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June 15, 2006

Via e-mail to OMB_RAbulletin@omb.eop.gov and
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Dr. Nancy Beck
Office of Information and Regulatory Affairs
Office of Management and Budget
Executive Office of the President
725 17th St., NW
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Re: Comments on OMB's Proposed IQA Risk Assessment Bulletin (http://www.whitehouse.gov/omb/inforeg/proposed_risk_assessment_bulletin_010906.pdf, Jan. 9, 2006; 71 FR 2600, Jan. 17, 2006)

Dear Dr. Beck:

CRE regards much of this proposal as a major step forward in applying the Congressional directives on data quality to health, safety, and environmental risk information disseminated to the public by federal agencies. The proposal particularly clarifies the application to risk assessments of the requirements for "objectivity" and "utility" that are mandated by the legislation and the existing guidelines. The intermingling of scientific knowledge with policy assumptions and views in many past agency risk assessments and risk characterizations has fostered public misunderstanding and generated incessant controversy. We believe that the separation of science from policy through implementation of the existing "objectivity", "absence of bias", transparency, and utility requirements should make risk assessments far less controversial and improve public understanding of risks and government decisions based on risk assessment.

In the comments below, we do note, however, the significant problems with the "exemptions" portion of the proposal; and we also recommend some significant refinements and clarifications in other portions of the draft. Particularly if the problems with the exemptions provision can be fixed, we believe this guidance will be a major advance in ensuring and maximizing the quality of risk information disseminated to the public.

Center for Regulatory Effectiveness

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Summary of Comments

- The term "technical" in "technical guidance" could be confusing and should be deleted. The objective of "utility" should be added. It would be useful to distinguish between risk characterization and risk communication.

- The definition of "risk assessment" should continue to cover hazard identification.

- The citation of legal authority for the bulletin is incomplete. The section of the 1995 Paperwork Reduction Act ("PRA") directing OMB to issue rules, regulations or procedures to provide guidance on the quality of information disseminations, § 3516, should be cited as legal authority, since it is explicitly incorporated by reference into the IQA.

- The proposed exemption from the guidance for individual adjudications and permit proceedings is inconsistent with the IQA and PRA. The IQA and PRA do not authorize any exemptions for information disseminations. At most, any exemptions should be limited to those set out in the PRA for information collections.

- The bulletin should address and apply to how risk assessment findings are characterized in documents that are not themselves risk assessments.

- Completeness with regard to significant data and analytical elements that would materially alter the risk assessment conclusions should be a requirement, not a goal..

- The bulletin should state that it clarifies how the already-existing IQA objectivity requirement applies specifically to risk assessments.

- The bulletin should clarify that hazard descriptors such as "known human carcinogen" should not be used in risk characterizations.

- Policy-driven assumptions that are intermingled with the description and analysis of scientific knowledge are not consistent with objectivity. When such intermingling occurs, it constitutes bias (*i.e.*, lack of objectivity). Risk assessments should make very clear where science ends and policy begins, and how much policy contributes cumulatively (not in a piecemeal fashion) to any final risk assessment conclusions.

- The portion of the bulletin directing agencies to employ risk comparisons in describing risk in the executive summary of the risk assessment should be expanded to direct that risk comparisons should (1) require risk comparisons, (2) make clear any differences in uncertainty in the risks compared, and (2) compare risks that are likely to be encountered by the target audience in choosing between alternatives or substitutes.

- In comparing a risk assessment with other risk assessments conducted by other qualified entities, such comparison should be mandatory and should take into account whether the other risk assessment(s) comply with the IQA guidance.

- Agencies should be required to refrain from highlighting only high-end or low-end risk estimates, not simply "discouraged" from doing so.

- The "uncertainty factors" often are not scientifically supported and are a type of policy-driven assumption. The bulletin should state that UFs must either be scientifically justified or else used only as a risk management tool. The risk assessment should explain why any individual uncertainty factor number was chosen, and make clear the cumulative impact of uncertainty factors on the overall assessment.

- The bulletin should state clearly that risk estimates must assess the risk of clinically-verifiable adverse effects, not simply biological effects (even if on the causal pathway) rather than simply advising agencies to discuss the distinction between adverse and non-adverse effects.

