.firstgov.gov/ http://www.regulations.gov/ http://www.reginfo.gov/
Congress	http://thomas.loc.gov/home/legbranch/legbranch.html
OMB	http://www.whitehouse.gov/omb/
Federal Register	http://www.gpoaccess.gov/fr/index.html
Regulatory process	http://www.mercatus.org/regradar/category.php/42.html
Electronic dockets by agency	http://www.thecre.com/emerging/20020624_e-dockets.html

Regulatory information

Rules	http://www.whitehouse.gov/omb/inforeg/regpol.html http://www.mercatus.org/regradar/
Paperwork	http://www.whitehouse.gov/library/omb/OMBPPRWK.html http://www.whitehouse.gov/omb/inforeg/infocoll.html
Circulars A-4	http://www.whitehouse.gov/omb/circulars/index.html
Information policy and Guidelines	http://www.whitehouse.gov/omb/inforeg/infopoltech.html http://www.thecre.com/quality/index.html http://www.whitehouse.gov/omb/inforeg/agency_info_quality_links.html http://www.uschamber.com/government/issues/regulatory/dataquality.html
Peer Review	http://www.whitehouse.gov/omb/inforeg/peer_review_and_info_quality.pdf
Data access	http://www.thecre.com/access/index.html http://www.uschamber.com/government/issues/regulatory/dataaccess.html http://www.whitehouse.gov/omb/circulars/a110/a110.html#36
Regulation by information / guidance	http://www.thecre.com/information/index.html http://www.uschamber.com/government/issues/regulatory/guidance.html http://www.uschamber.com/government/issues/regulatory/scientific_rulemaking.html
Regulation by Litigation	http://www.thecre.com/regbylit/index.html
Regulation by Appropriations	http://www.thecre.com/appropriation/index.html
Regulatory Watchdogs	http://www.thecre.com/wdw/home.html http://www.sba.gov/advo/laws/law_regalerts.html

ATTACHMENT—Continued

Agency	Contact
Central Intelligence Agency	CIA Office of Public Affairs, 703–482–0623. No Website available.
Federal Financial Institutions Examinations Council Appraisal Subcommittee.	Marc Weinberg, 202–872–7520 Website: www.asc.gov.
General Services Administration	Tom Fitzpatrick, 202–501–0324 Website: www.cfo.gsa.gov.
Housing and Urban Development	Janice Blake-Green, 202–708–0638 Website: www.hud.gov/cfo/cforept.html.
Justice	Larry Silvis, 202–616–3754 Website: www.usdoj.gov.
Labor	Kathy Alejandro, 202–693–4026 Website: www.dol.gov.
National Capital Planning Commission	Connie Harshaw, 202–482–7200 Website: www.ncpc.gov.
National Labor Relations Board (OIG)	Emil George, 202–273–1960 Website: www.nlrb.gov/active.html.
Social Security Administration	Phil Kelly, 410–965–4656 Website: www.ssa.gov/budget.
Smithsonian Institution	Bruce Dauer, 202–357–2917 Website: www.si.edu.
Transportation	Bill Moga, 202–366–9666 Website: www.dot.gov.
Treasury	Kevin Whitfield, 202–622–0248 Website: www.treas.gov/fair.
U.S. Commission on Civil Rights	George Harbison, 202–376–8356 Website: www.usccr.gov.
Woodrow Wilson Center	Ronnie Dempsey, 202–691–4216 Website: www.wilsoncenter.org.

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OFFICE OF MANAGEMENT AND BUDGET

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

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 (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 20001 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 guidelilnes 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 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 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 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 objectively. 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 particular instance. If agency-sponsored peer review is employed to help satisfy the objectively 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 disclosed 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 or 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 whole.'' (66 FR 52137, October 12, 2001).

Although such cases of falsification are presumably rare, there is a significance 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 no 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 analytical 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 date 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 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.

Commercial 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.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.

OMS'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 filed 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's mechanisms, under paragraph III.3., shall apply to information that the agency disseminates on or after October 1, 2001, 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 or 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 the OMB for review regarding consistency with these OMB guidelines no later than July 1, 2001. 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 reconsider the uses of the information not only from 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, presentations 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 specific, 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 vigorous manner.''

ii. If an agency is response 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 practicable 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 such 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 equality 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 tolerate 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.

[FR Doc. 02–59 Filed 1–2–02; 8:45 am]

BILLING CODE 3110–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No 34–45191; File No. SR–CBOE–2001–59]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change and Amendment No. 1 Thereto by the Chicago Board Options Exchange, Incorporated Relating to the Amendment of CBOE Disciplinary Rules 17.9 and 17.10 and the Addition of CBOE Disciplinary Rule 17.15

December 26, 2001.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and rule 19b–4 thereunder,[2] notice is hereby given that on December 6, 2001, the Chicago Board Options Exchange, Inc. (''CBOE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items, I, II, and III below, which Items have been prepared by the CBOE. The CBOE filed Amendment No. 1 on December 17, 2001.[3] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CBOE proposes to amend several provisions of its disciplinary rules and add a new disciplinary rule.

Below is the text of the proposed rule change, as amended. Proposed new language is *italicized* and proposed deletions are in brackets.

* * * * *

Chicago Board Options Exchange, Incorporated Rules

Chapter XVII—Discipline

Rule 17.9. Decision

Following a hearing conducted pursuant to Rule 17.6 of this Chapter, the Panel shall issue a decision in writing, based solely on the record, determining whether the Respondent has committed a violation and imposing the sanction, if any, therefor. Where the Panel is not composed of at least a majority of the members of the Business Conduct Committee, its determination shall be automatically reviewed by a majority of the Committee, which may affirm, reverse or modify in whole or in part or may remand the matter for additional findings or supplemental proceedings. Such modification may include an increase or decrease of the sanction. The decision shall include a statement of findings and conclusions, with the reasons therefor, upon all material issues presented on the record. Where a sanction is imposed, the decision shall include a statement specifying the acts or practices in which the Respondent has been found to have engaged and setting forth the specific provision of the Securities Exchange Act of 1934, as amended, rules and regulations promulgated thereunder, constitutional provisions, by-laws, rules, interpretations or resolutions of the Exchange of which the acts are deemed to be in violation. The Respondents *and the Office of Enforcement* shall be promptly sent a copy of the decision. After Board review pursuant to Rule 17.10, or the time for such review has expired, the decision will be considered final, and the Exchange shall publish a summary of the decision in the Exchange Bulletin.

Rule 17.10. Review

(a)(1) Petition. *Both t[T]he Respondent and the Office of Enforcement* shall have 15 days after service of notice of *any*[a] decision made pursant to Rule 17.9 of this Chapter to petition for review of the decision by filing a copy of the petition with the Secretary of the Exchange (''Secretary'') and *with all other parties to the hearing* [the Exchange's Office of Enforcement]. Such petition shall be in writing and shall specify the findings and conclusions to which exceptions are taken together with reasons for such exceptions. Any objections to a decision not specified by written exception shall be considered to have been abandoned.

(2) Written Submissions. Within 15 days after a [Respondent's]petition for review has been filed with the Secretary of the Exchange pursuant to paragraph (a)(1) of this Rule, *the other parties to the hearing*[Exchange staff] may *each* submit to the Secretary a written response to the petition. A copy of the response must be served upon the *petitioner*[Respondent]. *The petitioner*[A Respondent] has 15 days from the service of the response to file a reply with the Secretary and the *other parties* [Office of Enforcement].

(b) Conduct of Review. The review shall be conducted by the Board or a committee of the Board composed of at least three Directors whose decision must be ratified by the Board. Any Director who participated in a matter before the Business Conduct or other Committee may not participate in any review of that matter by the Board. Unless the Board shall decide to open the record for the introduction of evidence or to hear argument, such review shall be based solely upon the record and the written exceptions filed by the parties. New issues may be raised by the Board; *the parties to the hearing*[Respondents] shall be given notice of and any opportunity to address any such new issues. The Board may affirm, reverse or modify, in whole or in part, the decision of the Business Conduct Committee. Such modification may include an increase or decrease of the sanction. The decision of the Board shall be in writing, shall be promptly served on the Respondent *and the Office of Enforcement,* and shall be final.

(c) Review on Motion of Board. The Board may on its own initiative order review of a decision made pursuant to Rule 17.7 or 17.9 of this Chapter within 30 days after notice of the decision has

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter from Christopher R. Hill, Attorney II, Office of Enforcement, Legal Division, CBOE, to Sapna Patel, Attorney, Division of Market Regulation, Commission, dated December 13, 2001 (''Amendment No. 1''). In Amendment No. 1, the CBOE made some technical corrections to the proposed rule text.

to March 24, 2003. The results of this investigation indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated July 2, 2003. The Notice states the nature of the violation, the provision of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violation.

The Licensee responded to the Notice in a letter dated July 22, 2003. In its response, the Licensee contended the violation may have been based on false information; therefore, the violation may not have occurred. The Licensee also requested full mitigation of the proposed civil penalty.

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined that the violation occurred as stated and that the penalty proposed for the violation designated in the Notice should be imposed.

In view of the foregoing and pursuant to section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, *it is hereby ordered that:*

The Licensee pay a civil penalty in the amount of $5,500 within 30 days of the date of this Order, in accordance with NUREG/BR–0254. In addition, at the time of making the payment, the licensee shall submit a statement indicating when and by what method payment was made, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852–2738.

The Licensee may request a hearing within 30 days of the date of this Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and include a statement of good cause for the extension. A request for a hearing should be clearly marked as a ''Request for an Enforcement Hearing'' and shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Rulemakings and Adjudications Staff, Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Materials Litigation and Enforcement at the same address, and to the Regional Administrator, NRC Region III, 801 Warrenville Road, Lisle, IL 60532–4351. Because of continuing disruptions in delivery of mail to United States Government offices, it is requested that requests for hearing be transmitted to the Secretary of the Commission either by means of facsimile transmission to 301–415–1101 or by e-mail to *hearingdocket@nrc.gov* and also to the Office of the General Counsel either by means of facsimile transmission to 301–415–3725 or by e-mail to *OGCMailCenter@nrc.gov.*

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order (or if written approval of an extension of time in which to request a hearing has not been granted), the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

(a) Whether the Licensee was in violation of the Commission's requirements as set forth in the Notice referenced in Section II above, and

(b) Whether, on the basis of such violation, this Order should be sustained.

Dated this 5th day of September, 2003.

For the Nuclear Regulatory Commission.

James G. Luehman,

Deputy Director, Office of Enforcement.

[FR Doc. 03–23399 Filed 9–12–03; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards, Meeting of the Subcommittee on Reactor Fuels; Notice of Meeting

The ACRS Subcommittee on Reactor Fuels will hold a meeting on September 29–30, 2003, Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

Portions of the meeting on September 30, 2003 may be closed to public attendance to discuss Electric Power Research Institute (EPRI) proprietary information per 5 U.S.C. 552b(c)(4).

The agenda for the subject meeting shall be as follows:

Monday, September 29, 2003—8:30 a.m. until the conclusion of business

Tuesday, September 30, 2003—8:30 a.m. until the conclusion of business

The purpose of this meeting is to review progress by the Office of Nuclear Regulatory Research in the area of high burnup fuels and other fuel-related research, to understand industry activities associated with the ''Robust Fuel Program,'' and to hear the experience of industry related to crud deposits on reactor fuels. The Subcommittee will hear presentations by and hold discussions with representatives of the NRC staff, EPRI, and other interested persons regarding these matters. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official, Mr. Ralph Caruso (telephone 301–415–8065) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Electronic recordings will be permitted only during those portions of the meeting that are open to the public.

Further information regarding this meeting can be obtained by contacting the Designated Federal Official between 8 a.m. and 5:30 p.m. (ET). Persons planning to attend this meeting are urged to contact the above named individual at least two working days prior to the meeting to be advised of any potential changes to the agenda.

Dated: September 9, 2003.

Sher Bahadur,

Associate Director for Technical Support, ACRS/ACNW.

[FR Doc. 03–23401 Filed 9–12–03; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF MANAGEMENT AND BUDGET

Proposed Bulletin on Peer Review and Information Quality

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

ACTION: Notice and request for comments.

SUMMARY: OMB requests comments on a proposed bulletin under Executive Order No. 12866 and supplemental information quality guidelines. As part of an ongoing effort to improve the quality, objectivity, utility, and integrity of information disseminated by the Federal Government to the public, the Office of Management and Budget (OMB), in coordination with the Office of Science and Technology Policy

(OSTP), proposes to issue new guidance to realize the benefits of meaningful peer review of the most important science disseminated by the Federal Government regarding regulatory topics. The proposed bulletin would be issued under the authority of Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658); 44 U.S.C. 3504(d)(1), 3506(a)(1)(B); Executive Order No. 12866, as amended. Part I of the Supplementary Information below provides background and the request for comments. Part II provides the text of the proposed bulletin.

DATES: Interested parties should submit comments to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget, at the address shown below on or before December 15, 2003.

ADDRESSES: Due to potential delays in OMB's receipt and processing of mail, respondents are strongly encouraged to submit comments electronically to ensure timely receipt. We cannot guarantee that comments mailed will be received before the comment closing date. Electronic comments may be submitted to: *OMB_peer_review@omb.eop.gov.* Please put the full body of your comments in the text of the electronic message and as an attachment. Please include your name, title, organization, postal address, telephone number, and e-mail address in the text of the message. Comments may also be submitted via facsimile to (202) 395–7245. Comments may be mailed to Dr. Margo Schwab, Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., New Executive Office Building, Room 10201, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Dr. Margo Schwab, Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., New Executive Office Building, Room 10201, Washington, DC 20503 (tel. (202) 395–3093).

John D. Graham,

Administrator, Office of Information and Regulatory Affairs.

SUPPLEMENTARY INFORMATION:

Part I—Background and Request for Comment

A ''peer review,'' as used in this document for scientific and technical information relevant to regulatory policies, is a scientifically rigorous review and critique of a study's methods, results, and findings by others in the field with requisite training and expertise. Independent, objective peer review has long been regarded as a critical element in ensuring the reliability of scientific analyses. For decades, the American academic and scientific communities have withheld acknowledgement of scientific studies that have not been subject to rigorous independent peer review. Peer review ''has been an essential part of the American science scene and one of the reasons why American science has done so well.'' Columbia University Provost Jonathon R. Cole (quoted in Abate, Tom, ''What's the Verdict on Peer Review?'' 21st Century, volume 1 (No. 1), Spring 1995, Columbia University); *see also* GAO Report, Peer Review Practices at Federal Science Agencies Vary, at 1 (March 1999) (''To help ensure the quality and integrity of the research, U.S. science has traditionally relied on independent reviews by peers.'').

Independent peer review is especially important for information that is relevant to regulatory policies. Agencies often develop or fund the science that underlies their regulations, and then oversee the peer review of those studies. Unless the peer review is conducted with genuine independence and objectivity, this can create at least the appearance of a conflict-of-interest. For example, it might be thought that scientists employed or funded by an agency could feel pressured to support what they perceive to be the agency's regulatory position, first in developing the science, and then in peer reviewing it. Scientists with a financial interest in the subject matter of a study (*e.g.*, ties to a regulated business) face a similar issue. Given that genuinely independent and objective peer review can provide a vital second opinion on the science that underlies federal regulation, the peer review of such information should be carried out under proper and clearly-articulated procedures.

Scientists and government officials have recognized the importance of peer review in regulatory processes:

- Joint Presidential/Congressional Commission on Risk Assessment and Risk Management: ''Peer review of economic and social science information should have as high a priority as peer review of health, ecological, and engineering information.'' Risk Assessment and Risk Management in Regulatory Decision-Making, vol. 2, at 103 (1997).
- The National Academies' National Research Council: ''[B]enefit-cost analysis should be subject to systematic, consistent, formal peer review.'' Valuing Health Risks, Costs, and Benefits for Environmental Decision Making, at 207 (1990).
- Congress' General Accounting Office: ''Peer review is critical for improving the quality of scientific and technical products * * *'' GAO Testimony Before the House Subcommittee on Energy and Environment, Committee on Science, at 8 (Mar. 11, 1997).
- Sally Katzen, Former Administrator of OIRA: Scientific inferences ''should pass muster under peer review by those in the same discipline, who should have an opportunity for such review to ensure that the underlying work was done competently and that any assumptions made are reasonable.'' Testimony Before the Environment, Energy, and Natural Resources Subcommittee of the House Committee on Government Operations (Feb. 1, 1994).

In addition, many bipartisan legislative proposals have supported independent, external peer review. See, *e.g.*, S. 343, the ''Comprehensive Regulatory Reform Act of 1995;'' S. 1001, the ''Regulatory Procedures Reform Act of 1995;'' S. 291, the ''Regulatory Reform Act of 1995;'' H.R. 1022, the ''Risk Assessment and Cost-Benefit Act of 1995.'' In 1999, for instance, a bipartisan coalition (including Senators Frist and Daschle, among many others) proposed to require agencies to conduct genuinely independent and transparent peer reviews of their most important risk assessments and cost-benefit analyses. See S. 746, the ''Regulatory Improvement Act of 1999.''[1]

Existing agency peer review mechanisms have not always been sufficient to ensure the reliability of regulatory information disseminated or relied upon by federal agencies. While most agencies have policies that require or encourage peer review, they do not always conduct peer review according to their own policies—even for major rulemakings. Indeed, an agency Inspector General recently found that although one agency had issued extensive agency peer review policies and mandates, ''[t]he critical science supporting the [agency's] rules was often not independently peer reviewed. Consequently, the quality of some science remains unknown.'' EPA OIG, Science to Support Rulemaking, at ii (Nov. 15, 2002) (emphasis supplied).

Even when agencies do conduct timely peer reviews, such reviews are sometimes undertaken by people who

[1] This legislative proposal was sponsored by a bipartisan coalition of 21 Senators, including Senators Levin, Thompson, Daschle, Frist, Moynihan, Voinovich, Stevens, Rockefeller, Abraham, Breaux, Roth, Robb, Cochran, Lincoln, and Enzi.

are not independent of the agencies, or are not perceived to be independent. Simply put, the agency proposing or supporting a regulation or study may not always be the best entity to commission or supervise its own peer review. Nonetheless, some agencies sometimes use their own employees to do peer reviews—a practice forbidden by other agencies' peer review manuals. See, *e.g.*, Agency for Toxic Substances & Disease Registry Peer Review Policy (Mar. 1, 1996) (peer review is ''by outside (not ATSDR) expert scientists''); DOJ, Office of Juvenile Justice & Deliquency Prevention, Peer Review Guideline at 1 (''Peer review is * * * by experts from outside the Department''). As the National Academies' National Research Council has explained:

> External experts often can be more open, frank, and challenging to the status quo than internal reviewers, who may feel constrained by organizational concerns. Evaluation by external reviewers thus can enhance the credibility of the peer review process by avoiding both the reality and the appearance of conflict of interest.

