

# 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

<b>Peer Review Parameters</b>	<b>NHTSA SUV Safety Study</b>
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?	<b>No</b>
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?	<b>No</b>
Did the agency disseminate the peer review report(s) in a way similar to original document dissemination?	<b>No</b>
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

<b>Peer Review Parameters</b>	<b>OMB Circular A-4 RIA Guidelines</b>
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

<b>Peer Review Parameters</b>	<b>FDA Trans Fat RIA</b>
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

<b>Peer Review Parameters</b>	<b>EPA Benzene Cancer-Inhalation</b>
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?	<b>No</b>
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?	<b>No</b>
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

<b>Peer Review Parameters</b>	<b>EPA Diesel Engine Emissions</b>
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?	<b>No</b>
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 15<sup>th</sup>
- Agency comment period extended until January 16<sup>th</sup>
- We are looking for comment on all aspects of the bulletin