- The bulletin should state clearly a requirement that agencies must prepare a "response-to-comments" document for influential risk assessments, rather than stating that it is "typically useful" to prepare such a document.

- The bulletin should clearly state that agencies are required to update a risk assessment when significant new scientific data that is likely to alter materially the existing risk assessment is brought to its attention. The bulletin should also address how agencies should update influential risk assessments that do not conform to the new guidance.

- OMB should have oversight of any agency claim that deferral or waiver of the bulletin's requirements is necessary.

- The effective date provision is unclear with regard to whether the bulletin applies to risk assessments that were completed prior to the effective date but which are still disseminated after the date. It is also apparently in conflict with requirements for updates of existing risk assessments, and with the already-existing requirement for objectivity. A one-year effective date is too long, and six months should be sufficient.

- The disclaimer regarding judicial reviewability is factually inaccurate and inappropriate.

Comments on Specific Sections of the Proposal

Summary and Introduction (pp. 1-3)

The term "technical" in "technical guidance" is, we believe, likely to be confusing, and it would be clearer to state simply that OMB is issuing "guidance on how the requirements of the Information Quality Act and previous OMB IQA guidance apply specifically to health, safety,

and environmental[1] risk assessments and risk assessment information disseminated by federal agencies."

On p. 3, in the first sentence of the paragraph beginning "The purpose of this Bulletin", it should state that the purpose is to enhance the quality, objectivity, and utility of risk assessments.

The last paragraph of this section states that the bulletin does not address risk management and risk communication. It would be useful to explain that the bulletin does address risk management to the extent it seeks to inform risk managers, and reserve for them the policy discretion that arises from the need to sometimes bridge scientific uncertainties with "precautionary" assumptions or uncertainty or safety factors, some of which might be required by legislation. It would also be useful to explain that the bulletin does encompass "risk communication" to the extent that it addresses "risk characterization" (a distinction that, like the distinction between hazard and risk, is probably not understood by many).

Definition of risk assessment (pp.1, 8)

The definition encompasses not only full quantitative risk assessments, but also "qualitative" risk assessments and hazard identification. We view this coverage as not only appropriate but necessary. Objections have been raised on narrow technical grounds to referring to hazard identification as risk assessment[2]; however, as a practical matter hazard identification information is often disseminated to the public, either in the context of a full risk assessment or as stand-alone information, in a manner that conveys to the public the notion of risk. In our experience, few members of the public understand the distinction between hazard and risk, and they regard hazard information as a type of risk information. In addition, dissemination of "hazard" information often suffers from the same quality and utility deficiencies as full risk assessments: failure to provide full information on uncertainty and to explain whether or to what extent the information is relevant to the target audience. Moreover, as noted in the section below on risk characterization, hazard descriptors are often incorporated into "risk" characterizations, giving the clear impression that they are pertinent to risk. (We argue below that hazard descriptors should not be used in "risk" characterizations; however, if they are to be used, they must be used only as a way of describing why the risk assessment was undertaken or accompanied by information that clearly describes the limitations of the descriptor and its relevancy/irrelevancy in communicating a fuller description of risk to the target audience.) Regardless of how the definition is worded -- whether it refers to hazard information as risk

[1] "Environmental" risk assessments are also referred to as "ecological" risk assessments. Such risk assessments address risks of adverse impacts on the environment other than impacts on human health or safety (*e.g.*, impacts on plants, non-human species, or natural resources).

[2] During the first public meeting of the National Academies committee to peer review the proposed bulletin, a representative of NIEHS protested that risk assessment should not include hazard identification as presented in the Report on Carcinogens ("RoC"). However, a review of the legislative history of the statute requiring preparation of the RoCs shows that Congress regarded the information to be presented in the RoCs as a type of risk information. See H.R. Rep. No. 95-1192, May 15, 1978, at 28 (the RoCs should identify subpopulations "expected to be at higher than average risk"); Cong. Rec., Oct. 10, 1978, at 34938 (the Committee's intent is that the RoCs should estimate "the magnitude of the risk " and "relative risk").

information or draws a distinction -- the basic quality standards of objectivity, transparency, and utility should and must, as a matter of statutory mandate and existing guidance, apply to all types of risk or hazard information disseminated by federal agencies to the public.