Peer Review in Environmental Technology Development Programs: The Department of Energy's Office of Science and Technology 3 (1998) (''NRC Report'').

The American Geophysical Union has likewise recognized that ''real or perceived conflicts of interest'' include the review of papers ''from those in the same institution.'' AGU, Guidelines to Publication of Geophysical Research (Oct. 2000). Congress did the same in the Superfund legislation by providing that reviewers should not have ''institutional ties with any person involved in the conduct of the study or research under review.'' 42 U.S.C. 9604(i)(13).

When an agency does initiate a program to select outside peer reviewers for regulatory science, it sometimes selects the same reviewers for all or nearly all of its peer reviews on a particular topic. While this may be appropriate in limited circumstances, more often it could lead an observer to conclude that the agency continually selected the peer reviewers because of its comfort with them. This hardly satisfies the purposes and principles underlying independent peer review. Thus, the National Academies' National Research Council has stressed that even ''standing panels should have rotating membership terms to ensure that fresh perspectives are regularly replenished.'' NRC, Scientific Research in Education 138.

It is also important to understand the relationship of the peer reviewers with the agency, including their funding history. A peer reviewer who is financially dependent on the agency, or at least hopes to profit financially from other dealings with the agency, may not always be completely independent, or appear truly independent. One agency's Inspector General has encouraged the agency to do a better job of ''consistently inquir[ing] whether peer review candidates have any financial relationship with [the agency].'' EPA OIG Report No. 1999–P–217, at 10 (1999). Medical journals have similarly recognized the possibility that the receipt of significant funding from an interested entity can lead to bias, or the perception of bias, on the part of a reviewer. See ''Financial Associations of Authors,'' New England Journal of Medicine, vol. 346, 1901–02 (2002); Philip Campbell, ''Declaration of Financial Interests,'' Nature, vol. 412, 751 (2001). But while some federal agencies are becoming more sensitive to peer reviewers' financial ties to private interests, most have not been as focused on reviewers' ties to the agency itself. See, *e.g.*, Food & Drug Administration Guidance on Conflict of Interest for Advisory Committee Members, Consultants & Experts (Feb. 2000); National Institutes of Health Center for Scientific Review, Review Procedures for Scientific Review Group Meetings (Oct. 24, 2002).

In addition to selecting independent and qualified peer reviewers for regulatory science, it is also essential to grant the peer reviewers access to sufficient information and to provide them with an appropriately broad mandate. In the past, some agencies have sought peer review of only narrow questions regarding a particular study or issue. While the scope of peer reviewers' responsibilities will necessarily vary by context, peer reviewers must generally be able to render a meaningful review of the work as a whole. As one agency's peer review handbook explains, a good charge to the peer reviewers is ordinarily one that both ''focuses the review by presenting specific questions and concerns'' the agency is aware of, and also ''invites general comments on the entire work product'' so as to ensure that the peer review is not hemmed in by inappropriately narrow questions. EPA Science Policy Council, Peer Review Handbook, § 3.2.1 (2d ed. 2000).

Even when an agency solicits a comprehensive and independent peer review of regulatory science, the results are not always available for public scrutiny or comment. While a non-transparent peer review may be better than no peer review at all, public scrutiny of at least a summary of the peer reviewers' analyses and conclusions helps to ensure that the peer review process is meaningful and that the agency has fairly considered the peer reviewers' conclusions. Simply put, openness enhances the credibility of the peer review of regulatory science.

For these reasons, the Fish and Wildlife Service and the National Oceanic and Atmospheric Administration have required that peer reviewers' reports and opinions be included in the administrative record for the regulatory action at issue. See Endangered & Threatened Wildlife and Plants: Notice of Interagency Cooperative Policy for Peer Review in Endangered Species Act Activities, 59 FR 34,270 (July 1, 1994). The Agency for Toxic Substances and Disease Registry further requires that final research reports ''consider all peer review comments,'' and that the ''reasons for not adopting any peer reviewer's comment should be documented.'' Agency for Toxic Substances & Disease Registry Peer Review Policy at 5.

While the peer review policies described above promote independent and transparent peer review, experience has shown that they are not always followed by all of the federal agencies, and that actual practice has not always lived up to the ideals underlying the various agencies' manuals. In the National Science and Technology Policy, Organization, and Priorities Act of 1976 (Pub. L. 94–282), Congress called on OSTP to serve as a source of scientific and technological analysis and judgment for the President with respect to major policies, plans, and programs of the Federal Government. Pursuant to the 1976 Act, OSTP has evaluated the scale, quality, and effectiveness of the federal effort in science and technology, and has led interagency efforts to develop and to implement sound science and technology policies.

The President and the Congress have also granted OMB the authority and responsibility to address agency peer review practices. Executive Order 12866, issued in 1993 by President Clinton, specifies in section 1(b)(7) that ''[e]ach agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, or other information concerning the need for, and consequences of, the intended regulation.'' The Executive Order further requires OMB to provide guidance to the agencies regarding regulatory planning. *See id.* section 2(b).

Similarly, the Paperwork Reduction Act requires the Director of OMB to ''develop and oversee the implementation of policies, principles, standards, and guidelines to * * *

apply to Federal agency dissemination of public information,'' and specifies that agencies are ''responsible for * * * complying with the * * * policies established by the Director.'' 44 U.S.C. 3504(d)(1), 3506(a)(1)(B). In the Information Quality Act, Congress further specified that OMB's guidelines should ''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.'' Pub. L. 106–554, section 515(a).

Proposed Guidance

OMB's current information quality guidance encourages but does not require peer reviews, and identifies general criteria that agencies should consider when they conduct such reviews. See Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 FR 8,452, 8,454–55, 8,459–60 (Feb. 22, 2002). To best serve the President's policy of improving our federal regulatory system and the quality and integrity of information disseminated by the federal agencies, OMB, in coordination with OSTP, now proposes to ensure that agencies conduct peer reviews of the most important scientific and technical information relevant to regulatory policies that they disseminate to the public, and that the peer reviews are reliable, independent, and transparent. This notice seeks comment on the following proposed guidance, which would take the form of an OMB Bulletin, would supplement (but not replace) OMB's information quality guidelines pursuant to the Information Quality Act, Pub. L. 106–554, section 515(b), and would also serve as guidance pursuant to the Paperwork Reduction Act, 44 U.S.C. 3504(d), and Executive Order 12866. OIRA will consult with OSTP in implementing this Bulletin as it relates to the peer review process.

Many agencies already have extensive peer review requirements. This guidance would supplement those requirements for the peer review of ''*significant regulatory information,*'' which is scientific or technical information that (i) qualifies as ''influential'' under OMB's information quality guidelines and (ii) is relevant to regulatory policies. This category does not include most routine statistical and financial information, such as that distributed by the Census Bureau, the Bureau of Labor Statistics and the Federal Reserve. Nor does it include science that is not directed toward regulatory issues, such as most of the scientific research conducted by the National Institutes of Health and the National Science Foundation. It is also limited to the peer review of *studies* to be disseminated, as opposed to applications for grants. In order to avoid duplication of effort, we have also exempted information that has already been adequately peer-reviewed from the peer review requirements of this Bulletin. Finally, OMB has excluded some categories of information, such as national security information, and some types of proceedings, such as individual adjudications and permit applications, from the scope of this Bulletin. The Bulletin also recognizes that waivers of these requirements may be required in some circumstances, such as when court-imposed deadlines or other exigencies make full compliance with this Bulletin impractical.

This Bulletin requires peer review of the category of ''significant regulatory information'' described above. It also articulates specific requirements for the peer review of ''significant regulatory information'' that the agency intends to disseminate in support of a major regulatory action, that could have a clear and substantial impact on important public policies or important private sector decisions with a possible impact of more than $100 million in any year, or that the Administrator of OIRA determines to be of significant interagency interest or relevant to an Administration policy priority. Such an impact can occur whether or not a federal rulemaking is envisioned or considered likely to occur, in part because information might influence local, state, regional, or international decisions. For this category of especially important information, whose reliability is paramount, agencies must take care to select external peer reviewers who possess the requisite experience and independence from the agency. The agencies must also provide the peer reviewers with sufficient information and an appropriately broad charge. The agency must then publicly respond to the peer reviewers' written report, and make other appropriate disclosures.

In addition to setting forth basic peer review procedures, this guidance also elaborates on the reporting requirements of Executive Order 12866 and the Information Quality Act. Pursuant to these authorities, agencies already provide OMB with information regarding upcoming regulatory initiatives and information quality issues. In doing so, each agency should make sure to identify: studies that will be subject to the peer review requirements of this Bulletin; the agency's plan for conducting the peer review; and correction requests filed by members of the public regarding the quality of information disseminated by the agency. These reporting requirements will permit the public, OMB, and OSTP to monitor agency compliance throughout the peer review process.

Finally, this Bulletin provides that each agency that receives a non-frivolous administrative correction request challenging the agency's compliance with the Information Quality Act must promptly post the request on its Internet website or forward a copy to OIRA and, if requested, consult with OIRA regarding the request. This consulting requirement will assist OMB in discharging its responsibility under the Information Quality Act to monitor the quality of information disseminated to the public. Together with the peer review and reporting requirements discussed above, it should also give the public reasonable assurance that the most important regulatory science disseminated by the federal government comes with indicia of reliability.

Additional Requests for Comment

OMB seeks comments from all interested parties on all aspects of this proposed Bulletin and guidelines. In particular, OMB seeks comment on the scope of this Bulletin. As explained above, this proposal covers significant regulatory information, with some exceptions. It may be that the overall scope of this Bulletin should be reduced or enlarged, or that fewer or more exceptions should be made.

OMB also seeks comment on whether some provisions of this proposal should be strengthened, modified, or removed. While the bipartisan legislative proposal discussed above required all peer reviewers to be independent of the agency, this proposal leaves open the possibility that agency employees could serve on peer review panels in certain circumstances. This proposal also identifies circumstances that raise questions about the independence of peer reviewers (*e.g.*, agency employees and agency-supported research projects), but it does not flatly preclude the selection of peer reviewers who raise some of those concerns. Members of the public are welcome to comment on whether these provisions strike the appropriate balance between safeguarding the fact and appearance of impartiality, on the one hand, and ensuring that qualified peer reviewers will not be precluded from service

based on unnecessarily stringent conflict-of-interest requirements, on the other. OMB is especially concerned about the government's need to recruit the best qualified scientists to serve as peer reviewers.

For this reason, OMB also seeks comment on whether any of the provisions of this proposal would unnecessarily burden participating scientists or discourage qualified scientists from participating in agency peer reviews. Specifically, OMB seeks comment on whether peer reviewers' disclosure requirements should be limited to a specific numbers of years, perhaps to activities occurring during the previous five or ten years, instead of extending back indefinitely. More generally, OMB seeks suggestions regarding how agencies can encourage peer-review participation by qualified scientists.

In addition, OMB seeks comment on whether agencies should be permitted to select their own peer reviewers for regulatory information. Although some observers may favor a system whereby a centralized body would appoint peer reviewers or supervise the details of the peer review process, OMB is not proposing such a system. Within the broad confines of this guidance, the agencies would retain significant discretion in formulating a peer review plan appropriate to each study. It is, however, arguable that an entity outside of the agency should select the peer reviewers and perhaps even supervise the peer review process. The latter approach might lend the appearance of greater integrity to the peer review process, but could be unduly inefficient and raise other concerns.

Finally, OMB seeks comment from the affected agencies on the expected benefits and burdens of this proposed Bulletin. OMB believes that most agencies usually submit the types of studies covered by this Bulletin to at least some peer review. As a result, while this Bulletin should improve the quality of peer reviews, it may not impose substantial costs and burdens on the agencies that they are not already incurring. OMB seeks comment on this and all other aspects of this proposed Bulletin.

Part II—Proposed OMB Bulletin and Supplemental Information Quality Guidelines

Section 1. Definitions

For purposes of this Bulletin and guidance:

''Administrator'' means the Administrator of the Office of Information and Regulatory Affairs.

''Agency'' has the meaning ascribed to it in the Paperwork Reduction Act, 44 U.S.C. 3502(1).

''Dissemination'' has the meaning ascribed to it in OMB's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 FR 8,452, 8,460 (Feb. 22, 2002) (''OMB's Information-Quality Guidelines'').

''The Information Quality Act'' means Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658).

''Major regulatory action'' means the type of significant regulatory action that is defined in Section 1(f)(1) of Executive Order 12866 and is not exempt from the requirements of that Order.

''Regulatory information'' means any scientific or technical study that is relevant to regulatory policy. Information is relevant to regulatory policy if it might be used by local, state, regional, federal and/or international regulatory bodies.

''Significant regulatory information'' means regulatory information that satisfies the ''influential'' test in OMB's Information-Quality Guidelines.

''Study'' refers broadly to any research report, data, finding, or other analysis.

Section 2. Peer Review of Significant Regulatory Information

To the extent permitted by law, agencies shall have an appropriate and scientifically-rigorous peer review conducted on all significant regulatory information that the agency intends to disseminate. Agencies need not, however, have peer review conducted on studies that have already been subjected to adequate independent peer review. For purposes of this Bulletin, peer review undertaken by a scientific journal may generally be presumed to be adequate. This presumption is rebuttable based on a persuasive showing in a particular instance. In addition, agencies need not have peer review conducted on significant regulatory information that relates to national defense or foreign affairs, or that is disseminated in the course of an individual agency adjudication or proceeding on a permit application.

During the planning of a peer review for significant regulatory information, the agency should select an appropriate peer review mechanism based on the novelty and complexity of the science to be reviewed, the benefit and cost implications, and any controversy regarding the science. Depending on these factors, appropriate peer review mechanisms for significant regulatory information can range from review by qualified specialists within an agency (if they reside in a separate agency program) to formal review by an independent body of experts outside the agency. The experts may be selected by the agency or an outside group.

Section 3. Additional Peer Review Requirements for Especially Significant Regulatory Information

If significant regulatory information is subject to the peer review requirements of Section 2 of this Bulletin and (i) the agency intends to disseminate the information in support of a major regulatory action, (ii) the dissemination of the information could otherwise have a clear and substantial impact on important public policies or important private sector decisions with a possible impact of more than $100 million in any year, or (iii) the Administrator determines that the information is of significant interagency interest or is relevant to an Administration policy priority, then, to the extent permitted by law, the agency shall have a formal, independent, external peer review conducted on the information. The peer review shall proceed in accordance with the following guidance:

Selection of Peer Reviewers: Peer reviewers shall be selected primarily on the basis of necessary scientific and technical expertise. When multiple disciplines are required, the selected reviewers should include as broad a range of expertise as is necessary. When selecting reviewers from the pool of qualified external experts, the agency sponsoring the review shall strive to appoint experts who, in addition to possessing the necessary scientific and technical expertise, are independent of the agency, do not possess real or perceived conflicts of interest, and are capable of approaching the subject matter in an open-minded and unbiased manner. Factors relevant to whether an individual satisfies these criteria include whether the individual: (i) Has any financial interests in the matter at issue; (ii) has, in recent years, advocated a position on the specific matter at issue; (iii) is currently receiving or seeking substantial funding from the agency through a contract or research grant (either directly or indirectly through another entity, such as a university); or (iv) has conducted multiple peer reviews for the same agency in recent years, or has conducted a peer review for the same agency on the same specific matter in recent years. If it is necessary to select a reviewer who is or appears to be biased in order to obtain a panel with appropriate expertise, the agency shall ensure that

another reviewer with a contrary bias is appointed to balance the panel.

Charge to Peer Reviewers: The agency shall provide to peer reviewers an explicit, written charge statement describing the purpose and scope of the review. The charge shall be appropriately broad and specific to facilitate a probing, meaningful critique of the agency's work product. Peer reviewers shall be asked to review scientific and technical matters, leaving policy determinations for the agency. This must be clearly stated and adhered to during the peer review process so the review is based solely on the science being evaluated. In addition, the agency shall be careful not to divulge internal deliberative information to the peer reviewers. The charge should generally frame specific questions about information quality, assumptions, hypotheses, methods, analytic results, and conclusions in the agency's work product. It should ask reviewers to apply the standards of OMB's Information-Quality Guidelines and the agency's own information quality guidelines. Where reviewers are expected to identify scientific uncertainties, they should generally be asked to suggest ways to reduce or eliminate those uncertainties.

Information Access: The agency shall provide peer reviewers sufficient information to enable them to understand the data, methods, analytic results, and conclusions of the material to be peer reviewed, with due regard for the agency's interest in protecting its deliberative processes. Reviewers shall be informed of the reproducibility and other quality guidelines issued by OMB and federal agencies under the Information Quality Act. If the document is a formal regulatory analysis, reviewers should be briefed on the content of OMB's guidelines for regulatory analysis. If aspects of the agency's work are likely to be controversial, reviewers should be provided relevant background information on those potential sources of controversy.

Opportunity for Public Comment: The agency shall provide an opportunity for other interested agencies and persons to submit comments. The agency shall ensure that such comments are provided to the peer reviewers with ample time for consideration before the peer reviewers conclude their review and prepare their report.

Peer Review Reports: The agency shall direct peer reviewers of the regulatory information—individually or often as a group—to issue a final report detailing the nature of their review and their findings and conclusions. The peer review report shall also disclose the names, organizational affiliations, and qualifications of all peer reviewers, as well as any current or previous involvement by a peer reviewer with the agency or issue under peer review consideration. If there is a group report, any partial or complete dissenting statements should be included with the group's final report. The agency shall also provide a written response to the peer review report(s) explaining: The agency's agreement or disagreement with the report(s), including any recommendations expressed therein; the basis for that agreement or disagreement; any actions the agency has undertaken or proposed to undertake in response to the report(s); and (if applicable) the reasons the agency believes those actions satisfy any concerns or recommendations expressed by the report(s). The agency shall disseminate the final peer review report(s) and the agency's written statement of response in the same manner that it disseminates the work product that was reviewed. All of these written materials should be included in the administrative record for any related rulemakings.

