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04/26/2004 10:32:29 AM

Record Type: Record

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cc:

Subject: Submission for Public Comment Record on Revised Information Quality Bulletin 15 April 2004

26 April, 2004

TO: OMB/OIRA PUBLIC COMMENT DOCKET

FROM: Gilbert S. Omenn, M.D., Ph.D.
Professor of Internal Medicine, Human Genetics, and
Public Health
Former Associate Director, OMB and OSTP
(Bio, CV, & bibliography attached [not attached])

RE: 15 April Revised Information Quality Bulletin on Peer Review of
Scientific Information

This very substantial and appropriate revision of the original Peer Review Information Quality Bulletin addresses many issues raised at the NAS November 2003 Workshop and in extensive public comment. I was one of the invited speakers at the NAS Workshop and also publicly addressed the proposed Bulletin as an invited speaker at the January 2004 ILSI/HESI conference.

The explicit narrowing of the applicable situations is a major improvement. The use of NAS, HEI, and NCRPM peer reviews is helpful in setting standards for quality and process, and efficient for the agencies. The reliance on well-justified discretion by the agencies is pragmatic and appropriate. The guidance about appointing and rotating peer reviewers (p.21-22, e.g.) is reasonable.

I have two major recommendations for clarification of the Bulletin:
(1) Under "transparency", the release of individual peer reviews, and
(2) overlap between criteria for distinguishing Section II and Section III assessments.

1. The requirement, with regard to highly influential scientific information, that all peer reviewers be identified and have their peer review comments fairly summarized in the aggregate seems sufficient; such is the practice of the National Research Council, under the guidance of the Academies' Report Review Committee. The release of the specific review documents from individual reviewers, especially in a

group process, is not at all consistent with the NRC procedures or the usual practices of peer review in the other settings you describe, even though public comment has identified some settings in which individual letter review reports may already be released.

I think it would be wise to utilize the NRC procedures here. In fact, the guidance of section III(5) on p.33 (and comment on p.22) for a summary peer review report, generally without attributions to specific reviewers, seems quite reasonable. I recommend that specific attributions be removed. While I respect the desire to hold reviewers accountable for their comments and discourage any unfair or nasty comments, we have learned from the public release of letters of recommendation and other potentially critical documents that candor and detail are often (though not always, of course) sacrificed under conditions requiring such release. Allowing a lot of discretion on this process may exacerbate the criticism of inconsistency across the whole government and even within particular agencies. OMB/OIRA and OSTP might reconsider whether discretion on this point is needed as part of the general strategy on agency discretion.

2. It would be wise to clarify that "highly influential" scientific information is a subset of "influential scientific information" and that Section II language in the preamble and the Bulletin itself about "novelty and complexity" and "benefit and cost implications" is intended to move such assessments into Section III.

Presently p.10ff, Section II, and p.31, section II/2 have too many paragraphs with various phrases that push the requirements into "rigorous peer review" (p.10) "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". On p.12, "more rigorous" applies to "novel or precedent-setting". These phrases are, indeed, criteria for "highly influential". Within Section II, language should be added to make clear what these thresholds are for moving the assessments into Section III, as with the \$500 million estimated cost impact.

A few other specific comments:

p.8: The disclaimer is fine. However, the guidance to "discourage state, local, international, and private organizations" may have to be balanced with the need or desire of the federal agency to exchange information and utilize final or even draft documents from those agencies. Such interactions are fairly common in this federal system, reflecting Justice Brandeis' admonition in 1932 in the Oklahoma ice company case to "learn from social experiments" at the state level.

p.9: Clarify whether peer reviews specific for newsletters, website additions, and other communication vehicles would be required each time such a missive were prepared or modified. Presumably, reasonable use of previously peer reviewed material would be permissible.

p.17: Consultants and advisers on such panels as the EPA Scientific Advisory Board and its many committees should be stated to be eligible

here, as well as on p.21, where such individuals are stated to be classified as "special government employees", who are declared eligible even for Section III reviews (p.21).

p.24, Section V: This guidance about planning would be improved if the comments above about confusion between Section II and Section III were clarified. Surely (p.24), one of the key determinations by the Agency should be classification of the document under development as "influential" versus "highly influential". This point is omitted currently.

p.25: Phased introduction of Section III before Section II: good plan.

p.27: Not clear why RIAs, even with interagency preparation and review, should be excluded from peer review. See your citation on p.6, footnote 8, from the Risk Commission.

p.29: OIRA + OSTP review process: good plan.

I trust that these comments will be helpful in the final revision of the proposed Bulletin.

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