Legal Authority (p. 7)

The explanation of legal authority contains only one of the provisions of the Paperwork Reduction Act of 1995 ("PRA") that are incorporated by reference into the Information Quality Act ("IQA"). The IQA specifically incorporates sections 3504(d)(1) and 3516 of the PRA as pre-existing legal authority, and also states that it (the IQA) is in furtherance of the other PRA provisions and goals. The "Legal Authority" section of the bulletin should therefore also quote and cite section 3516, which states that OMB "shall promulgate rules, regulations, or procedures necessary to exercise the authority provided by this chapter." A United States Code citation should also be provided for section 3504(d)(1) after it is quoted (just ahead of the sentence beginning "Moreover, Section 624 . . . .").

A citation to the United States Code should also be provided for the IQA. This citation should follow the existing citation to the Public Law (Pub. L. No. 106-554, § 515(a)) and should read "44 U.S.C. § 3516, note."[3] Title 44 of the United States Code has been enacted into positive law and therefore should be regarded as the primary reference.[4]

We believe it would also be useful to add a sentence stating that "the central purpose of this guidance is to clarify how the requirements for 'quality, objectivity, utility, and integrity' contained in the legislation and as defined in OMB's initial government-wide guidance (67 FR 8452, Feb. 22, 2002) apply specifically to risk assessments disseminated to the public."

Sec. II. Applicability (pp. 9-10, 23)

Agency discretion (p. 9)

The qualifying language "*to the extent appropriate*" [original italics] should be revised because it could be misconstrued as giving the agencies complete discretion as to whether to follow the bulletin. Such language an interpretation would conflict with other portions of the bulletin that clearly indicate the bulletin is binding. To the extent it could be construed as giving the agencies complete discretion, or very broad discretion, it is also inconsistent with the plain directions of § 3506(a)(1)(B) of the PRA, which requires all agencies to comply with information dissemination and quality policies established by OMB pursuant to §§ 3504(d)(1) and 3516, which are the legal authorities for issuing the bulletin guidance. Substitute language could be "to the extent feasible".

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[3] That the Office of the Law Revision Counsel, which has statutory responsibility for preparing and updating the United States Code, placed sec. 515 only as a note under sec. 3516 of the PRA in the United States Code emphasizes the importance of sec. 3516. See http://uscode.house.gov/about/info.shtml.

[4] See http://uscode.house.gov/about/info.shtml.

Exemption for Individual Adjudications and Permit Proceedings (pp. 10, 23)

The Bulletin includes the following exemptions from its applicability:

> 2. This Bulletin does not apply to risk assessments performed with respect to:
> . . .
> b. individual agency adjudications or permit proceedings (including a registration, approval, or licensing) unless the agency determines that
> i. compliance with this Bulletin is practical and appropriate and
> ii. the risk assessment is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings . . . .

These exemptions are inconsistent with the IQA and PRA, which OMB cites as legal authority for issuing the Bulletin. The proposed bulletin does not provide any legal justification for such exemptions.

The IQA contains no exemptions to its applicability.

The PRA contains only the following exemptions, and they are exemptions only to the PRA's information collection -- not information dissemination -- requirements:

> (c)(1) Except as provided in paragraph (2), this subchapter 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 againstspecific 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.[5]

These statutory exemptions do not include the adjudication/permit exemptions in the proposed bulletin. Congress chose to allow exemptions only to the information collection requirements of the PRA; it chose not to provide any exemptions to the information dissemination requirements.

[5] 44 U.S.C. § 3518(c).

The legislative history to the PRA confirms that these statutory exemptions to the information collection provisions are limited to criminal and civil investigations and adversarial administrative actions:

> [S]ection 3518(C)(1) creates certain exemptions for civil and criminal law enforcement that apply to collection of evidence pursuant to investigations whether before or after initiation of formal charges. These exemptions are not limited to formal discovery or analogous stages in administrative processing and include interrogatories, depositions and subpoenas. . . . The language in this subsection regarding 'an administrative action or investigation involving an agency against specific individuals or entities' is intended to preserve a well-settled exception for subpoenas and similar forms of compulsory process used for the collection of evidence or other information in an adjudication or investigation for law enforcement purposes. See 4 C.F.R. Section 10.6 (c)(5), (c)(8). Section 3518(c)(1)(B) is not limited to agency proceedings of a prosecutorial nature but also includes any agency proceeding involving specific adversary parties. Similar to the collection of information in litigation, an agency's intended use of investigatory and adjudicative process is sufficiently safeguarded through judicial superintendence to render unnecessary the administrative clearance process of this Act."[6]