Consultation with OIRA and OSTP: Agencies shall consult with OIRA and OSTP concerning the sufficiency of their planned peer review policies. Upon request, an agency should discuss with OIRA how the agency plans to review a specific document covered by the Bulletin and whether such a plan is sufficient. This consultation is understood to serve as one of the pre-dissemination quality procedures envisioned by the Information Quality Act.

Certification in Administrative Record: If an agency relies on significant regulatory information subject to the requirements of this section in support of a major regulatory action, it shall include in the administrative record for that action a certification explaining how the agency has complied with the requirements of this Bulletin and the Information Quality Act with respect to the significant regulatory information at issue.

Section 4. Peer Review Procedures

a. Federal Advisory Committee Act

When considering selection of an outside panel of peer reviewers for regulatory information subject to the requirements of this Bulletin, an agency should assess the treatment of such a panel under the Federal Advisory Committee Act, and may retain a firm to oversee the peer review process with instructions to comply with principles consistent with those set forth in this Bulletin. See *Byrd* v. *EPA,* 174 F.3d 239 (D.C. Cir. 1999) (holding that peer review panels selected and supervised by outside consultants are not governed by the Federal Advisory Committee Act, 5 U.S.C.S. App. II §§ 1–15). Although such a firm can be engaged to oversee multiple peer review processes for an agency, the agency shall ensure that the firm itself possesses independence (and the appearance of independence) from the agency.

b. Agency Guidelines

Based on this supplement to OMB's information quality guidelines, each agency shall supplement or amend its own information quality guidelines to incorporate the requirements of Sections 2 and 3 herein on a prospective basis, except that an agency need not amend its guidelines if there is no reasonable likelihood that the agency will disseminate information covered by the requirements of Sections 2 and/or 3 of this Bulletin. In addition to incorporating these requirements, agencies should have specific guidelines as to what entanglements with agencies or affected businesses are so significant as to preclude an individual's participation as a peer reviewer, irrespective of other factors. Agency guidance should also address the following additional aspects of the peer review process, as well as any other matters they wish to address: the protection of confidential business information; any other needs for confidentiality in the peer review process (including any privacy interests of peer reviewers); and any types of information regarding the peer reviewers that should be publicly disclosed in addition to the information identified in Section 3 of this Bulletin (potentially including prior service as an expert witness, sources of personal or institutional funding, and/or other matters that might suggest a possible conflict of interest or appearance of a conflict of interest).

c. Waiver

The Administrator may waive some or all of the peer review requirements of Sections 2 and/or 3 of this Bulletin if an agency makes a compelling case that waiver is necessitated for specific information by an emergency, imminent health hazard, homeland security threat, or some other compelling rationale. As appropriate, the Administrator shall consult with the Director of OSTP before deciding whether to grant a waiver.

Section 5. Interagency Work Group on Peer Review Policies

The Administrator will periodically convene a meeting of an interagency group of peer review specialists and program managers, including the OSTP Associate Director for Science. The group may make recommendations regarding best peer review practices and may recommend other steps to expedite and improve agency processes.

Section 6. Reports on Agency Peer Reviews

Each agency shall provide to OIRA at least once each year:

- A summary description of any existing, ongoing, or contemplated scientific or technical studies that might (in whole or in part) constitute or support significant regulatory information the agency intends to disseminate within the next year; and
- The agency s plan for conducting a peer review of such studies under the requirements of this Bulletin, including the identification of an agency contact to whom inquiries may be directed to learn the specifics of the plan.

In order to minimize the paperwork involved, agencies should include this information in one of the periodic reports they submit to OMB under Executive Order 12866 or the Information Quality Act.

Section 7. Correction Requests Under the Information Quality Act

The Information Quality Act requires OMB to issue guidance concerning administrative mechanisms by which members of the public may seek to obtain correction of information maintained and disseminated by an agency. See Pub. L. 106–554, section 515(b)(2)(B). OMB must also monitor the agencies' handling of such correction requests. See id.(C).

In order to improve OMB's ability to assess the quality of information disseminated to the public and the adequacy of agencies' request-handling processes, an agency shall, within seven days of receipt, provide OIRA with a copy of each non-frivolous information quality correction request. If an agency posts such a request on its Internet website within seven days of receipt, it need not provide a copy to OIRA.

Upon request by OIRA, each agency shall provide a copy of its draft response to any such information quality correction request or appeal at least seven days prior to its intended issuance, and consult with OIRA to ensure the response is consistent with the Information Quality Act, OMB's government-wide Information Quality Guidelines, and the agency's own information quality guidelines. The agency shall not issue its response until OIRA has concluded consultation with the agency. OIRA may consult with OSTP as appropriate if a request alleges deficiencies in the peer review process.

Section 8. Interagency Comment

Interagency comment can assist in identifying questions or weaknesses in scientific and technical analyses. As part of its consideration of peer reviews, information quality correction requests, or major regulatory actions, OIRA may exercise its authority to request comment from other agencies. OIRA may make such comment public, or direct that it be included in the Administrative Record for any related rulemakings. Interagency comment may be conducted in addition to peer review, or may comprise the peer review required by Sections 2 and/or 3 of this Bulletin if it is conducted in accordance with the requirements of this Bulletin.

Section 9. Effective Date and Existing Law

The requirements of this Bulletin apply to information disseminated on or after January 1, 2004. The requirements are not intended to displace other peer review mechanisms already created by law. Any such mechanisms should be employed in a manner as consistent as possible with the practices and procedures laid out herein. Agencies may consult with OIRA regarding the relationship of this Bulletin with preexisting law.

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PENSION BENEFIT GUARANTY CORPORATION

Required Interest Rate Assumption for Determining Variable-Rate Premium; Interest Assumptions for Multiemployer Plan Valuations Following Mass Withdrawal

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of interest rates and assumptions.

SUMMARY: This notice informs the public of the interest rates and assumptions to be used under certain Pension Benefit Guaranty Corporation regulations. These rates and assumptions are published elsewhere (or can be derived from rates published elsewhere), but are collected and published in this notice for the convenience of the public. Interest rates are also published on the PBGC's Web site (*http://www.pbgc.gov*).

DATES: The required interest rate for determining the variable-rate premium under part 4006 applies to premium payment years beginning in September 2003. The interest assumptions for performing multiemployer plan valuations following mass withdrawal under part 4281 apply to valuation dates occurring in October 2003.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION:

Variable-Rate Premiums

Section 4006(a)(3)(E)(iii)(II) of the Employee Retirement Income Security Act of 1974 (ERISA) and § 4006.4(b)(1) of the PBGC's regulation on Premium Rates (29 CFR part 4006) prescribe use of an assumed interest rate (the ''required interest rate'') in determining a single-employer plan's variable-rate premium. The required interest rate is the ''applicable percentage'' (currently 100 percent) of the annual yield on 30-year Treasury securities for the month preceding the beginning of the plan year for which premiums are being paid (the ''premium payment year''). (Although the Treasury Department has ceased issuing 30-year securities, the Internal Revenue Service announces a surrogate yield figure each month—based on the 30-year Treasury bond maturing in February 2031—which the PBGC uses to determine the required interest rate.)

The required interest rate to be used in determining variable-rate premiums for premium payment years beginning in September 2003 is 5.31 percent.

The following table lists the required interest rates to be used in determining variable-rate premiums for premium payment years beginning between October 2002 and September 2003.

For premium payment years beginning in:	The required interest rate is:
October 2002	4.76
November 2002	4.93
December 2002	4.96
January 2003	4.92
February 2003	4.94
March 2003	4.81
April 2003	4.80
May 2003	4.90
June 2003	4.53
July 2003	4.37

April 15, 2004

OFFICE OF MANAGEMENT AND BUDGET
Revised Information Quality Bulletin for Peer Review

INTRODUCTION

On September 15, 2003, OIRA published a draft Peer Review Bulletin for public comment. We received 187 comments during the public comment period, participated in a public workshop at the National Academy of Sciences (NAS), and undertook an interagency review process. This process led to a substantially revised Bulletin, which incorporates many of the diverse perspectives and suggestions voiced during the comment period.

As almost all commenters recognized, peer review is an important way to enhance the quality of information. When done in an open, rigorous manner, independent peer review improves both the quality of scientific information and the public's confidence in the integrity of science.

Under this Bulletin, agencies must undertake a peer review of influential scientific information before they disseminate the information to the public. Different types of peer review are appropriate for different types of information products, and agencies are granted under this Bulletin appropriate discretion to weigh the benefits and costs of using a particular peer review mechanism for a particular information product. This Bulletin leaves the selection of a peer review mechanism for influential scientific information to the agency's discretion. Based on public and agency comments, we also exempted various types of information products from the requirements of this Bulletin, including time-sensitive medical, health, and safety determinations, in order to ensure that peer review does not unduly delay the release of time-sensitive findings.

This Bulletin also imposes minimum requirements for the peer review of highly influential scientific assessments, which are a subset of influential scientific information. A scientific assessment is an evaluation of a body of scientific or technical knowledge which typically synthesizes multiple factual inputs, data, models, assumptions, and/or

applies best professional judgment to bridge uncertainties in the available information. Although the proposed Bulletin imposed heightened peer review requirements on a broader array of information products, we agree with some commenters that, in order to ensure that the Bulletin is not too costly or rigid, more intensive peer review should be restricted to the more important information disseminated by the federal government.

Even for this category of highly influential scientific assessments, the revised Bulletin leaves broad discretion to the agency formulating the peer review plan. In general, an agency conducting a peer review of a highly influential scientific assessment must ensure that the peer review process is transparent by making available to the public a written charge to the peer reviewers, the peer reviewers' report, and the agency's response to the peer reviewers' report. The agency selecting peer reviewers must ensure that the reviewers possess the necessary expertise. In addition, the agency must address reviewers' potential conflicts of interest (including those stemming from ties to regulated businesses) and independence from the agency. In response to comments, this revised Bulletin encourages agencies to consider using the panel selection criteria employed by the NAS. The use of a transparent process, coupled with the selection of objective and independent peer reviewers, should improve the quality of government science while promoting public confidence in the integrity of the government's scientific products.

PEER REVIEW

Peer review is one of the important procedures used in science to ensure that the quality of published information meets the standards of the scientific community. It is a form of deliberation involving an exchange of judgments about the appropriateness of methods and the strength of the author's inferences.[1] Peer review occurs when a draft product is reviewed for quality by specialists who were not involved in producing the draft.

[1] Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving Regulatory Decision Making, Carnegie Commission, New York, 1993: 75.

The peer reviewer's report is an evaluation or critique that is used by the authors of the draft to improve the product. Peer review typically evaluates the clarity of hypotheses, the validity of the research design, the quality of the data collection procedures, the robustness of the methods employed, the appropriateness of the methods for the hypotheses being tested, the extent to which the conclusions follow from the analysis, and the strengths and limitations of the overall product.

Peer review has diverse purposes. Editors of scientific journals use reviewer comments to help determine whether a draft scientific article is of sufficient quality, importance, and interest to a field of study to justify publication. Research funding organizations often use peer review to evaluate research proposals. In addition, some federal agencies make use of peer review to obtain evaluations of draft information products that contain important scientific determinations.

Peer review should not be confused with public comment and other stakeholder processes. The selection of participants in a peer review is based on expertise, independence, and the absence of conflict of interest. Furthermore, notice-and-comment procedures for agency rulemaking do not provide an adequate substitute for peer review, as disinterested experts -- especially those most knowledgeable in a field -- often do not file public comments with federal agencies.

The critique provided by a peer review often suggests ways to clarify assumptions, findings, and conclusions. For instance, peer reviews can filter out biases and identify oversights, omissions, and inconsistencies.[2] Peer review also may encourage authors to more fully acknowledge limitations and uncertainties. In some cases, reviewers might recommend major changes to the draft, such as refinement of hypotheses, reconsideration of research design, modifications of data collection or analysis methods, or alternative conclusions. However, peer review does not always lead to specific modifications in the draft product. In some cases, a draft is in excellent shape

[2] William W. Lowrance, Modern Science and Human Values, Oxford University Press, New York, NY 1985: 85.

prior to being submitted for review. In others, the authors do not concur with changes suggested by one or more reviewers.

Peer review may take a variety of forms, depending upon the nature and importance of the product. For example, the reviewers may represent one scientific discipline or a variety of disciplines; the number of reviewers may range from a few to more than a dozen; the names of each reviewer may be disclosed publicly or may remain anonymous (e.g., to encourage candor); the reviewers may be blinded to the authors of the report or the names of the authors may be disclosed to the reviewers; the reviewers may prepare individual reports or a panel of reviewers may be constituted to produce a collaborative report; panels may do their work electronically or they may meet together in person to discuss and prepare their evaluations; and reviewers may be compensated for their work or they may donate their time as a contribution to science or public service.

For large, complex reports, different reviewers may be assigned to different chapters or topics. Such reports may be reviewed in stages, sometimes with blinded, confidential reviews that precede a public process of panel review. As part of peer review, there may be opportunity for written and/or oral public comments on the draft product.

The results of peer review are often only one of the criteria used to make decisions about journal publication, grant funding, and information dissemination. For instance, the editors of scientific journals (rather than the peer reviewers) make final decisions about a manuscript's appropriateness for publication based on a variety of considerations. In research-funding decisions, the reports of peer reviewers often play an important role, but the final decisions about funding are often made by accountable officials based on a variety of considerations. Similarly, when a government agency sponsors peer review of its own draft documents, the peer review reports are an important factor in information dissemination decisions, but are rarely the sole consideration. Agencies are not expected to cede their discretion with regard to dissemination or use of

information to peer reviewers; accountable agency officials must make the final decisions.

THE NEED FOR STRONGER PEER REVIEW POLICIES

There are a multiplicity of science advisory procedures used at federal agencies and across the wide variety of scientific products prepared by agencies[3]. In response to congressional inquiry, the U.S. General Accounting Office documented the variability in both the definition and implementation of peer review across agencies.[4] The Carnegie Commission on Science, Technology and Government[5] has highlighted the importance of "internal" scientific advice (within the agency) and "external" advice (through scientific advisory boards and other mechanisms).

A wide variety of authorities have argued that peer review practices at federal agencies need to be strengthened.[6] Other arguments focus on specific types of scientific products (e.g., assessments of health, safety and environmental hazards).[7] Indeed, the Congressional/Presidential Commission on Risk Assessment and Risk Management

[3] Sheila Jasanoff, The Fifth Branch: Science Advisors as Policy Makers ,Harvard University Press, Boston, 1990.
[4] U.S. General Accounting Office, Federal Research: Peer Review Practices at Federal Agencies Vary, GAO/RCED-99-99, Washington, D.C., 1999.
[5] Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving Regulatory Decision Making, Carnegie Commission, New York, 1993: 90.
[6] National Academy of Sciences, Peer Review in the Department of Energy – Office of Science and Technology, Interim Report, National Academy Press, Washington, D.C., 1997; National Academy of Sciences, Peer Review in Environmental Technology Development: The Department of Energy – Office of Science and Technology, National Academy Press, Washington, D.C., 1998; National Academy of Sciences, Strengthening Science at the U.S. Environmental Protection Agency: Research-Management and Peer-Review Practices, National Academy Press, Washington, D.C. 2000; U.S. General Accounting Office, EPA's Science Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance, GAO-01-536, Washington, D.C., 2001; U. S. Environmental Protection Agency, Office of Inspector General, Pilot Study: Science in Support of Rulemaking 2003-P-00003, Washington, D.C., 2002; Carnegie Commission on Science, Technology, and Government, In the National Interest: The Federal Government in the Reform of K-12 Math and Science Education, Carnegie Commission, New York, 1991; U.S. General Accounting Office, Endangered Species Program: Information on How Funds Are Allocated and What Activities are Emphasized, GAO-02-581, Washington, D.C. 2002.
[7] National Research Council, Science and Judgment in Risk Assessment, National Academy Press, Washington, D.C., 1994.

suggests that "peer review of economic and social science information should have as high a priority as peer review of health, ecological, and engineering information."[8]

Some agencies have formal peer review policies, while others do not. Even agencies that have such policies do not always follow them prior to the release of important scientific products.

Prior to the development of this Bulletin, there were no government-wide standards concerning when peer review is required and, if required, what type of peer review processes are appropriate. No formal interagency mechanism existed to foster cross-agency sharing of experiences with peer review practices and policies. Despite the importance of peer review for the credibility of agency scientific products, the public lacks a consistent way to determine when an important scientific information product is being developed by an agency, the type of peer review planned for that product, or whether there will be an opportunity to provide comments and data to the reviewers.

This Bulletin establishes minimum standards for when peer review is required for scientific information and the types of peer review that should be considered by agencies in different circumstances. It also establishes a transparent process for public disclosure of peer review planning, including the establishment of an agenda that describes the peer review process that the agency has chosen for each of its forthcoming influential scientific information products.

LEGAL AUTHORITY FOR THE BULLETIN

This Bulletin is issued under the Information Quality Act and OMB's general authorities to oversee the quality of agency information, analyses, and regulatory actions. In the Information Quality Act, Congress directed OMB to issue guidelines to "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the

[8] Presidential/Congressional Commission on Risk Assessment and Risk Management, Risk Commission Report, Volume 2, Risk Assessment and Risk Management in Regulatory Decision-Making, 1997:103.

quality, objectivity, utility and integrity of information" disseminated by Federal agencies. Pub. L. 106-554, § 515(a). The Information Quality Act was crafted as an amendment to the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq., which requires OMB, among other things, to "develop and oversee the implementation of policies, principles, standards, and guidelines to . . . apply to Federal agency dissemination of public information." In addition, Executive Order 12866, 58 Fed. Reg. 51735 (Oct. 4, 1993), establishes that OIRA is "the repository of expertise concerning regulatory issues," and it directs OMB to provide guidance to the agencies on regulatory planning. E.O. 12866, § 2(b). The Order also requires that "[e]ach agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, or other information." E.O. 12866, § 1(b)(7). Finally, OMB has general authority to manage the agencies under the purview of the President's Constitutional authority to oversee the unitary Executive Branch. See, e.g., the Budget and Accounting Procedures Act of 1950, as amended, 31 U.S.C. § 1111; Reorganization Plan No. 2 of 1970, 84 Stat. 2085; Executive Order 11541, 35 Fed. Reg. 10737 (July 1, 1970); Executive Order 12866. All of these authorities support this Bulletin.

