

Office of Management and Budget Proposed Bulletin on Peer Review and Information Quality

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Information Quality Act

- The government-wide Information Quality Law requires agencies to:
 - Develop **pre-dissemination** procedures to ensure the quality of information disseminated by the agencies.
 - Develop an administrative mechanism whereby affected parties can request that agencies correct poor quality information.
- The peer review bulletin is designed to clarify and give operational force to the pre-dissemination requirements of the Information Quality Law.

Why Peer Review is Useful

- Peer review improves the technical quality of information products.
- Peer review enhances the credibility of governmental information.

Proposed Bulletin on Peer Review

- The objective is to define government-wide expectations for the peer review of significant regulatory information.
- The proposed bulletin instructs the agencies to develop peer review guidelines for the most important scientific and technical information relevant to regulatory policies.

History Shows that Agency Peer Review Practices are Uneven

- Some agencies have no peer review policies.
- Some agencies have peer review policies in place or encourage peer review, but peer reviews are not always conducted according to agency policies, even for major rulemakings.
- No oversight mechanism currently exists.

Coverage of the Proposed Bulletin

- Applies to all agencies covered by the Paperwork Reduction Act, including independent agencies.
- It does not apply to third parties (e.g., grantees, contractors).

OMB Definitions

- **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 that the information satisfies the **influential** test in OMB's Information Quality Guidelines.
 - **Influential:** “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.” (OMB)

OMB Definitions (continued)

- **Especially Significant Regulatory Information** is defined as significant regulatory information that
 - (i) the agency intends to disseminate in support of an “economically significant” regulatory action, or
 - (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 information is of significant interagency interest or is related to an Administration priority.

Expectations for Especially Significant Regulatory Information

- External peer reviewers with the necessary experience and independence.
- The agencies must provide the peer reviewers with sufficient information and an appropriately broad charge.
- The agencies must publicly respond to the peer reviewers' written reports, and make other appropriate disclosures (e.g., disclose names of reviewers).

Types of Information Covered

- Scientific or technical studies, reports
 - Not limited to the physical sciences – includes social sciences
- Reviews of the literature (state of the science)
- Risk Assessments
- Regulatory Analyses (science, engineering, and economic inputs)

Types of Information Not Covered

- Grant applications
- Material already peer reviewed
- Internal documents (not disseminated)
- Individual adjudications and permit applications
- National security (defense/foreign affairs)
- Routine financial and statistical information
- Waiver for emergencies, imminent health hazards (e.g., national security concerns)

Advance Notice of Peer Review Plans

- Proposes that agencies will periodically publish a list of forthcoming reports and disclose peer review plans for these reports.
 - This will allow oversight by OIRA and OSTP as well as public participation.

Topics to be Addressed in Agency Guidelines

- Real or perceived conflicts (e.g., business ties)
- Entanglements with the sponsoring agency (e.g., grants)
- Bias

Review of Five Recent Agency Reports

Agency

Report

NHTSA

SUV Safety Study

OMB

**Circular A-4: Regulatory Impact
Analyses (RIA) Guidelines**

FDA

Trans Fat RIA

EPA

Benzene Inhalation Cancer Value

EPA

**Diesel Engine Emissions (inhalation
cancer and non-cancer values)**

Report #1

Peer Review Parameters	NHTSA SUV Safety Study
Were Reviewers External to the Agency?	Yes
Was there a written explicit charge?	Yes
Was the charge focused on science, not policy?	Yes
Was there a public comment period?	No
Were public comments provided to peer reviewers in advance?	Not Applicable
Did the peer reviewers provide a written detailed report(s)?	Yes
Did reviewers work as individuals or as a group?	Individual
Did the agency provide a written response to the peer review document?	No
Did the agency disseminate the peer review report(s) in a way similar to original document dissemination?	No
What was the length of time of the peer review process?	4 months
What was the approximate budgetary cost of the peer review process?	\$8,000

Report #2

Peer Review Parameters	OMB Circular A-4 RIA Guidelines
Were Reviewers External to the Agency?	Yes
Was there a written explicit charge?	No
Was the charge focused on science, not policy?	Yes
Was there a public comment period?	Yes
Were public comments provided to peer reviewers in advance?	No
Did the peer reviewers provide a written detailed report(s)?	Yes
Did reviewers work as individuals or as a group?	Individual
Did the agency provide a written response to the peer review document?	Yes
Did the agency disseminate the peer review report(s) in a way similar to original document dissemination?	Yes
What was the length of time of the peer review process?	6-8 weeks
What was the approximate budgetary cost of the peer review process?	zero

Report #3

Peer Review Parameters	FDA Trans Fat RIA
Were Reviewers External to the Agency?	Yes
Was there a written explicit charge?	Yes
Was the charge focused on science, not policy?	Yes
Was there a public comment period?	Yes
Were public comments provided to peer reviewers in advance?	No
Did the peer reviewers provide a written detailed report(s)?	Yes
Did reviewers work as individuals or as a group?	Individual
Did the agency provide a written response to the peer review document?	Yes
Did the agency disseminate the peer review report(s) in a way similar to original document dissemination?	No
What was the length of time of the peer review process?	1 week
What was the approximate budgetary cost of the peer review process?	zero

Report #4

Peer Review Parameters	EPA Benzene Cancer-Inhalation
Were Reviewers External to the Agency?	Yes
Was there a written explicit charge?	Yes
Was the charge focused on science, not policy?	Yes
Was there a public comment period?	Yes
Were public comments provided to peer reviewers in advance?	No
Did the peer reviewers provide a written detailed report(s)?	Yes
Did reviewers work as individuals or as a group?	Group
Did the agency provide a written response to the peer review document?	Yes
Did the agency disseminate the peer review report(s) in a way similar to original document dissemination?	No
What was the length of time of the peer review process?	135 days
What was the approximate budgetary cost of the peer review process?	\$36,000

Report #5

Peer Review Parameters	EPA Diesel Engine Emissions
Were Reviewers External to the Agency?	Yes
Was there a written explicit charge?	Yes
Was the charge focused on science, not policy?	Yes
Was there a public comment period?	Yes
Were public comments provided to peer reviewers in advance?	No
Did the peer reviewers provide a written detailed report(s)?	Yes
Did reviewers work as individuals or as a group?	Group
Did the agency provide a written response to the peer review document?	Yes
Did the agency disseminate the peer review report(s) in a way similar to original document dissemination?	Yes and No
What was the length of time of the peer review process?	60-90 days per review*
What was the approximate budgetary cost of the peer review process?	\$340,000

*There were 5 external review drafts, 5 public comment periods, and a CASAC consultation.

Lessons from the Reports Examined

- Much peer review already occurs
- Peer review practices are variable (e.g., group vs. individual reviews)
- Peer review is not necessarily expensive or time consuming for the agencies

Public Comment

- Public comment period extended until December 15th
- Agency comment period extended until January 16th
- We are looking for comment on all aspects of the bulletin