If any exemptions are made to the IQA in general, and to the risk assessment bulletin specifically, then those exemptions should be no broader than the express statutory exemptions Congress crafted for information collection requests under the PRA. There is no textual or legislative history support for any broader exemptions.

Reference To Risk Assessment Findings In Other Information Disseminations

Either in this section or the section on risk characterization, the guidance should address the issue of how risk assessment findings should be addressed in information dissemination documents that are not themselves "risk assessments" (as defined in Sec. I, pp. 8-9). For example, a rulemaking notice, Q and A information, a fact sheet posted on an agency website, or a press release or other media materials, should not focus solely on worst-case or single-point estimates, since to do so would seriously undermine the "utility" and public information aims of the risk assessment guidance. On the other hand, such cross-references need not usually contain the amount of detail (*e.g.*, reproducibility requirements) contained in risk assessments. Although descriptions of risk assessment findings in such information disseminations are presumably already covered by the 2002 OMB government-wide guidance, a reminder here would be useful. This issue could also be handled by revising the definition of "risk assessment", for example, to also include "any disseminated document or other information derived from or referencing any covered document."

[6] S. Rep. No. 930, 96th Cong., 2nd Sess. at 2980, reprinted in 1980 USCCAN 6241, 6295-96.

Sec. III: Goals (pp. 10-11, 23)

Subsection 2 on "Goals Related to Completeness" should be clarified to ensure that it does not allow omission of important data/studies or analytical elements on the basis that "completeness" is aspirational, rather than a requirement, because it is referred to as a "goal". The OMB government-wide guidelines require completeness as an aspect of "objectivity" in order to ensure lack of bias.[7] (Omission of key data or an analytical element such as an explanation of uncertainties is likely to bias the assessment.) The focus of this subsection appears to be on whether to delay a risk assessment in order to acquire new data, but it is not clear. Completeness with regard to existing data or analytical elements required by the OMB guidance that would materially affect the risk assessment findings should be a requirement, not a goal. Completeness is also necessary to ensure reproducibility in influential risk assessments. Language at the top of p. 13 and the third paragraph of subsection 4 on p. 14 indicates that OMB recognizes that completeness is required.

Sec. IV: General Risk Assessment and Reporting Standards (pp. 11-16, 23-25)

The introduction to this section on p. 11 appears to state that the standards of objectivity, utility, and integrity are being introduced through these guidelines. The introduction should explain that the standards of objectivity, utility, and integrity were required by the original OMB government-wide guidelines of Feb. 22, 2002 (and the interim final guidelines of Sept. 28, 2001), and that this bulletin clarifies how those standards apply specifically to risk assessments.

3. Standards Related to Characterization of Risk (p. 13)

A particular embedded problem with current risk characterization practices of some agencies deserves specific attention in this section. Some agency risk assessments, and their risk assessment guidelines, frequently employ hazard descriptors, such as "known", "probable", "likely", or "reasonably anticipated" human carcinogen or "endocrine disruptor", in their risk characterizations. Use of such hazard descriptors in a risk characterization is usually misleading. A particular substances may be "known" to cause cancer in humans only at extremely high exposure levels that have been experienced in the distant past or serious industrial accidents. Stating that the substance is "known" to cause cancer in a risk assessment that focuses on exposures likely to be experienced under normal circumstances totally obscures uncertainty related to dose-response and other exposure circumstances (*e.g.*, pathway, co-carcinogenicity, use of required personal protective equipment).