THE REQUIREMENTS OF THIS BULLETIN

This Bulletin addresses peer review of scientific information disseminations that contain findings or conclusions that represent the official position of one or more Departments or agencies of the federal government.

Section I: Definitions

Section I provides definitions that are central to this Bulletin. Several terms are identical to or based on those used in OMB's government-wide information quality guidelines 67 Fed. Reg. 8452 (Feb. 22, 2002), and the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq. The term "Administrator" means the Administrator of the Office of Information and Regulatory Affairs in the Office of Management and Budget. The term "agency" includes all agencies subject to the Paperwork Reduction Act, see 44 U.S.C. § 3502(1).

The term "Information Quality Act" means Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. Law 106-554; H.R. 5658).

The term "dissemination" means agency initiated or sponsored distribution of information to the public. Dissemination does not include distribution limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; or responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or similar law. This definition also excludes distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas and adjudicative processes. Finally, "dissemination" also excludes information distributed for peer review in compliance with this Bulletin, provided that the distributing agency includes an appropriate and clear disclaimer on the information, as explained more fully below.

In the context of this Bulletin, the definition of "dissemination" also goes beyond the definition in OMB's government-wide information quality guidelines to address the need for peer review prior to official dissemination of the information product. In cases where a draft report or other information is released by an agency for purposes of peer review, a question may arise as to whether the draft report constitutes an official "dissemination" under information-quality guidelines. Normally, draft reports undergoing peer review are not intended as disseminations -- because they are not yet final -- and thus Section I instructs agencies to make this clear by presenting the following disclaimer in the report:

> "THIS INFORMATION IS DISTRIBUTED SOLELY FOR THE PURPOSE OF PRE-DISSEMINATION PEER REVIEW UNDER APPLICABLE INFORMATION QUALITY GUIDELINES. IT HAS NOT BEEN FORMALLY DISSEMINATED BY [THE AGENCY] AND SHOULD NOT BE CONSTRUED TO REPRESENT ANY AGENCY DETERMINATION OR POLICY."

This disclaimer should appear on each page of a draft report in cases where the information is highly relevant to specific policy or regulatory deliberations. Agencies also should discourage state, local, international and private organizations from using

information in draft reports that are undergoing peer review. Draft influential scientific information being presented at scientific meetings prior to peer review must include the disclaimer: "THE VIEWS IN THIS REPORT (PRESENTATION) ARE THOSE OF THE AUTHOR(S) AND DO NOT NECESSARILY REPRESENT THE VIEWS OF THE FUNDING AGENCY."

For the purposes of the peer review Bulletin, the term "scientific information" means factual inputs, data, models, analyses, or scientific assessments related to such disciplines as the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences. This includes 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 on a web page to information that others disseminate. This definition excludes opinions, where the agency's presentation makes clear that an individual's opinion, rather than a statement of fact or of the agency's views, is being offered.

The term "influential scientific information" means the scientific information the dissemination of which the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions. In OMB's government-wide information quality guidelines, the term "influential information" is used in the context of "influential scientific, financial, or statistical information." However, this Bulletin only covers "influential scientific information."

For the purposes of this Bulletin, the term "scientific assessment" means an evaluation of a body of scientific or technical knowledge which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. These assessments include, but are not limited to, state-of-science reports, technology assessments, weight-of-evidence analyses, meta-analyses, risk assessments, toxicological profiles of substances, integrated assessment models, hazard determinations, exposure assessments, or health,

ecological, or safety assessments. The assessment will often draw upon knowledge from multiple disciplines.

Section II: Peer Review of Influential Scientific Information

Section II requires each agency to subject "influential" scientific information to peer review prior to dissemination. For dissemination of influential scientific information, Section II provides agencies broad discretion in determining what type of peer review is appropriate and what procedures should be employed to select appropriate reviewers.

The National Academy of Public Administration suggests that the intensity of peer review should be commensurate with the significance of the information being disseminated and the likely implications for policy decisions.[9] Furthermore, agencies need to consider tradeoffs between depth of peer review and timeliness.[10] More rigorous peer review is necessary for information that is based on novel methods or presents complex challenges for interpretation. Furthermore, the need for rigorous peer review is greater when the information contains precedent-setting methods or models, presents conclusions that are likely to change prevailing practices, or is likely to affect policy decisions that have a significant impact.

This tradeoff can be considered in a benefit-cost framework. The costs of peer review are the direct costs of the peer review activity, and the potential delay in government and private actions that can result from peer review. The benefits of peer review are equally clear: the insights offered by peer reviewers may lead to policy with more benefits and/or fewer costs. In addition to contributing to strong science, peer review, if performed fairly and rigorously, can build consensus among stakeholders and

[9] National Academy of Public Administration, Setting Priorities, Getting Results: A New Direction for EPA, National Academy Press, Washington, D.C., 1995:23.
[10] Presidential/Congressional Commission on Risk Assessment and Risk Management, Risk Commission Report, 1997.

reduce the temptation for courts and legislators to second-guess agency actions.[11] While it will not always be easy for agencies to quantify the benefits and costs of peer review, we encourage agencies to approach peer review from a benefit-cost perspective.

Regardless of the peer review mechanism chosen, agencies should strive to ensure that their peer review practices are characterized by both scientific integrity and process integrity. "Scientific integrity," in the context of peer review, refers to such issues as "expertise and balance of the panel members, the identification of the scientific issues and clarity of the charge to the panel, and the quality, focus and depth of the discussion of the issues by the panel, the rationale and supportability of the panel's findings, and the accuracy and clarity of the panel report." "Process integrity" includes such issues as "transparency and openness, avoidance of real or perceived conflicts of interest, a workable process for public comment and involvement," as well as adhering to defined procedures.[12]

When deciding what type of peer review mechanism is appropriate for a specific information product, agencies will need to consider at least the following issues: individual versus panel review; timing; the scope of the review; the selection of reviewers; disclosure; public participation; and disposition of reviewer comments. These issues are relevant to any peer review under this Bulletin.

Individual versus Panel Review

Letter reviews by several experts generally will be more expeditious than convening a panel of a dozen or more experts. Individual letters are more appropriate when a draft document covers only one discipline or when premature disclosure of a sensitive report to a public panel could cause harm to government or private interests.

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[11] Mark R. Powell, Science at EPA: Information in the Regulatory Process, Resources for the Future, Washington, D.C., 1999: 148, 176; Sheila Jasanoff, The Fifth Branch: Science Advisors as Policy Makers, Harvard University Press, Boston, 1990: 242.

[12] ILSI Risk Sciences Institute, "Policies and Procedures: Model Peer Review Center of Excellence," 2002: 4. Available at http://rsi.ilsi.org/file/Policies&Procedures.pdf.

When time and resources warrant, panels are preferable, as they tend to be more deliberative than individual letter reviews and the reviewers can learn from each other. There are also multi-stage processes in which confidential letter reviews are conducted prior to release of a draft document for public notice and comment, followed by a formal panel review. These more rigorous and expensive processes are appropriate for highly complex, multidisciplinary, and more important documents, especially those that are novel or precedent-setting.

Timing of Peer Review

As a general rule, it is most useful to consult with peers early in the process of producing an information product. For example, in the context of risk assessments, it is valuable to have the choice of input data and the specification of the model reviewed by peers before the agency invests time and resources in implementing the model and interpreting the results. "Early" peer review occurs in time to "focus attention on data inadequacies in time for corrections."[13]

When an information product is a critical component of rule-making, it is important to obtain peer review before the agency announces its regulatory options so that any technical corrections can be made before the agency becomes invested in a specific approach or the positions of interest groups have hardened. If review occurs too late, it is unlikely to contribute to the course of a rulemaking. For instance, use of peer review is more often regarded as "generally successful" when it occurs "early" in the agency's deliberative process. Furthermore, investing in a more rigorous peer review early in the process "may provide net benefit by reducing the prospect of challenges to a regulation that later may trigger time consuming and resource-draining litigation."[14]

[13] Testimony of Bruce Alberts, PhD., President, National Academy of Sciences, February 24, 1998, Hearing on S. 981, before Senate Committee on Governmental Affairs.

[14] Fred Anderson, Mary Ann Chirba Martin, E Donald Elliott, Cynthia Farina, Ernest Gellhorn, John D. Graham, C. Boyden Gray, Jeffrey Holmstead, Ronald M. Levin, Lars Noah, Katherine Rhyne, Jonathan Baert Wiener, "Regulatory Improvement Legislation: Risk Assessment, Cost-Benefit Analysis, and Judicial Review," Duke Environmental Law and Policy Forum, Fall 2000, vol. XI (1): 132.

Scope of the Review

The "charge" contains the instructions to the peer reviewers regarding the objective of the peer review and the specific advice sought. The importance of the information, which shapes the goal of the peer review, influences the charge. For instance, the goal of the review might be to determine the utility of a body of literature for drawing certain conclusions about the feasibility of a technology or the safety of a product. In this context, an agency might ask reviewers to determine the relevance of conclusions drawn in one context for other contexts (e.g., different exposure conditions or patient populations).

The charge to the reviewers should be determined in advance of the selection of the reviewers. In drafting the charge, it is important to remember the strengths and limitations of peer review. Peer review is most powerful when the charge is specific and steers the reviewers to specific technical questions while also directing reviewers to offer a broad evaluation of the overall product.

Uncertainty is inherent in science, and in many cases individual studies do not produce conclusive evidence. Rather, what is being reviewed in the case of scientific assessments is a scientific judgment rather than "scientific fact."[15] Specialists attempt to reach a consensus by weighing the accumulated evidence. As such, it is important that peer reviewers be asked to ensure that scientific uncertainties are clearly identified and characterized. Furthermore, since not all uncertainties will have an equal effect on the conclusions drawn, reviewers can be asked to ensure that the potential implications of the uncertainties for the technical conclusions drawn are clear. Within this context, peer reviewers can make an important contribution by distinguishing scientific facts from professional judgments. Reviewers might be asked to provide advice on reasonable judgments that can be made from the scientific evidence, but the charge should make clear that the reviewers are not to provide advice on the policy (e.g., the amount of

[15] Mark R. Powell, Science at EPA: Information in the Regulatory Process, Resources for the Future, Washington, D.C., 1999: 139.

uncertainty that is acceptable or the amount of precaution that should be embedded in an analysis). Such considerations are the purview of the government.[16] In addition, peer reviewers might be asked to consider value-of-information analyses that identify whether more research is likely to decrease key uncertainties.[17] Value-of-information analysis was suggested for this purpose in the reports of the Presidential/Congressional Commission on Risk Assessment and Risk Management.[18] A description of additional research that would appreciably influence the conclusions of the assessment might help an agency target any additional research resources available for this problem.

Selection of Reviewers

Expertise. The most important factor in selecting reviewers is expertise: ensuring that the selected reviewer has the knowledge, experience, and skills necessary to perform the review. In cases where the document being reviewed spans a variety of scientific disciplines or areas of technical expertise, reviewers who represent the necessary spectrum of knowledge should be chosen. For instance, expertise in applied mathematics and statistics is essential in the review of models, thereby allowing an audit of calculations and claims of significance and robustness based on the numeric data.[19] For some reviews, evaluation of biological plausibility is as important as statistical modeling.

Balance. Reviewers should also be selected to represent a diversity of scientific perspectives relevant to the subject. On most controversial issues, there exists a range of respected scientific viewpoints regarding interpretation of the available literature. Inviting reviewers with competing views on the science may lead to a sharper, more focused peer review. Indeed, as a final layer of review, some organizations (e.g., the

[16] Ibid.
[17] Granger Morgan and Max Henrion, "The Value of Knowing How Little You Know," Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis, Cambridge University Press, 1990: 307.
[18] Presidential/Congressional Commission on Risk Assessment and Risk Management, Risk Commission Report, 1997, Volume 1: 39, Volume 2: 91.
[19] William W. Lowrance, Modern Science and Human Values, Oxford University Press, New York, NY 1985: 86.

National Academy of Sciences) specifically recruit reviewers with strong opinions to test the scientific strength and balance of their reports.

Independence. In its narrowest sense, independence in a reviewer means that the reviewer was not involved in producing the draft document to be reviewed. However, for peer review of some documents, a broader view of independence is often necessary to assure credibility of the process. Reviewers are generally not employed by the agency or office producing the document. As the National Academy of Sciences has stated, "external experts often can be more open, frank, and challenging to the status quo than internal reviewers, who may feel constrained by organizational concerns."[20] The Carnegie Commission on Science, Technology, and Government notes that "external science advisory boards serve a critically important function in providing regulatory agencies with expert advice on a range of issues."[21] However, the choice of reviewers requires a case-by-case analysis. In some instances, reviewers employed by other federal and state agencies may be sufficiently independent.

A related issue raised by some commentators is whether government-funded scientists in universities and consulting firms have sufficient independence from the federal agencies that support their work to be appropriate peer reviewers for those agencies.[22] This concern can be mitigated in situations where the scientist determines the hypothesis to be tested or the method to be developed, which effectively creates a buffer between the scientist and the agency. Similarly, when an agency awards grants through a competitive process that includes peer review, the agency's potential to influence the scientist's research is limited. As such, when a scientist is awarded a government research grant through an investigator-initiated, peer-reviewed competition, there generally should be no question as to that scientist's ability to offer independent scientific advice to the agency on other projects. This contrasts, for example, to a situation in

[20] National Research Council, Peer Review in Environmental Technology Development Programs: The Department of Energy's Office of Science and Technology, National Academy Press, Washington, D.C., 1998: 3.
[21] Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving Regulatory Decision Making, Carnegie Commission, New York, 1993: 90.

which a scientist has a consulting or contractual arrangement with the agency or office sponsoring a peer review. Likewise, when the agency and a researcher work together to design or implement a study, there is less independence from the agency. Furthermore, if a scientist has repeatedly served as a reviewer for the same agency, some may question whether that scientist is sufficiently independent from the agency to be employed as a peer reviewer on agency-sponsored projects.

As the foregoing suggests, independence issues pose a complex set of questions which much be considered by agencies when peer reviewers are selected. In general, agencies should make an effort to rotate peer review responsibilities across the available pool of qualified reviewers, recognizing that in some cases repeated service by the same reviewer is needed because of essential expertise.

Some agencies have built entire organizations to provide independent scientific advice while other agencies tend to employ ad hoc scientific panels on specific issues. Respect for the independence of reviewers may be enhanced if an agency collects names of potential reviewers based on considerations of expertise and reputation for objectivity from the public, including scientific or professional societies. The Department of Energy's use of the American Society of Mechanical Engineers to identify potential peer reviewers from a variety of different scientific societies provides an example of how professional societies can assist in the development of an independent peer review panel.[23]

Conflict of Interest. The National Academy of Sciences defines "conflict of interest" as any financial or other interest that conflicts with the service of an individual on the review panel because it could impair the individual's objectivity or could create an unfair

[22] Lars Noah, "Scientific 'Republicanism': Expert Peer Review and the Quest for Regulatory Deliberation, Emory Law Journal, Atlanta, Fall 2000:1066.
[23] American Society for Mechanical Engineers, Assessment of Technologies Supported by the Office of Science and Technology, Department of Engineering: Results of the Peer Review for Fiscal Year 2002, ASME Technical Publishing, Danvers, MA, 2002.

competitive advantage for a person or organization.[24] This standard provides a useful benchmark for agencies to consider in selecting peer reviewers. Agencies should make a special effort to examine prospective reviewers' potential financial conflicts, including significant investments, consulting arrangements, employer affiliations and grants/contracts. Financial ties of potential reviewers to regulated entities and regulatory agencies should be scrutinized when the information being reviewed is likely to be relevant to regulatory policy. The inquiry into potential conflicts goes beyond financial investments and business relationships and includes work as an expert witness, consulting arrangements, honoraria and sources of grants and contracts. To prevent any real or perceived conflicts of interest with potential reviewers and questions regarding the independence of reviewers, we refer agencies to federal ethics requirements, applicable standards issued by the Office of Government Ethics, and the prevailing practices of the National Academy of Sciences. Specifically, peer reviewers who are federal employees (including special government employees) are subject to federal requirements governing conflicts of interest. See, e.g., 18 U.S.C. § 208; 5 C.F.R. Part 2635. With respect to reviewers who are not federal employees, agencies should adopt or adapt the prevailing practices of the NAS regarding committee composition, conflicts, and balance[25] and/or the applicable ethics requirements that have been developed by the U.S. government, including the standards of the Office of Government Ethics.[26] Both NAS and the federal government recognize that under certain circumstances some conflict may be unavoidable in order to obtain the necessary expertise. See, for example, 18 U.S.C. § 208(b)(3).

[24] National Academy of Science, "Policy and Procedures on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports," May 2003: Available at: http://www.nationalacademies.org/coi/index.html.
[25] Ibid.

Disclosure Policies: Anonymous versus Identified Reviewers

In choosing the appropriate peer review mechanism, agencies must balance the need for confidentiality of reviews with the need for transparency. In a journal review, the most common practice is to keep the names and affiliations of the reviewers confidential. This confidentiality is designed to encourage reviewers to be candid in their evaluations of the draft product under review. Such confidentiality may also encourage participation by qualified scientists. However, in the context of peer review of government products, such confidentiality may not always add to the credibility of the review process. Where the issue under review is likely to have large public or private sector impacts, the agency may decide that more transparency is in the public interest. In such cases, disclosure of the slate of reviewer names and their qualifications can strengthen public confidence in the peer review process. It may be feasible to disclose information about reviewers without disclosing their specific opinions. The degree of public disclosure of information about reviewers should balance the need for transparency with the need to protect the privacy of scientists.

Public Participation

Public comments can be important in shaping expert deliberations. Agencies may decide that peer review should precede an opportunity for public comment to ensure that the public receives the most scientifically strong product (rather than one that may change substantially as a result of peer reviewer suggestions). However, there are situations in which public participation in peer review is an important aspect of obtaining a high-quality product through a credible process. Agencies, however, should avoid open-ended comment periods, which may delay completion of peer reviews and complicate the completion of the final work product.

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[26] United States Office of Government Ethics, "Standards of Ethical Conduct for Employees of the Executive Branch," Washington, D.C., 2002. Available at: http://www.usoge.gov/pages/forms_pubs_otherdocs/fpo_files/reference/rfsoc_02.pdf

Public participation can take a variety of forms, including opportunities to provide oral comments before a peer review or requests to provide written comment to the peer reviewers. Another option is for agencies to publish a "request for comment" or other notice in which they solicit public comment before a panel of peer reviewers performs its work.

Disposition of Reviewer Comments

A peer review is considered completed once the Agency considers and addresses the reviewers' comments. All reviewer comments should be given reasonable consideration and be incorporated where relevant and valid. As part of the peer review planning process, agencies should determine whether they will consider reviewer comments confidential or make them available to the public once the reviewed document is disseminated. For instance, in the context of risk assessments, the National Academy of Sciences recommends that peer review include a written evaluation made available for public inspection.[27] Reviewers should be informed about how their comments will be disseminated, whether they will be disclosed with attribution, or whether they will be summarized without attribution. In cases where there is a public panel, the agency should plan publication of both the peer review report(s) and the Agency's response to peer reviewer comments.

Section III: Peer Review of Highly Influential Scientific Assessments

Whereas Section II leaves most of the considerations regarding the form of the peer review to the agency's discretion, Section III requires a more rigorous form of peer review for highly influential scientific assessments. The requirements of Section II of this Bulletin apply to Section III. In addition, Section III has some specific requirements, which are discussed below. In planning a peer review under Section III, agencies typically will have to devote greater resources and attention to the issues discussed in

[27] National Research Council, Risk Assessment in the Federal Government: Managing the Process, National Academy Press, Washington, D.C., 1983.

Section II, i.e., individual versus panel review; timing; the scope of the review; the selection of reviewers; disclosure; public participation; and disposition of reviewer comments.

The term “scientific assessment” means an evaluation of a body of scientific or technical knowledge which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. These assessments include, but are not limited to, state-of-science reports, technology assessments, weight-of-evidence analyses, meta-analyses, risk assessments, toxicological profiles of substances, integrated assessment models, hazard determinations, exposure assessments, or health, ecological, or safety assessments. Typically, the data and models used in scientific assessments have already been subject to some form of peer review (e.g., refereed journal peer review or peer review under Section II of this Bulletin).

A scientific assessment is considered "highly influential" if the agency or the OIRA Administrator determines that the dissemination could have a clear and substantial impact on important public policies (including regulatory actions) or private sector decisions with a potential effect of more than $500 million in any one year or that the dissemination involves precedent setting, novel and complex approaches, or significant interagency interest. One of the ways information can exert economic impact is through the costs or benefits of a regulation based on the disseminated information. The qualitative aspect of this definition may be most useful in cases where it is difficult for an agency to predict the potential economic effect of dissemination. If information is covered by Section III, an agency is required to adhere to the peer-review procedures specified in Section III.

With regard to the selection of reviewers, Section III(2)(a) emphasizes consideration of expertise and balance. Expertise refers to the required knowledge, experience and skills required to perform the review whereas balance refers to the need for diversity in scientific perspective and disciplines. We emphasize that the term "balance" here refers not to balancing of stakeholder or political interests but rather to a broad and diverse

representation of respected perspectives and intellectual traditions within the scientific community.

Section III(2)(b) instructs agencies to consider barring participation by scientists with a conflict of interest. The conflict of interest standards for Sections II and III of the Bulletin are identical. As discussed under Section II, those peer reviewers who are federal employees, including Special Government Employees, are subject to applicable statutory and regulatory standards for federal employees. For non-government employees, agencies should adopt or adapt the applicable ethical standards used by the federal government and/or the NAS.

Section III(2)(c) instructs agencies to ensure that reviewers are independent of the agency sponsoring the review. Scientists employed by the sponsoring agency are not permitted to serve as reviewers for highly influential scientific information. This does not preclude Special Government Employees, such as academics appointed to advisory committees, from serving as peer reviewers. Agencies (or their contractors) should seek and consider potential reviewers who have been nominated based on their expertise and objectivity by the public, including scientific and professional societies. We considered whether a reviewer is independent of the agency if that reviewer receives a substantial amount of research funding from the agency sponsoring the review. Research grants that were awarded to the scientist based on investigator-initiated, competitive, peer-reviewed proposals do not generally raise issues of independence. However, significant consulting and contractual relationships with the agency may raise issues of independence or conflict, depending upon the situation. Repeated use of the same reviewer in multiple assessments may raise issues of independence unless the particular reviewer's expertise is essential. Agencies can generally avoid the effect of use of the same reviewer by rotating membership across the available pool of qualified reviewers. Similarly, when using standing panels of scientific advisors, we suggest rotating membership among qualified scientists in order to obtain fresh perspectives and reinforce the reality and perception of independence from the agency. Section III(3)(c) also requires agencies to consider the

prevailing selection practices used by the National Academy of Sciences, since they were designed to ensure independence from sponsors in the federal government.

Section III(3) requires agencies to provide reviewers with sufficient background information, including access to key studies, data and models, to perform their role as peer reviewers. In this respect, the peer review envisioned in Section III is more rigorous than some forms of journal peer review, where the reviewer is often not provided access to underlying data or models. Reviewers should be informed of applicable access, objectivity, reproducibility and other quality standards under federal information quality laws.

Section III(4) addresses opportunity for public participation in peer review, and provides that the agency should, wherever possible, provide for public participation. In some cases, an assessment may be so sensitive that it is critical that the agency's assessment achieve a high level of quality before it is publicized. In those situations, a rigorous yet confidential peer-review process may be appropriate, prior to public release of the assessment. If an agency decides to make a draft assessment publicly available at the onset of a peer review process, the agency shall, whenever possible, provide a vehicle for the public to provide written comments, make an oral presentation before the peer reviewers, or both. When written public comments are received, the agency should ensure that peer reviewers receive copies of comments that address significant scientific issues with ample time to consider them in their review.

Section III(5) requires that agencies instruct reviewers to prepare a peer review report that describes the nature and scope of their review and their findings and conclusions. The report should disclose the name of each peer reviewer and a brief description of their organizational affiliation, credentials and relevant experiences. When the agency uses a panel, the peer review report should either summarize the views of the group as a whole (including any dissenting views) or summarize the views of individual reviewers (with or without attribution of specific views to specific names). The agency must also prepare a written response to the peer review report, indicating whether the agency agrees with the

reviewers and what actions the agency has taken or plans to take to address the points made by reviewers. The agency is required to disseminate the peer review report and the agency's response to the report on the agency's web site, including all the materials related to the peer review such as charge statement, peer review report, and agency response to the review.

Section III(6) authorizes but does not require an agency to commission an entity independent of the agency to select peer reviewers and/or manage the peer review process in accordance with this section. The entity may be a scientific or professional society, a firm specializing in peer review, or a non-profit organization with experience in peer review.

Section IV: Alternative Procedures

Peer review as described in this Bulletin is only one of many procedures that agencies can employ to ensure an appropriate degree of pre-dissemination quality of influential scientific information. As an alternative to complying with Sections II and III of this Bulletin, an agency may instead (1) rely on scientific information produced by the National Academy of Sciences, (2) commission the National Academy of Sciences to peer review an agency draft scientific information product, or (3) employ an alternative procedure or set of procedures, specifically approved by the OIRA Administrator in consultation with OSTP, that ensures that the scientific information product meets applicable information-quality standards. For example, an agency might choose to commission a respected third party other than the NAS (e.g., the Health Effects Institute or the National Commission on Radiation Protection and Measurement) to conduct an assessment or series of related assessments. The purpose of Section IV is to encourage innovation in the methods used to ensure pre-dissemination quality control of influential scientific information.

Section V: Peer Review Planning

Section V requires agencies to begin a systematic process of peer review planning for influential scientific information and highly influential scientific assessments that the agency plans to disseminate in the foreseeable future. A key feature of planning is a web site listing of forthcoming influential scientific disseminations that is regularly updated by the agency, at least every six months. Each entry on the list of forthcoming disseminations should include a preliminary title of the planned report, a short paragraph describing the subject and purpose of the planned report, and an agency contact person. In addition, the agency should briefly describe its peer review plan, including the anticipated number of reviewers (3 or less; 4-10; more than 10), whether they shall work as individuals or a panel, and a succinct description of the primary disciplines or types of skills, expertise and experience needed in the review.

In addition, each peer review plan shall include the following: (1) whether reviewers will be selected by the agency or by a designated outside organization; (2) whether the public, including scientific or professional societies, will be asked to nominate potential peer reviewers; (3) whether there will be opportunities for the public to comment on the work product to be peer reviewed, and if so, how and when these opportunities will be provided; and (4) whether or not the agency will provide peer reviewers copies of significant and relevant public comments prior to doing their work.

The peer review agenda will allow agencies to gauge the extent of public interest in the peer review process for influential scientific information. The agenda can also be used by the public to monitor agency compliance with this Bulletin. The Bulletin requires agencies to update their peer review agenda at least every six months. However, in some cases -- particularly for highly influential scientific assessments and other particularly important information products -- more frequent updates of existing entries on the agenda, or the addition of new entries to the agenda, may be warranted. When new entries are added to the agenda of forthcoming reports and other information products, the public should be provided with sufficient time to comment on the agency's

peer review plan for that report or product. Agencies shall consider public comments on the peer review plan. Agencies are encouraged to offer some form of listserve for members of the public who would like to be notified by email each time an agency's peer review agenda has been updated.

The peer review planning requirements of this Bulletin are designed to be implemented in phases. Specifically, the planning requirements of the Bulletin will go into effect for documents subject to Section III of the Bulletin (highly influential scientific assessments) four months after publication. However, the planning requirements do not go into effect for documents subject to Section II of the Bulletin until one year after publication. It is expected that agency experience with the planning requirements of the Bulletin for the smaller scope of documents encompassed in Section III will be used to inform implementation of these planning requirements for the larger scope of documents covered under Section II.

Section VI: Certification in the Administrative Record.

If an agency relies on influential scientific information subject to the requirements of this Bulletin in support of a regulatory action, the agency shall include in the administrative record for that action a certification that explains how the agency has complied with this Bulletin and the Information Quality Act. Relevant materials are to be placed in the administrative record.

Section VII: Safeguards and Waivers

Section VII establishes basic procedures to protect privacy and confidentiality concerns, and to allow for waiver of the requirements of the Bulletin where necessary. First, peer review must be conducted in a manner that respects privacy interests, confidential business information, and intellectual property. Second, the agency head may waive or defer some or all of the peer review requirements of Sections II or III of this Bulletin if there is a compelling rationale for waiver or deferral. If the agency head

waives the peer review requirements prior to dissemination, peer review should be conducted as soon as practicable thereafter.

Section VIII: Exemptions

There are a variety of situations where agencies need not conduct peer review under this Bulletin. These include, for example, disseminations of sensitive information related to national security, foreign affairs, or negotiations involving international treaties and trade where compliance with this Bulletin would interfere with the need for secrecy or promptness.

An information product is not covered by the Bulletin unless it represents an official view of one or more Departments or agencies of the federal government. Since the Bulletin covers only official "disseminations" of the U.S. government, it does not cover information products released by government-funded scientists (e.g., those supported extramurally or intramurally by federal agencies, or those working in state or local governments with federal support) if those information products are not represented as the views of the agency or Department supporting the research. In cases where the imprimatur of the federal government is not intended, government-funded scientists are advised to include a statement with their disseminated work indicating that "the views in this report are those of the author(s) and do not necessarily represent the views of the funding agency".

This Bulletin does not cover official disseminations that arise in adjudications and permit proceedings, unless the agency determines that the influential dissemination is scientifically or technically novel (i.e., a major change in accepted practice) and likely to have precedent-setting influence on future adjudications or permit proceedings. This exclusion is intended to cover, among other things, licensing, approval and registration processes for specific products and development activities, as well as site-specific disseminations such as those made under Superfund or the National Environmental Policy Act (NEPA). The Bulletin also does not directly cover information supplied to the

government by third parties (e.g., studies by private consultants, companies and private, non-profit organizations, or research institutions such as universities). However, if a Department or agency plans to disseminate information supplied by a third party (i.e., using this information to support decisions, thereby adopting this information as an official dissemination), the requirements of the Bulletin apply, assuming the dissemination is "influential".

The Bulletin does not cover time-sensitive medical, health, and safety disseminations (for this purpose, “health” includes public health, or plant or animal infectious diseases), or disseminations based primarily on data from a recent clinical trial that was adequately peer reviewed before the trial began.

This Bulletin covers original data and formal analytic models used by agencies in Regulatory Impact Analyses (RIAs). However, the RIA documents themselves are already reviewed through an interagency review process under EO 12866 that involves application of the principles and methods defined in OMB Circular A-4. In that respect, RIAs are excluded from coverage by this Bulletin, although agencies are encouraged to have RIAs reviewed by peers within the government for adequacy and completeness. One model for such a review prior to submission to OIRA is offered by the Interagency Economic Peer Review (IEPR). The IEPR comprises agency economists engaged in benefit-cost analysis from across the federal government.

The Bulletin does not cover accounting, budget, and financial information including that which is generated or used by agencies that focus on interest rates, banking, currency, securities, commodities, futures, or taxes.

Routine statistical information released by federal statistical agencies (e.g., periodic demographic and economic statistics) and the analysis of these data to compute standard indicators and trends (e.g., unemployment and poverty rates) is excluded from this Bulletin.

The Bulletin does not cover information disseminated in connection with rules that materially alter entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof, other than influential scientific information disseminated in connection with non-routine rules in this category.

In general, the Bulletin does not impose new peer-review requirements on information that has already been adequately peer reviewed. Under the terms of the Bulletin, agencies should exercise discretion in determining when a draft information product has already been adequately peer reviewed. The mere existence of a public comment process (*e.g.*, notice-and-comment procedures under the Administrative Procedures Act) does not constitute adequate peer review, because it does not assure that qualified, impartial specialists in relevant fields have performed a critical evaluation of the agency's draft product.[28] For both Sections II and III of this Bulletin, principal findings, conclusions and recommendations in official reports of the National Academy of Sciences are generally presumed to have been adequately peer reviewed. Publication in a refereed scientific journal may mean that adequate peer review has been performed. However, because the intensity of journal review is highly variable, there may be cases in which an agency determines that a more rigorous or transparent review process is necessary. For instance, an agency may determine a particular journal review process did not address all of the questions that the agency should address before publishing a report. In addition, because science primarily advances through further research in which new data challenges prior theories, prior peer review and publication is not by itself sufficient grounds for determining that no further review is necessary.

Congress has assigned the NAS a special role in advising the federal government on scientific and technical issues. The peer-review procedures of the NAS are generally quite rigorous, and thus agencies should presume that major findings from NAS reports have been adequately peer reviewed.

[28] William W. Lowrance, Modern Science and Human Values, Oxford University Press, New York, NY 1985: 86.

If information is disseminated pursuant to an exemption to this Bulletin, subsequent disseminations are not automatically exempted. For example, if influential scientific information is first disseminated in the course of an exempt agency adjudication, but is later disseminated in the context of a non-exempt rulemaking, the subsequent dissemination will be subject to the requirements of this Bulletin even though the first dissemination was not.

Section IX: OIRA and OSTP Responsibilities

OIRA, in consultation with OSTP, is responsible for overseeing agency implementation of the requirements of this Bulletin. In order to foster learning about peer review practices across agencies, OIRA and OSTP shall form an interagency workgroup on peer review that meets regularly, discusses progress and challenges, and recommends improvements to peer review practices under the Bulletin.

Section X: Effective Date and Existing Law

The requirements of this Bulletin, with the exception of Section V, apply to information disseminated on or after four months after publication of this Bulletin. However, the Bulletin does not apply to information products that are already being addressed by an agency-initiated peer review process (e.g., a draft is already being reviewed by a formal scientific advisory committee established by the agency). An existing peer review mechanism mandated by law should be implemented by the agency in a manner as consistent as possible with the practices and procedures outlined in this Bulletin. As noted above, the requirements in Section V apply to "highly influential scientific assessments," as designated in Section III of the Bulletin, within four months of publication of the final Bulletin. The requirements in Section V apply to documents subject to Section II of the Bulletin one year after publication of the final Bulletin.

Section XI: Judicial Review

This Bulletin is intended to improve the internal management of the executive branch and is not intended to create any new right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its departments, agencies, or other entities, its officers or employees, or any other person. Nor does this Bulletin abridge any existing rights of action. Consistent with current law, materials generated during the peer review process may be considered by courts adjudicating existing rights of action.

Bulletin for Peer Review

I. Definitions.

For purposes of this Bulletin --

1. the term "Administrator" means the Administrator of the Office of Information and Regulatory Affairs in the Office of Management and Budget;
2. the term "agency" has the same meaning as in the Paperwork Reduction Act, 44 U.S.C. § 3502(1);
3. the term "dissemination" means agency initiated or sponsored distribution of information to the public (see 5 C.F.R. 1320(d) (definition of "Conduct or Sponsor")). Dissemination does not include distribution limited to government employees or agency contracts or grantees; intra- or inter-agency use or sharing of government information; or responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or similar law. This definition also excludes distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas and adjudicative processes. The term "dissemination" also excludes information distributed for peer review in compliance with this Bulletin, provided that the distributing agency includes a clear disclaimer on the information as follows: "THIS INFORMATION IS DISTRIBUTED SOLELY FOR THE PURPOSE OF PRE-DISSEMINATION PEER REVIEW UNDER APPLICABLE INFORMATION QUALITY GUIDELINES. IT HAS NOT BEEN FORMALLY DISSEMINATED BY [THE AGENCY] AND SHOULD NOT BE CONSTRUED TO REPRESENT ANY AGENCY DETERMINATION OR POLICY";
4. the term "influential scientific information" means scientific information the dissemination of which the agency reasonably can determine that dissemination of which will have or does have a clear and substantial impact on important public policies or private sector decisions;
5. the term "Information Quality Act" means Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. Law 106-554; H.R. 5658);

6. the term "scientific assessment" means an evaluation of a body of scientific or technical knowledge which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. These assessments include, but are not limited to, state-of-science reports, technology assessments, weight-of-evidence analyses, meta-analyses, risk assessments, toxicological profiles of substances, integrated assessment models, hazard determinations, exposure assessments, or health, ecological, or safety assessments, and
7. the term "scientific information" means factual inputs, data, models, analyses, or scientific assessments related to the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences. This includes 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 clear that what is being offered is someone's opinion rather than fact or the agency's views.