Unfortunately, the definitions for, and use of, such hazard descriptors have generated enormous controversy, when they should be considered irrelevant to anything but a screening assessment. Any statement that an agent is "carcinogenic", or a "known" or "anticipated" human carcinogen, or similar statements, should always be accompanied by information concerning the level of exposure and other relevant circumstances under which it is "known" or "anticipated" to cause adverse effects. Recent revisions to some agency risk assessment guidelines appear to

[7] 67 FR 8452, 8453 3d col., 8459 3d col., 8460 1st col., Feb. 22, 2002.

have addressed this issue[8]; but not all agencies have rejected the practice of using hazard descriptors in connection with risk[9], and therefore it bears further emphasis here, particularly since it is well-known that such hazard descriptors are widely misused out of context by non-governmental entities. Hazard descriptors are only useful for describing the screening determinations that led, or might lead, the agency to undertake a more comprehensive risk assessment.

So-called "qualitative" risk assessments raise similar issues. Such assessments usually do not contain dose-response or other qualifying exposure information. However, especially because such assessments are often used to inform the public, they should include information on how the risks are affected by certain variables, such as level of exposure and duration, as well as other types of information that contribute to uncertainty in application of the assessment to individual or site-specific circumstances.

4. Standards Related to Objectivity (pp. 14-15)

Bias From Policy-Driven Assumptions

This section in particular raises the issue of the role of policy-driven assumptions in risk assessment. Agency assumptions -- sometimes referred to as "default" assumptions, "uncertainty factors", or "safety factors" -- are usually intentionally biased in the direction of conservatism or "precaution". This bias is usually argued to be justified by the agency's general mission to protect public health/safety and/or to comply with specific legislative regulatory directives that demand a margin of safety or protection of public health or safety. On the other hand, such bias appears clearly to violate the "objectivity" requirement of the IQA/PRA when applied to risk assessment as a science-based endeavor.

We suggest that the solution to this apparent conflict is to require that risk assessments make clear where scientific knowledge leaves off and policy takes over -- in other words, what is known, not known, or uncertain in the realm of scientific knowledge, and then how policy is used to compensate for any gaps or uncertainties in the knowledge base, and the justification for the particular policy decisions. The description and analysis of the extent of scientific knowledge should not be intermingled with policy-driven assumptions in such a way that it is not clear how much of the ultimate risk assessment conclusions is based on science and how much is based on policy. This confusing intermingling of science and policy is often found currently in agency risk assessments. The use of the term "assumptions" at several points in the draft guidance could be construed as condoning such intermingling of scientific knowledge and policy-driven assumptions, uncertainty factors, or safety factors in a risk assessment in such a way that that the objectivity of the assessment is no longer defensible.[10] (See, *e.g.*, pp. 14, 15.)

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[7] See the EPA final cancer risk assessment guideline revisions issued in 2005, at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=116283, in particular sections 1.33, 1.37, 2.1, 2.5, 5.3, and 5.4.

[9] This is particularly true when an agency claims to be presenting a "qualitative" risk assessment.

[10] Scientific knowledge, lack of knowledge, or uncertainty can be stated objectively. Policy can also be stated objectively. However, when science and policy are intermingled in such a way that is unclear in

6. Standards Related to the Executive Summary

The Critical Role of Comparative Risk Assessment (p. 15)

The requirement for risk comparisons is critically important for implementing the "utility" requirements of the legislation and guidance. The practice of providing a risk assessment number (such as 2.0×10^{-6} or 0.003 µg/l or a particular measure of sound, motion, or impact) is generally meaningless to the general public unless it is put into a context to which the public can relate. This requires that the risk conclusions be compared with risks from other exposures/effects which the reader is likely to consider as alternatives or closely related to the primary risk. In short, comparisons should be required and should be readily understandable and meaningful to the general public or any other target audience. We suggest expanding this section in the following respects: (1) Risk comparisons, when reasonably available, should be required as a matter of "utility". (2) Risk comparisons must make clear any differences in levels of uncertainty between the risks being compared. (3) Risk comparisons must, where feasible, compare risks that are likely to be encountered by the target audience in choosing between alternatives or substitutes.[11] (4) The guidance should provide that agencies should solicit recommendations from the public on risk comparisons that would enhance the utility of the assessment.