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II. Peer Review of Influential Scientific Information.

1. In General: To the extent permitted by law, each agency shall have a peer review conducted on all influential scientific information that the agency intends to disseminate. Agencies need not, however, have peer review conducted on information that has already been subjected to adequate peer review.
2. Adequacy of Peer Review: To be considered "adequate" for purposes of the preceding paragraph, a peer review need not comply with all of the requirements of this Bulletin. An agency may deem a prior peer review adequate if it determines that the peer review was sufficiently rigorous in light of the novelty and complexity of the science to be reviewed and the benefit and cost implications. For both Sections II and III of this Bulletin, principal findings, conclusions and recommendations in official reports of the National Academy of Sciences are generally presumed to have been adequately peer reviewed.
3. Choice of Peer Review Mechanism: When planning a peer review for influential scientific information, the agency shall select an appropriate peer review mechanism based on the novelty and complexity of the science to be reviewed and the benefit and cost implications. Depending on these factors, appropriate peer review mechanisms can range from review by qualified specialists within the federal government to formal review by an independent body of experts outside the government. Peer reviewers shall be selected on the basis of necessary technical or scientific expertise, and should not have participated in development of the work product.
4. Conflicts: In order to properly handle participation by scientists with a conflict of interest, the agency – or the entity selecting the peer reviewers – shall (i) ensure that those reviewers serving as federal employees (including special government employees as defined in 18 U.S.C. 202(a)) comply with applicable federal ethics requirements (ii) apply or adapt the federal ethics requirements for reviewers who are not federal

employees; and (iii) consider the conflict of interest policy used by the National Academy of Sciences, including principles regarding potential financial conflicts arising from factors such as a reviewers' investments, employer and business affiliations, grants, contracts and consulting income. For scientific assessments relevant to specific regulations, a reviewer's financial ties to both regulated entities (e.g., businesses) and the agency should be examined.

5. Transparency: A detailed summary or copy of the reviewers' comments, as a group or individually, shall be made available to the public and, where appropriate, be made part of the administrative record for related agency actions. Agencies shall consider the comments of the reviewers.

III. Additional Peer Review Requirements for Highly Influential Scientific Assessments.

1. Applicability: This section applies to influential scientific information which the agency or the Administrator determines is a scientific assessment that:

(i) could have a clear and substantial impact on important public policies (including regulatory actions) or private sector decisions with a potential effect of more than $500 million in any year, or

(ii) involves precedent setting, novel, and complex approaches, or significant interagency interest.

2. Selection of Reviewers:

a. Expertise and Balance: Peer reviewers shall be selected to provide the necessary expertise, experience and skills, including specialists from multiple disciplines, as necessary. The group of reviewers shall be sufficiently broad and diverse to fairly represent the relevant scientific perspectives and fields of knowledge.

b. Conflicts: In order to properly handle participation by scientists with a conflict of interest, the agency – or the entity selecting the peer reviewers – shall (i) ensure that those reviewers serving as federal employees (including special government employees) comply with applicable federal ethics requirements; (ii) apply or adapt the federal ethics requirements for reviewers who are not federal employees; and (iii) consider the conflict of interest policy used by the National Academy of Sciences, including principles regarding potential financial conflicts arising from factors such as a reviewers' investments, employer and business affiliations, grants, contracts and consulting income. For scientific assessments relevant to specific regulations, a reviewer's financial ties to both regulated entities (e.g., businesses) and the agency should be examined.

c. Independence: In order to ensure participation by scientists who are independent of the agency sponsoring the review, the agency – or entity selecting the reviewers – shall (i) bar participation by scientists employed by the agency sponsoring the review unless the reviewer's service as a peer reviewer defines the government employment (i.e., special government employees); (ii) consider requesting the nomination of potential reviewers based on expertise and objectivity from the public, including scientific and professional societies; and (iii) consider the prevailing selection practices of the National Academy of Sciences concerning ties of a potential committee members to the sponsoring agency. Agencies should avoid repeated use of the same reviewer on multiple assessments unless his or her participation is essential. Agencies

are encouraged to rotate membership on panels across the pool of qualified reviewers. Research grants that were awarded to scientists based on investigator-initiated, competitive, peer-reviewed proposals generally do not raise issues as to independence or conflicts.

3. Information Access: The agency – or entity managing the peer review -- shall provide the reviewers with sufficient information – including background information about key studies or models -- to enable them to understand the data, analytic procedures, and assumptions used to support the key findings or conclusions of the draft assessment. Reviewers shall be informed of applicable access, objectivity, reproducibility and other quality standards under the federal laws governing information access and quality.

4. Opportunity for Public Participation: If the agency decides to make a draft assessment publicly available at the same time it is submitted for peer review (or during the peer review process), the agency shall, whenever practical, provide to peer reviewers a compilation or summary of relevant public comments on the draft assessment that address significant scientific or technical issues. When there is sufficient public interest, the agency -- or entity managing the peer review -- shall consider establishing a public comment period for a draft report and sponsoring a public meeting where oral presentations on scientific issues can be made to the peer reviewers by interested members of the public. Time limits for public participation shall be specified.

5. Peer Review Reports: The agency – or entity managing the peer review-- shall instruct peer reviewers to prepare a report that describes the nature of their review and their findings and conclusions. The peer review report should either summarize the views of individual reviewers (either with or without specific attributions, as long as the reviewers are informed in advance of the agency's plans for disclosure) or represent the views of the group as a whole (including any dissenting views). The peer review report shall also disclose the names, organizational affiliations, and a short paragraph on the credentials and relevant experiences of each peer reviewer. The agency is required to prepare a written response to the peer review report explaining: the agency's agreement or disagreement; any actions the agency has undertaken or will undertake in response to the report; and (if applicable) the reasons the agency believes those actions satisfy any key concerns or recommendations in the report. The agency shall disseminate the final peer review report and the agency's written statement of response on the agency's web site, and all the materials related to the peer review (charge statement, peer review report, and agency response) shall be included in the administrative record for any related agency action.

6. Selection and Management of Peer Review Panel: The agency may commission entities independent of the agency to select peer reviewers and/or manage the peer review process in accordance with this section.

IV. Alternative Procedures.

As an alternative to complying with Sections II and III of this Bulletin, an agency may instead: (i) rely on a scientific information produced by the National Academy of Sciences; (ii) commission the National Academy of Sciences to peer review an agency draft scientific information product; or (iii) employ an alternative scientific procedure or process, specifically approved by the Administrator in consultation with OSTP, that ensures that the scientific information product satisfies applicable information quality standards. The alternative procedure(s) may be applied to a single report or group of reports.

V. Peer Review Planning.

1. Peer Review Agenda: Each agency shall post on its Internet website, and update at least every six months, an agenda designating all planned and ongoing influential scientific information subject to Section II and highly influential scientific assessments subject to Section III of this Bulletin.
2. Peer Review Plans:
    a. General Requirements: For each entry on the agenda that is subject to this Bulletin, the agency shall describe the peer review plan. Each peer review plan shall include: (i) a paragraph including the title, subject and purpose of the planned report, as well as an agency contact to whom inquiries may be directed to learn the specifics of the plan; (ii) whether the review will be conducted by a panel or individual letters; (iii) the anticipated number of reviewers (3 or less; 4-10; or more than 10); and (iv) a succinct description of the primary disciplines or types of expertise needed in the review.
    b. Designations: Each peer review plan shall designate the following: (i) whether reviewers will be selected by the agency or by a designated outside organization; (ii) whether the public, including scientific or professional societies, will be asked to nominate potential peer reviewers; (iii) whether there will be opportunities for the public to comment on the work product to be peer reviewed, and if so, how and when these opportunities will be provided; and (iv) whether the agency will provide peer reviewers copies of significant and relevant public comments prior to doing their work.
    c. Agenda Updates: Agencies are encouraged to offer a listserve to alert interested members of the public when new entries are added or updated.
    d. Public Comment: Agencies shall establish a mechanism for allowing the public to comment on the adequacy of the peer review plans and designations. Agencies must consider public comments on peer review plans.

VI. Certification in the Administrative Record.

If an agency relies on influential scientific information or a highly influential scientific assessment subject to the requirements of this Bulletin in support of a regulatory action, it shall include in the administrative record for that action a certification explaining how the

agency has complied with the requirements of this Bulletin and the Information Quality Act.

VII. Safeguards and Waivers.

1. Privacy and Confidentiality: Peer review shall be conducted in a manner that respects (i) privacy interests; (ii) confidential business information; and (iii) intellectual property.
2. Waiver: The agency head may waive or defer some or all of the peer review requirements of Section II and III of this Bulletin where warranted by a compelling rationale. If the agency head waives the peer review requirements prior to dissemination, peer review should be conducted as soon as practicable thereafter.

VIII. Exemptions.

Agencies need not have peer review conducted on information that is:
1. related to national security, foreign affairs, or negotiations involving international trade or treaties where compliance with this Bulletin would interfere with the need for secrecy or promptness;
2. produced by government-funded scientists (e.g., those supported extramurally or intramurally by federal agencies or those working in state or local governments with federal support) if those information products are not represented as the views of a Department or agency. To qualify for this exemption, scientists are advised to include in their information product a clear disclaimer that "the views in this report are those of the author(s) and do not necessarily represent the views of the funding agency";
3. disseminated in the course of an individual agency adjudication or permit proceeding (including a registration, approval, licensing, site-specific determination), unless the agency determines that the influential dissemination is scientifically or technically novel and likely to have precedent-setting influence on future adjudications and/or permit proceedings;
4. a medical, health, or safety dissemination where the agency determines that the dissemination is time-sensitive or is based primarily on data from a recent clinical trial that was adequately peer reviewed before the trial began.
5. an agency regulatory impact analysis or regulatory flexibility analysis subject to interagency review under Executive Order 12866;
6. routine statistical information released by federal statistical agencies (e.g., periodic information about unemployment and poverty rates);
7. accounting, budget, and financial information, including that which is generated or used by agencies that focus on interest rates, banking, currency, securities, commodities, futures, or taxes; or
8. information disseminated in connection with rules that materially alter entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof, except that influential scientific information disseminated in connection with non-routine rules is not exempt.

IX. Responsibilities of OIRA and OSTP.

OIRA, in consultation with OSTP, shall be responsible for overseeing implementation of the requirements of this Bulletin. An interagency group, chaired by OSTP and OIRA, shall meet periodically to foster better understanding about peer review practices and to assess progress in the implementation of this Bulletin.

X. Effective Date and Existing Law.

The requirements of this Bulletin, with the exception of those in Section V (Peer Review Planning), apply to information disseminated on or after four months after publication, except that they do not apply to information for which an agency has already commenced a peer-review process. Any existing peer review mechanisms mandated by law should be employed in a manner as consistent as possible with the practices and procedures laid out herein. The requirements in Section V apply to "highly influential scientific assessments," as designated in Section III of this Bulletin, within four months of publication. The requirements in Section V apply to documents subject to Section II of this Bulletin one year after publication.

XI. Judicial Review

This Bulletin is intended to improve the internal management of the executive branch, and is not intended to create any new right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its departments, agencies, or other entities, its officers or employees, or any other person. Nor does this Bulletin abridge any existing rights of action. Consistent with current law, materials generated during the peer review process may be considered by courts adjudicating existing rights of action.

[DOCID: f:publ13.104]

[[Page 109 STAT. 163]]

Public Law 104-13
104th Congress

An Act

To further the goals of the Paperwork Reduction Act to have Federal agencies become more responsible and publicly accountable for reducing the burden of Federal paperwork on the public, and for other purposes. <<NOTE: May 22, 1995 - [S. 244]>>

Be it enacted by the Senate and House of Representatives of the United States of America in Congress <<NOTE: Paperwork Reduction Act of 1995. Information resources management.>> assembled,

SECTION 1. <<NOTE: 44 USC 101 note.>> SHORT TITLE.

This Act may be cited as the Paperwork Reduction Act of 1995''.

SEC. 2. COORDINATION OF FEDERAL INFORMATION POLICY.

Chapter 35 of title 44, United States Code, is amended to read as follows:

CHAPTER 35--COORDINATION OF FEDERAL INFORMATION POLICY

Sec. 3501. Purposes

The purposes of this chapter are to--

(1) minimize the paperwork burden for individuals, small businesses, educational and nonprofit institutions, Federal contractors, State, local and tribal governments, and other persons resulting from the collection of information by or for the Federal Government;

(2) ensure the greatest possible public benefit from and maximize the utility of information created, collected, main [[Page 109 STAT. 164]] tained, used, shared and disseminated by or for the Federal Government;

(3) coordinate, integrate, and to the extent practicable and appropriate, make uniform Federal information resources management policies and practices as a means to improve the productivity, efficiency, and effectiveness of Government programs, including the reduction of information collection burdens on the public and the improvement of service delivery to the public;

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

(5) minimize the cost to the Federal Government of the creation, collection, maintenance, use, dissemination, and disposition of information;

(6) strengthen the partnership between the Federal Government and State, local, and tribal governments by minimizing the burden and maximizing the utility of information created, collected, maintained, used, disseminated, and retained by or for the Federal Government;

(7) provide for the dissemination of public information on a timely basis, on equitable terms, and in a manner that promotes the utility of the information to the public and makes effective use of information technology;

(8) ensure that the creation, collection, maintenance, use, dissemination, and disposition of information by or for the Federal Government is consistent with applicable laws, including laws relating to--

(A) privacy and confidentiality, including section 552a of title 5;

(B) security of information, including the Computer Security Act of 1987 (Public Law 100-235); and

(C) access to information, including section 552 of title 5;

(9) ensure the integrity, quality, and utility of the Federal statistical system;

(10) ensure that information technology is acquired, used, and managed to improve performance of agency missions, including the reduction of information collection burdens on the public; and

(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 chapter.

Sec. 3502. Definitions

As used in this chapter--

(1) the term `agency' means any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency, but does not include--

(A) the General Accounting Office;

(B) Federal Election Commission; [[Page 109 STAT. 165]]

(C) the governments of the District of Columbia and of the territories and possessions of the United States, and their various subdivisions; or

(D) Government-owned contractor-operated facilities, including laboratories engaged in national defense research and production activities;

(2) the term `burden' means time, effort, or financial resources expended by persons to generate, maintain, or provide information to or for a Federal agency, including the resources expended for--

(A) reviewing instructions;

(B) acquiring, installing, and utilizing technology and systems;

(C) adjusting the existing ways to comply with any previously applicable instructions and requirements;

(D) searching data sources;
(E) completing and reviewing the collection of information; and
(F) transmitting, or otherwise disclosing the information;
(3) the term `collection of information'--
(A) means the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format, calling for either--
(i) answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, ten or more persons, other than agencies, instrumentalities, or employees of the United States; or
(ii) answers to questions posed to agencies, instrumentalities, or employees of the United States which are to be used for general statistical purposes; and
(B) shall not include a collection of information described under section 3518(c)(1);
(4) the term `Director' means the Director of the Office of Management and Budget;
(5) the term `independent regulatory agency' means the Board of Governors of the Federal Reserve System, the Commodity Futures Trading Commission, the Consumer Product Safety Commission, the Federal Communications Commission, the Federal Deposit Insurance Corporation, the Federal Energy Regulatory Commission, the Federal Housing Finance Board, the Federal Maritime Commission, the Federal Trade Commission, the Interstate Commerce Commission, the Mine Enforcement Safety and Health Review Commission, the National Labor Relations Board, the Nuclear Regulatory Commission, the Occupational Safety and Health Review Commission, the Postal Rate Commission, the Securities and Exchange Commission, and any other similar agency designated by statute as a Federal independent regulatory agency or commission;
(6) the term `information resources' means information and related resources, such as personnel, equipment, funds, and information technology; [[Page 109 STAT. 166]]
(7) the term `information resources management' means the process of managing information resources to accomplish agency missions and to improve agency performance, including through the reduction of information collection burdens on the public;
(8) the term `information system' means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information;

(9) the term `information technology' has the same meaning as the term `automatic data processing equipment' as defined by section 111(a) (2) and (3)(C) (i) through (v) of the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 759(a) (2) and (3)(C) (i) through (v));

(10) the term `person' means an individual, partnership, association, corporation, business trust, or legal representative, an organized group of individuals, a State, territorial, tribal, or local government or branch thereof, or a political subdivision of a State, territory, tribal, or local government or a branch of a political subdivision;

(11) the term `practical utility' means the ability of an agency to use information, particularly the capability to process such information in a timely and useful fashion;

(12) the term `public information' means any information, regardless of form or format, that an agency discloses, disseminates, or makes available to the public;

(13) the term `recordkeeping requirement' means a requirement imposed by or for an agency on persons to maintain specified records, including a requirement to--

(A) retain such records;

(B) notify third parties, the Federal Government, or the public of the existence of such records;

(C) disclose such records to third parties, the Federal Government, or the public; or

(D) report to third parties, the Federal Government, or the public regarding such records; and

(14) the term `penalty' includes the imposition by an agency or court of a fine or other punishment; a judgment for monetary damages or equitable relief; or the revocation, suspension, reduction, or denial of a license, privilege, right, grant, or benefit.

Sec. 3503. <<NOTE: Establishment.>> Office of Information and Regulatory Affairs

(a) There is established in the Office of Management and Budget an office to be known as the Office of Information and Regulatory Affairs.

(b) There shall be at the head of the Office an Administrator who shall be appointed by the President, by and with the advice and consent of the Senate. The Director shall delegate to the Administrator the authority to administer all functions under this chapter, except that any such delegation shall not relieve the Director of responsibility for the administration of such functions. The Administrator shall serve as principal adviser to the Director on Federal information resources management policy. [[Page 109 STAT. 167]]

Sec. 3504. Authority and functions of Director

(a)(1) The Director shall oversee the use of information resources to improve the efficiency and effectiveness of governmental operations to serve agency missions, including burden reduction and service delivery to the public. In performing such oversight, the Director shall--

(A) develop, coordinate and oversee the implementation of Federal information resources management policies, principles, standards, and guidelines; and

(B) provide direction and oversee--

(i) the review and approval of the collection of information and the reduction of the information collection burden;

(ii) agency dissemination of and public access to information;

(iii) statistical activities;

(iv) records management activities;

(v) privacy, confidentiality, security, disclosure, and sharing of information; and

(vi) the acquisition and use of information technology.

(2) The authority of the Director under this chapter shall be exercised consistent with applicable law.

(b) With respect to general information resources management policy, the Director shall--

(1) develop and oversee the implementation of uniform information resources management policies, principles, standards, and guidelines;

(2) foster greater sharing, dissemination, and access to public information, including through--

(A) the use of the Government Information Locator Service; and

(B) the development and utilization of common standards for information collection, storage, processing and communication, including standards for security, interconnectivity and interoperability;

(3) initiate and review proposals for changes in legislation, regulations, and agency procedures to improve information resources management practices;

(4) oversee the development and implementation of best practices in information resources management, including training; and

(5) oversee agency integration of program and management functions with information resources management functions.

(c) With respect to the collection of information and the control

of paperwork, the Director shall--

(1) review and approve proposed agency collections of information;

(2) coordinate the review of the collection of information associated with Federal procurement and acquisition by the Office of Information and Regulatory Affairs with the Office of Federal Procurement Policy, with particular emphasis on applying information technology to improve the efficiency and effectiveness of Federal procurement, acquisition and payment, and to reduce information collection burdens on the public;

(3) minimize the Federal information collection burden, with particular emphasis on those individuals and entities most adversely affected; [[Page 109 STAT. 168]]

(4) maximize the practical utility of and public benefit from information collected by or for the Federal Government; and

(5) establish and oversee standards and guidelines by which agencies are to estimate the burden to comply with a proposed collection of information.

(d) With respect to information dissemination, the Director 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; and

(2) promote public access to public information and fulfill the purposes of this chapter, including through the effective use of information technology.

(e) With respect to statistical policy and coordination, the Director shall--

(1) coordinate the activities of the Federal statistical system to ensure--

(A) the efficiency and effectiveness of the system; and

(B) the integrity, objectivity, impartiality, utility, and confidentiality of information collected for statistical purposes;

(2) ensure that budget proposals of agencies are consistent with system-wide priorities for maintaining and improving the quality of Federal statistics and prepare an annual report on statistical program funding;

(3) develop and oversee the implementation of Governmentwide policies, principles, standards, and guidelines concerning--

(A) statistical collection procedures and methods;

(B) statistical data classification;

(C) statistical information presentation and dissemination;

(D) timely release of statistical data; and
(E) such statistical data sources as may be required for the administration of Federal programs;
(4) evaluate statistical program performance and agency compliance with Governmentwide policies, principles, standards and guidelines;
(5) promote the sharing of information collected for statistical purposes consistent with privacy rights and confidentiality pledges;
(6) coordinate the participation of the United States in international statistical activities, including the development of comparable statistics;
(7) appoint a chief statistician who is a trained and experienced professional statistician to carry out the functions described under this subsection;
(8) <<NOTE: Establishment.>> establish an Interagency Council on Statistical Policy to advise and assist the Director in carrying out the functions under this subsection that shall--
(A) be headed by the chief statistician; and
(B) consist of--
(i) the heads of the major statistical programs; and [[Page 109 STAT. 169]]
(ii) representatives of other statistical agencies under rotating membership; and
(9) provide opportunities for training in statistical policy functions to employees of the Federal Government under which--
(A) each trainee shall be selected at the discretion of the Director based on agency requests and shall serve under the chief statistician for at least 6 months and not more than 1 year; and
(B) all costs of the training shall be paid by the agency requesting training.

(f) <<NOTE: Records.>> With respect to records management, the Director shall--
(1) provide advice and assistance to the Archivist of the United States and the Administrator of General Services to promote coordination in the administration of chapters 29, 31, and 33 of this title with the information resources management policies, principles, standards, and guidelines established under this chapter;
(2) review compliance by agencies with--
(A) the requirements of chapters 29, 31, and 33 of this title; and
(B) <<NOTE: Regulations.>> regulations promulgated by the Archivist of the United States and the Administrator of General Services; and

(3) oversee the application of records management policies, principles, standards, and guidelines, including requirements for archiving information maintained in electronic format, in the planning and design of information systems.

(g) With respect to privacy and security, the Director shall--

(1) develop and oversee the implementation of policies, principles, standards, and guidelines on privacy, confidentiality, security, disclosure and sharing of information collected or maintained by or for agencies;

(2) oversee and coordinate compliance with sections 552 and 552a of title 5, the Computer Security Act of 1987 (40 U.S.C. 759 note), and related information management laws; and

(3) require Federal agencies, consistent with the Computer Security Act of 1987 (40 U.S.C. 759 note), to identify and afford security protections commensurate with the risk and magnitude of the harm resulting from the loss, misuse, or unauthorized access to or modification of information collected or maintained by or on behalf of an agency.

(h) With respect to Federal information technology, the Director shall--

(1) in consultation with the Director of the National Institute of Standards and Technology and the Administrator of General Services--

(A) develop and oversee the implementation of policies, principles, standards, and guidelines for information technology functions and activities of the Federal Government, including periodic evaluations of major information systems; and

(B) oversee the development and implementation of standards under section 111(d) of the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 759(d)); [[Page 109 STAT. 170]]

(2) monitor the effectiveness of, and compliance with, directives issued under sections 110 and 111 of the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 757 and 759);

(3) coordinate the development and review by the Office of Information and Regulatory Affairs of policy associated with Federal procurement and acquisition of information technology with the Office of Federal Procurement Policy;

(4) ensure, through the review of agency budget proposals, information resources management plans and other means--

(A) agency integration of information resources management plans, program plans and budgets for acquisition and use of information technology; and

(B) the efficiency and effectiveness of inter-agency information technology initiatives to improve agency performance and the accomplishment of agency missions; and

(5) promote the use of information technology by the Federal Government to improve the productivity, efficiency, and effectiveness of Federal programs, including through dissemination of public information and the reduction of information collection burdens on the public.

Sec. 3505. Assignment of tasks and deadlines

(a) In carrying out the functions under this chapter, the Director shall--

(1) in consultation with agency heads, set an annual Governmentwide goal for the reduction of information collection burdens by at least 10 percent during each of fiscal years 1996 and 1997 and 5 percent during each of fiscal years 1998, 1999, 2000, and 2001, and set annual agency goals to--

(A) reduce information collection burdens imposed on the public that--

(i) represent the maximum practicable opportunity in each agency; and

(ii) are consistent with improving agency management of the process for the review of collections of information established under section 3506(c); and

(B) improve information resources management in ways that increase the productivity, efficiency and effectiveness of Federal programs, including service delivery to the public;

(2) with selected agencies and non-Federal entities on a voluntary basis, conduct pilot projects to test alternative policies, practices, regulations, and procedures to fulfill the purposes of this chapter, particularly with regard to minimizing the Federal information collection burden; and

(3) in consultation with the Administrator of General Services, the Director of the National Institute of Standards and Technology, the Archivist of the United States, and the Director of the Office of Personnel Management, develop and maintain a Governmentwide strategic plan for information resources management, that shall include--

(A) a description of the objectives and the means by which the Federal Government shall apply information resources to improve agency and program performance;

(B) plans for-- [[Page 109 STAT. 171]]

(i) reducing information burdens on the public, including reducing such burdens through

the elimination of duplication and meeting shared data needs with shared resources;

(ii) enhancing public access to and dissemination of, information, using electronic and other formats; and

(iii) meeting the information technology needs of the Federal Government in accordance with the purposes of this chapter; and

(C) a description of progress in applying information resources management to improve agency performance and the accomplishment of missions.

(b) For purposes of any pilot project conducted under subsection (a)(2), the Director may, after consultation with the agency head, waive the application of any administrative directive issued by an agency with which the project is conducted, including any directive requiring a collection of information, after giving timely notice to the public and the Congress regarding the need for such waiver.

Sec. 3506. Federal agency responsibilities

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

(A) carrying out the agency's information resources management activities to improve agency productivity, efficiency, and effectiveness; and

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

(2)(A) <<NOTE: Reports.>> Except as provided under subparagraph (B), the head of each agency shall designate a senior official who shall report directly to such agency head to carry out the responsibilities of the agency under this chapter.

(B) <<NOTE: Reports.>> The Secretary of the Department of Defense and the Secretary of each military department may each designate senior officials who shall report directly to such Secretary to carry out the responsibilities of the department under this chapter. If more than one official is designated, the respective duties of the officials shall be clearly delineated.

(3) The senior official designated under paragraph (2) shall head an office responsible for ensuring agency compliance with and prompt, efficient, and effective implementation of the information policies and information resources management responsibilities established under this chapter, including the reduction of information collection burdens on the public. The senior official and employees of such office shall be selected with special attention to the professional qualifications required to administer the functions described under this chapter.

(4) Each agency program official shall be responsible and

accountable for information resources assigned to and supporting the programs under such official. In consultation with the senior official designated under paragraph (2) and the agency Chief Financial Officer (or comparable official), each agency program official shall define program information needs and develop strategies, systems, and capabilities to meet those needs.

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

(1) manage information resources to--

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(A) reduce information collection burdens on the public;

(B) increase program efficiency and effectiveness; and

(C) 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;

(2) in accordance with guidance by the Director, develop and maintain a strategic information resources management plan that shall describe how information resources management activities help accomplish agency missions;

(3) develop and maintain an ongoing process to--

(A) ensure that information resources management operations and decisions are integrated with organizational planning, budget, financial management, human resources management, and program decisions;

(B) in cooperation with the agency Chief Financial Officer (or comparable official), develop a full and accurate accounting of information technology expenditures, related expenses, and results; and

(C) establish goals for improving information resources management's contribution to program productivity, efficiency, and effectiveness, methods for measuring progress towards those goals, and clear roles and responsibilities for achieving those goals;

(4) in consultation with the Director, the Administrator of General Services, and the Archivist of the United States, maintain a current and complete inventory of the agency's information resources, including directories necessary to fulfill the requirements of section 3511 of this chapter; and

(5) in consultation with the Director and the Director of the Office of Personnel Management, conduct formal training programs to educate agency program and management officials about information resources management.

(c) With respect to the collection of information and the control of paperwork, each agency shall--

(1) establish a process within the office headed by the official designated under subsection (a), that is sufficiently independent of program responsibility to evaluate fairly whether proposed collections of information should be approved under this chapter, to--

(A) review each collection of information before submission to the Director for review under this chapter, including--

(i) an evaluation of the need for the collection of information;

(ii) a functional description of the information to be collected;

(iii) a plan for the collection of the information;

(iv) a specific, objectively supported estimate of burden;

(v) a test of the collection of information through a pilot program, if appropriate; and

(vi) a plan for the efficient and effective management and use of the information to be collected, including necessary resources; [[Page 109 STAT. 173]]

(B) ensure that each information collection--

(i) is inventoried, displays a control number and, if appropriate, an expiration date;

(ii) indicates the collection is in accordance with the clearance requirements of section 3507; and

(iii) informs the person receiving the collection of information of--

(I) the reasons the information is being collected;

(II) the way such information is to be used;

(III) an estimate, to the extent practicable, of the burden of the collection;

(IV) whether responses to the collection of information are voluntary, required to obtain a benefit, or mandatory; and

(V) the fact that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number; and

(C) assess the information collection burden of proposed legislation affecting the agency;

(2)(A) <<NOTE: Federal Register, publication.>> except as provided under subparagraph (B) or section 3507(j), provide 60-day notice in the Federal Register, and otherwise consult with members of the public and affected agencies concerning each proposed collection of information, to solicit comment to--

(i) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;

(ii) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;

(iii) enhance the quality, utility, and clarity of the information to be collected; and

(iv) minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology; and

(B) <<NOTE: Regulations.>> for any proposed collection of information contained in a proposed rule (to be reviewed by the Director under section 3507(d)), provide notice and comment through the notice of proposed rulemaking for the proposed rule and such notice shall have the same purposes specified under subparagraph (A) (i) through (iv); and

(3) certify (and provide a record supporting such certification, including public comments received by the agency) that each collection of information submitted to the Director for review under section 3507--

(A) is necessary for the proper performance of the functions of the agency, including that the information has practical utility;

(B) is not unnecessarily duplicative of information otherwise reasonably accessible to the agency;

(C) reduces to the extent practicable and appropriate the burden on persons who shall provide information to or for the agency, including with respect to small entities, [[Page 109 STAT. 174]] as defined under section 601(6) of title 5, the use of such techniques as--

(i) establishing differing compliance or reporting requirements or timetables that take into account the resources available to those who are to respond;

(ii) the clarification, consolidation, or simplification of compliance and reporting requirements; or

(iii) an exemption from coverage of the collection of information, or any part thereof;

(D) is written using plain, coherent, and unambiguous terminology and is understandable to those who are to respond;

(E) is to be implemented in ways consistent and compatible, to the maximum extent practicable, with the existing reporting and recordkeeping practices of those who are to respond;

(F) indicates for each recordkeeping requirement the length of time persons are required to maintain the records specified;

(G) contains the statement required under paragraph (1)(B)(iii);

(H) has been developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected, including the processing of the information in a manner which shall enhance, where appropriate, the utility of the information to agencies and the public;

(I) uses effective and efficient statistical survey methodology appropriate to the purpose for which the information is to be collected; and

(J) to the maximum extent practicable, uses information technology to reduce burden and improve data quality, agency efficiency and responsiveness to the public.

(d) <<NOTE: Public information.>> With respect to information dissemination, each agency shall--

(1) ensure that the public has timely and equitable access to the agency's public information, including ensuring such access through--

(A) encouraging a diversity of public and private sources for information based on government public information;

(B) in cases in which the agency provides public information maintained in electronic format, providing timely and equitable access to the underlying data (in whole or in part); and

(C) agency dissemination of public information in an efficient, effective, and economical manner;

(2) regularly solicit and consider public input on the agency's information dissemination activities;

(3) provide adequate notice when initiating, substantially modifying, or terminating significant information dissemination products; and

(4) not, except where specifically authorized by statute--
(A) establish an exclusive, restricted, or other distribution arrangement that interferes with timely and equitable availability of public information to the public; [[Page 109 STAT. 175]]
(B) restrict or regulate the use, resale, or redissemination of public information by the public;
(C) charge fees or royalties for resale or redissemination of public information; or
(D) establish user fees for public information that exceed the cost of dissemination.

(e) With respect to statistical policy and coordination, each agency shall--
(1) ensure the relevance, accuracy, timeliness, integrity, and objectivity of information collected or created for statistical purposes;
(2) inform respondents fully and accurately about the sponsors, purposes, and uses of statistical surveys and studies;
(3) protect respondents' privacy and ensure that disclosure policies fully honor pledges of confidentiality;
(4) observe Federal standards and practices for data collection, analysis, documentation, sharing, and dissemination of information;
(5) ensure the timely publication of the results of statistical surveys and studies, including information about the quality and limitations of the surveys and studies; and
(6) make data available to statistical agencies and readily accessible to the public.

(f) <<NOTE: Records.>> With respect to records management, each agency shall implement and enforce applicable policies and procedures, including requirements for archiving information maintained in electronic format, particularly in the planning, design and operation of information systems.

(g) <<NOTE: Privacy. Computer technology.>> With respect to privacy and security, each agency shall--
(1) implement and enforce applicable policies, procedures, standards, and guidelines on privacy, confidentiality, security, disclosure and sharing of information collected or maintained by or for the agency;
(2) assume responsibility and accountability for compliance with and coordinated management of sections 552 and 552a of title 5, the Computer Security Act of 1987 (40 U.S.C. 759 note), and related information management laws; and
(3) consistent with the Computer Security Act of 1987 (40 U.S.C. 759 note), identify and afford security protections

commensurate with the risk and magnitude of the harm resulting from the loss, misuse, or unauthorized access to or modification of information collected or maintained by or on behalf of an agency.

(h) <<NOTE: Science and technology.>> With respect to Federal information technology, each agency shall--

(1) implement and enforce applicable Governmentwide and agency information technology management policies, principles, standards, and guidelines;

(2) assume responsibility and accountability for information technology investments;

(3) promote the use of information technology by the agency to improve the productivity, efficiency, and effectiveness of agency programs, including the reduction of information collection burdens on the public and improved dissemination of public information;

(4) propose changes in legislation, regulations, and agency procedures to improve information technology practices, includ [[Page 109 STAT. 176]] ing changes that improve the ability of the agency to use technology to reduce burden; and

(5) assume responsibility for maximizing the value and assessing and managing the risks of major information systems initiatives through a process that is--

(A) integrated with budget, financial, and program management decisions; and

(B) used to select, control, and evaluate the results of major information systems initiatives.

Sec. 3507. Public information collection activities; submission to Director; approval and delegation

(a) An agency shall not conduct or sponsor the collection of information unless in advance of the adoption or revision of the collection of information--

(1) the agency has--

(A) conducted the review established under section 3506(c)(1);

(B) evaluated the public comments received under section 3506(c)(2);

(C) submitted to the Director the certification required under section 3506(c)(3), the proposed collection of information, copies of pertinent statutory authority, regulations, and other related materials as the Director may specify; and

(D) <<NOTE: Federal Register, publication.>> published a notice in the Federal Register--

(i) stating that the agency has made such submission; and

(ii) setting forth--

(I) a title for the collection of information;

(II) a summary of the collection of information;

(III) a brief description of the need for the information and the proposed use of the information;

(IV) a description of the likely respondents and proposed frequency of response to the collection of information;

(V) an estimate of the burden that shall result from the collection of information; and

(VI) notice that comments may be submitted to the agency and Director;

(2) the Director has approved the proposed collection of information or approval has been inferred, under the provisions of this section; and

(3) the agency has obtained from the Director a control number to be displayed upon the collection of information.

(b) The Director shall provide at least 30 days for public comment prior to making a decision under subsection (c), (d), or (h), except as provided under subsection (j).

(c)(1) For any proposed collection of information not contained in a proposed rule, the Director shall notify the agency involved of the decision to approve or disapprove the proposed collection of information.

(2) The Director shall provide the notification under paragraph (1), within 60 days after receipt or publication of the notice under subsection (a)(1)(D), whichever is later. [[Page 109 STAT. 177]]

(3) If the Director does not notify the agency of a denial or approval within the 60-day period described under paragraph (2)--

(A) the approval may be inferred;

(B) a control number shall be assigned without further delay; and

(C) the agency may collect the information for not more than 1 year.

(d)(1) <<NOTE: Proposed rule.>> For any proposed collection of information contained in a proposed rule--

(A) as soon as practicable, but no later than the date of publication of a notice of proposed rulemaking in the Federal Register, each agency shall forward to the Director a copy of any proposed rule which contains a collection of information and any information requested by the Director necessary to make the determination required under this subsection; and

(B) <<NOTE: Federal Register, publication.>> within 60 days after the notice of proposed rulemaking is published in the Federal Register, the Director may file public comments pursuant to the standards set forth in section 3508 on the collection of information contained in the proposed rule;

(2) <<NOTE: Regulations. Federal Register, publication.>> When a final rule is published in the Federal Register, the agency shall explain--

(A) how any collection of information contained in the final rule responds to the comments, if any, filed by the Director or the public; or

(B) the reasons such comments were rejected.

(3) If the Director has received notice and failed to comment on an agency rule within 60 days after the notice of proposed rulemaking, the Director may not disapprove any collection of information specifically contained in an agency rule.

(4) No provision in this section shall be construed to prevent the Director, in the Director's discretion--

(A) from disapproving any collection of information which was not specifically required by an agency rule;

(B) from disapproving any collection of information contained in an agency rule, if the agency failed to comply with the requirements of paragraph (1) of this subsection;

(C) from disapproving any collection of information contained in a final agency rule, if the Director finds within 60 days after the publication of the final rule that the agency's response to the Director's comments filed under paragraph (2) of this subsection was unreasonable; or

(D) from disapproving any collection of information contained in a final rule, if--

(i) the Director determines that the agency has substantially modified in the final rule the collection of information contained in the proposed rule; and

(ii) the agency has not given the Director the information required under paragraph (1) with respect to the modified collection of information, at least 60 days before the issuance of the final rule.

(5) This subsection shall apply only when an agency publishes a notice of proposed rulemaking and requests public comments.

(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. [[Page 109 STAT. 178]]

(e)(1) Any decision by the Director under subsection (c), (d), (h), or (j) to disapprove a collection of information, or to instruct the agency to make substantive or material change to a collection of information, shall be publicly available and include an explanation of the reasons for such decision.

(2) Any written communication between the Administrator of the Office of Information and Regulatory Affairs, or any employee of the Office of Information and Regulatory Affairs, and an agency or person not employed by the Federal Government concerning a proposed collection of information shall be made available to the public.

(3) This subsection shall not require the disclosure of--

(A) any information which is protected at all times by procedures established for information which has been specifically authorized under criteria established by an Executive order or an Act of Congress to be kept secret in the interest of national defense or foreign policy; or

(B) any communication relating to a collection of information which is not approved under this chapter, the disclosure of which could lead to retaliation or discrimination against the communicator.

(f)(1) An independent regulatory agency which is administered by 2 or more members of a commission, board, or similar body, may by majority vote void--

(A) any disapproval by the Director, in whole or in part, of a proposed collection of information of that agency; or

(B) an exercise of authority under subsection (d) of section 3507 concerning that agency.

(2) The agency shall certify each vote to void such disapproval or exercise to the Director, and explain the reasons for such vote. The Director shall without further delay assign a control number to such collection of information, and such vote to void the disapproval or exercise shall be valid for a period of 3 years.

(g) The Director may not approve a collection of information for a period in excess of 3 years.

(h)(1) If an agency decides to seek extension of the Director's approval granted for a currently approved collection of information, the agency shall--

(A) conduct the review established under section 3506(c), including the seeking of comment from the public on the continued need for, and burden imposed by the collection of information; and

(B) after having made a reasonable effort to seek public comment, but no later than 60 days before the expiration date of the control number assigned by the Director for the currently approved collection of information, submit the collection of

information for review and approval under this section, which shall include an explanation of how the agency has used the information that it has collected.

(2) If under the provisions of this section, the Director disapproves a collection of information contained in an existing rule, or recommends or instructs the agency to make a substantive or material change to a collection of information contained in an existing rule, the Director shall--

(A) <<NOTE: Federal Register, publication. [[Page 109 STAT. 179]] >> publish an explanation thereof in the Federal Register; and [[Page 109 STAT. 179]]

(B) instruct the agency to undertake a rulemaking within a reasonable time limited to consideration of changes to the collection of information contained in the rule and thereafter to submit the collection of information for approval or disapproval under this chapter.

(3) An agency may not make a substantive or material modification to a collection of information after such collection has been approved by the Director, unless the modification has been submitted to the Director for review and approval under this chapter.

(i)(1) If the Director finds that a senior official of an agency designated under section 3506(a) is sufficiently independent of program responsibility to evaluate fairly whether proposed collections of information should be approved and has sufficient resources to carry out this responsibility effectively, the Director may, by rule in accordance with the notice and comment provisions of chapter 5 of title 5, United States Code, delegate to such official the authority to approve proposed collections of information in specific program areas, for specific purposes, or for all agency purposes.

(2) A delegation by the Director under this section shall not preclude the Director from reviewing individual collections of information if the Director determines that circumstances warrant such a review. The Director shall retain authority to revoke such delegations, both in general and with regard to any specific matter. In acting for the Director, any official to whom approval authority has been delegated under this section shall comply fully with the rules and regulations promulgated by the Director.

(j)(1) The agency head may request the Director to authorize a collection of information, if an agency head determines that--

(A) a collection of information--

(i) is needed prior to the expiration of time periods established under this chapter; and

(ii) is essential to the mission of the agency; and

(B) the agency cannot reasonably comply with the provisions of this chapter because--

(i) public harm is reasonably likely to result if normal clearance procedures are followed;
(ii) an unanticipated event has occurred; or
(iii) the use of normal clearance procedures is reasonably likely to prevent or disrupt the collection of information or is reasonably likely to cause a statutory or court ordered deadline to be missed.

(2) The Director shall approve or disapprove any such authorization request within the time requested by the agency head and, if approved, shall assign the collection of information a control number. Any collection of information conducted under this subsection may be conducted without compliance with the provisions of this chapter for a maximum of 90 days after the date on which the Director received the request to authorize such collection.

Sec. 3508. Determination of necessity for information; hearing

Before approving a proposed collection of information, the Director shall determine whether the collection of information by the agency is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility. Before making a determination the Director may give the agency and other interested persons an opportunity to be heard [[Page 109 STAT. 180]] or to submit statements in writing. To the extent, if any, that the Director determines that the collection of information by an agency is unnecessary for any reason, the agency may not engage in the collection of information.

Sec. 3509. Designation of central collection agency

The Director may designate a central collection agency to obtain information for two or more agencies if the Director determines that the needs of such agencies for information will be adequately served by a single collection agency, and such sharing of data is not inconsistent with applicable law. In such cases the Director shall prescribe (with reference to the collection of information) the duties and functions of the collection agency so designated and of the agencies for which it is to act as agent (including reimbursement for costs). While the designation is in effect, an agency covered by the designation may not obtain for itself information for the agency which is the duty of the collection agency to obtain. The Director may modify the designation from time to time as circumstances require. The authority to designate under this section is subject to the provisions of section 3507(f) of this chapter.

Sec. 3510. Cooperation of agencies in making information available

(a) The Director may direct an agency to make available to another agency, or an agency may make available to another agency, information obtained by a collection of information if the disclosure is not inconsistent with applicable law.

(b)(1) If information obtained by an agency is released by that agency to another agency, all the provisions of law (including penalties) that relate to the unlawful disclosure of information apply to the officers and employees of the agency to which information is released to the same extent and in the same manner as the provisions apply to the officers and employees of the agency which originally obtained the information.

(2) The officers and employees of the agency to which the information is released, in addition, shall be subject to the same provisions of law, including penalties, relating to the unlawful disclosure of information as if the information had been collected directly by that agency.

Sec. 3511. Establishment and operation of Government Information Locator Service

(a) In order to assist agencies and the public in locating information and to promote information sharing and equitable access by the public, the Director shall--

(1) cause to be established and maintained a distributed agency-based electronic Government Information Locator Service (hereafter in this section referred to as the `Service'), which shall identify the major information systems, holdings, and dissemination products of each agency;

(2) require each agency to establish and maintain an agency information locator service as a component of, and to support the establishment and operation of the Service;

(3) [[Page 109 STAT. 181]] <<NOTE: Establishment.>> in cooperation with the Archivist of the United States, the Administrator of General Services, the Public Printer, and the Librarian of Congress, establish an interagency committee [[Page 109 STAT. 181]] to advise the Secretary of Commerce on the development of technical standards for the Service to ensure compatibility, promote information sharing, and uniform access by the public;

(4) consider public access and other user needs in the establishment and operation of the Service;

(5) ensure the security and integrity of the Service, including measures to ensure that only information which is intended to be disclosed to the public is disclosed through the Service; and

(6) periodically review the development and effectiveness of the Service and make recommendations for improvement, including other mechanisms for improving public access to Federal agency public information.

(b) This section shall not apply to operational files as defined by the Central Intelligence Agency Information Act (50 U.S.C. 431 et seq.).

Sec. 3512. Public protection

(a) Notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information that is subject to this chapter if--

(1) the collection of information does not display a valid control number assigned by the Director in accordance with this chapter; or

(2) the agency fails to inform the person who is to respond to the collection of information that such person is not required to respond to the collection of information unless it displays a valid control number.

(b) The protection provided by this section may be raised in the form of a complete defense, bar, or otherwise at any time during the agency administrative process or judicial action applicable thereto.

Sec. 3513. Director review of agency activities; reporting; agency response

(a) In consultation with the Administrator of General Services, the Archivist of the United States, the Director of the National Institute of Standards and Technology, and the Director of the Office of Personnel Management, the Director shall periodically review selected agency information resources management activities to ascertain the efficiency and effectiveness of such activities to improve agency performance and the accomplishment of agency missions.

(b) Each agency having an activity reviewed under subsection (a) shall, within 60 days after receipt of a report on the review, provide a written plan to the Director describing steps (including milestones) to--

(1) be taken to address information resources management problems identified in the report; and

(2) improve agency performance and the accomplishment of agency missions.

Sec. 3514. Responsiveness to Congress

(a)(1) The Director shall--

(A) keep the Congress and congressional committees fully and currently informed of the major activities under this chapter; and [[Page 109 STAT. 182]]

(B) <<NOTE: Reports.>> submit a report on such activities to the President of the Senate and the Speaker of the House of Representatives annually and at such other times as the Director determines necessary.

(2) The Director shall include in any such report a description of the extent to which agencies have--

(A) reduced information collection burdens on the public, including--

(i) a summary of accomplishments and planned initiatives to reduce collection of information burdens;

(ii) a list of all violations of this chapter and of any rules, guidelines, policies, and procedures issued pursuant to this chapter;

(iii) a list of any increase in the collection of information burden, including the authority for each such collection; and

(iv) a list of agencies that in the preceding year did not reduce information collection burdens in accordance with section 3505(a)(1), a list of the programs and statutory responsibilities of those agencies that precluded that reduction, and recommendations to assist those agencies to reduce information collection burdens in accordance with that section;

(B) improved the quality and utility of statistical information;

(C) improved public access to Government information; and

(D) improved program performance and the accomplishment of agency missions through information resources management.

(b) The preparation of any report required by this section shall be based on performance results reported by the agencies and shall not increase the collection of information burden on persons outside the Federal Government.

Sec. 3515. Administrative powers

Upon the request of the Director, each agency (other than an independent regulatory agency) shall, to the extent practicable, make its services, personnel, and facilities available to the Director for the performance of functions under this chapter.

Sec. 3516. Rules and regulations

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

Sec. 3517. Consultation with other agencies and the public

(a) In developing information resources 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.

(b) Any person may request the Director to review any collection of information conducted by or for an agency to determine, if, under this chapter, a person shall maintain, provide, or disclose the information to or for the agency. Unless the request is frivolous, the Director shall, in coordination with the agency responsible for the collection of information-- [[Page 109 STAT. 183]]

(1) respond to the request within 60 days after receiving the request, unless such period is extended by the Director to a specified date and the person making the request is given notice of such extension; and

(2) take appropriate remedial action, if necessary.

Sec. 3518. Effect on existing laws and regulations

(a) Except as otherwise provided in this chapter, the authority of an agency under any other law to prescribe policies, rules, regulations, and procedures for Federal information resources management activities is subject to the authority of the Director under this chapter.

(b) Nothing in this chapter shall be deemed to affect or reduce the authority of the Secretary of Commerce or the Director of the Office of Management and Budget pursuant to Reorganization Plan No. 1 of 1977 (as amended) and Executive order, relating to telecommunications and information policy, procurement and management of telecommunications and information systems, spectrum use, and related matters.

(c)(1) Except as provided in paragraph (2), this chapter shall not apply to the collection of information--

(A) during the conduct of a Federal criminal investigation or prosecution, or during the disposition of a particular criminal matter;

(B) during the conduct of--

(i) a civil action to which the United States or any official or agency thereof is a party; or

(ii) an administrative action or investigation involving an agency against specific individuals or entities;

(C) by compulsory process pursuant to the Antitrust Civil Process Act and section 13 of the Federal Trade Commission Improvements Act of 1980; or

(D) during the conduct of intelligence activities as defined in section 3.4(e) of Executive Order No. 12333, issued December 4, 1981, or successor orders, or during the conduct of cryptologic activities that are communications security activities.

(2) This chapter applies to the collection of information during the conduct of general investigations (other than information collected in an antitrust investigation to the extent provided in subparagraph (C) of paragraph (1)) undertaken with reference to a category of individuals or entities such as a class of licensees or an entire industry.

(d) Nothing in this chapter shall be interpreted as increasing or decreasing the authority conferred by Public Law 89-306 on the Administrator of the General Services Administration, the Secretary of Commerce, or the Director of the Office of Management and Budget.

(e) Nothing in this chapter shall be interpreted as increasing or decreasing the authority of the President, the Office of Management and Budget or the Director thereof, under the laws of the United States, with respect to the substantive policies and programs of departments, agencies and offices, including the substantive authority of any Federal agency to enforce the civil rights laws.

Sec. 3519. Access to information

Under the conditions and procedures prescribed in section 716 of title 31, the Director and personnel in the Office of Informa [[Page 109 STAT. 184]] tion and Regulatory Affairs shall furnish such information as the Comptroller General may require for the discharge of the responsibilities of the Comptroller General. For the purpose of obtaining such information, the Comptroller General or representatives thereof shall have access to all books, documents, papers and records, regardless of form or format, of the Office.

Sec. 3520. Authorization of appropriations

There are authorized to be appropriated to the Office of Information and Regulatory Affairs to carry out the provisions of this chapter, and for no other purpose, $8,000,000 for each of the fiscal years 1996, 1997, 1998, 1999, 2000, and 2001.''.

SEC. 3. BURDEN REDUCTION REGARDING QUARTERLY FINANCIAL REPORT PROGRAM AT BUREAU OF THE CENSUS.

Section 91 of title 13, United States Code, is amended by adding at the end the following new subsection:

(d)(1) The Secretary shall not select an organization or entity for participation in a survey, if--

(A) the organization or entity--

(i) has assets of less than $50,000,000;

(ii) completed participation in a prior survey in the preceding 10-year period, as determined by the Secretary; and

(iii) was selected for that prior survey participation after September 30, 1990; or

(B) the organization or entity--

(i) has assets of more than $50,000,000 and less than $100,000,000;

(ii) completed participation in a prior survey in the preceding 2-year period, as determined by the Secretary; and

(iii) was selected for that prior survey participation after September 30, 1995.

(2)(A) The Secretary shall furnish advice and similar assistance to ease the burden of a small business concern which is attempting to compile and furnish the business information required of organizations and entities participating in the survey.

(B) To facilitate the provision of the assistance under subparagraph (A), the Secretary shall establish a toll-free telephone number.

(C) The Secretary shall expand the use of statistical sampling techniques to select organizations and entities having assets less than $100,000,000 to participate in the survey.

(3) The Secretary may undertake such additional paperwork burden reduction initiatives with respect to the conduct of the survey as may be deemed appropriate by the Secretary.

(4) For purposes of this subsection:

(A) The term `small business concern' means a business concern that meets the requirements of section 3(a) of the Small Business Act and the regulations promulgated pursuant thereto.

(B) The term `survey' means the collection of information by the Secretary pursuant to this section for the purpose of preparing the publication entitled `Quarterly Financial Report for Manufacturing, Mining, and Trade Corporations'.''. [[Page 109 STAT. 185]]

SEC. 4. <<NOTE: 44 USC 3501 note.>> EFFECTIVE DATE.

(a) In General.--Except as otherwise provided in this section, this Act and the amendments made by this Act shall take effect on October 1, 1995.

(b) Authorization of Appropriations.--Section 3520 of title 44, United States Code, as amended by this Act, shall take effect on the date of enactment of this Act.

(c) Delayed Application.--In the case of a collection of information for which there is in effect on September 30, 1995, a control number issued by the Office of Management and Budget under chapter 35 of title 44, United States Code--

(1) the amendments made by this Act shall apply to the collection of information beginning on the earlier of--

(A) the first renewal or modification of that collection of information after September 30, 1995; or

(B) the expiration of its control number after September 30, 1995.

(2) prior to such renewal, modification, or expiration, the collection of information shall be subject to chapter 35 of title 44, United States Code, as in effect on September 30, 1995.

Approved May 22, 1995.

LEGISLATIVE HISTORY--S. 244 (H.R. 830):

HOUSE REPORTS: No.. 104-37 accompanying H.R. 830 (Comm. on Government Reform and Oversight) and 104-99 (Comm. of Conference).
SENATE REPORTS: No. 104-8 (Comm. on Governmental Affairs).
CONGRESSIONAL RECORD, Vol. 141 (1995):
Feb. 22, H.R. 830 considered and passed House.
Mar. 6, 7, S. 244 considered and passed Senate.
Mar. 10, considered and passed House, amended.
Apr. 6, Senate and House agreed to conference report.
WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 31 (1995):
May 22, Presidential remarks.

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