Sec. V: Special Standards for Influential Risk Assessments (pp. 16-21, 25)

2. Standard for Comparison to Other Risk Assessments (pp. 17, 25)

This section should state that an agency "should" or "shall" undertake such comparisons, rather than that it is "appropriate" to do so. The phrase "previously conducted risk assessments" should be clarified. It appears that what is meant is not risk assessments previously conducted by the agency now undertaking the new risk assessment, but risk assessments that have been conducted by another qualified federal, state, or international agency that is still being disseminated widely and that might be considered up-to-date by the target audience.

In making any such comparisons, agencies should be instructed by the bulletin to take into account and explain whether or not the other risk assessment(s) comply with IQA guidance.

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the ultimate risk conclusions what is due to science and what is due to policy, then the assessment would have to be considered to be biased and lacking in objectivity and the clarity and transparency necessary to provide utility.

[11] The use of risk comparisons has long been supported on a bi-partisan basis. In testifying for the Administration on the PRA in 1995, Sally Katzen, then-Administrator of OIRA, stated: "There is general agreement that agencies should . . . provide meaningful explanations of risks (including comparisons that are meaningful to the public and relevant to the decision being made)." Hearings on H.R. 830 before the Subcomm. on National Economic Growth, Natural Resources, and Regulatory Affairs of the House Comm. on Gov. Reform and Oversight, Feb. 7, 1995, at 18 (88-696 CC, GPO 1996).

3. Standard for Presentation of Numerical Estimates (p. 17, 25)

The use of the term "discouraged" at the end of the first paragraph is an inadequate expression of a "standard". We suggest that this should state simply: "Risk assessments shall not highlight only high-end or low-end estimates of risk."

4. Standard for Characterizing Uncertainty (pp. 17-19, 25)

This appears to be the most appropriate section for addressing the use of "uncertainty factors" (UFs) in non-cancer risk assessment. The use of UFs is a very-high-impact procedure used in setting reference doses (RfDs), reference concentrations (RfCs), population adjusted doses (PADs) and similar health, safety, or environmental effects levels. These reference levels are then used as a type of risk level (a level of safety) in setting regulatory levels. Thus, one of the major problems with UFs is that they are not used simply to "characterize" uncertainty, or to conduct a sensitivity analysis; rather, they are actually utilized to set a single-point risk number that is biased by policy.

While one of the UFs, the 10x UF for intra-species (human) variability, arguably has some empirical basis (though limited), the other UFs are primarily policy-driven assumptions similar to the linear no-threshold default low-dose extrapolation model used in cancer risk assessment. The UF/RfD system is convenient, but it is not science-driven. For example, the inter-species UF of 10x assumes that humans are 10x more sensitive than non-human experimental study subjects, in the absence of contrary data (which is hard to come by). This assumption has been frequently demonstrated to be at odds with scientific data, and is therefore clearly no more than a policy assumption. The same is true for the default 10x UF when there is only a LOAEL and no NOAEL, and the default 10x for an incomplete database.[12]

The guidance should state that UFs must either be scientifically justified in the risk assessment, with risk reference levels being set on the basis of best supportable scientific judgment, or else should be used only as a risk management tool.[13] In any event, the agency should be required to explain why it chose to apply any individual UF number. The agency should also be required to make clear to the reader the cumulative impact of UFs on the overall assessment.

7. Standard for Characterizing Human Health Effects (p. 20, 25)

The point made here -- that adverse effects must be distinguished from those that are non-adverse -- is very useful and important. There has been confusion over the frequently

[12] It is recognized that the default 10x UFs are not infrequently adjusted downward (and potentially upward) based on scientific data and judgment; however, the fact remains that they are designated as a fixed starting point that are used as defaults in the absence of sufficient data to override the default.

[13] Even as a risk management tool, the UFs have never been adequately justified quantitatively. For example, it has frequently been questioned why the default UFs are all 10x , why they are multiplicative rather than additive (i.e., 10x + 10x + 5x = 500x rather than 25x), and why each is considered and decided on in isolation rather than considered together in arriving at a cumulative UF that is on the basis of best scientific judgment.

interchanged terms LOEL (lowest observable effect level) and LOAEL (lowest observable adverse effect level). The term LOEL does not have any utility for risk assessment, and that point should be made. What this section needs, however, is a clear requirement that estimates of risk should be derived from (or be based on) levels at which clinically-verifiable adverse effects are expected to occur. At present, the draft bulletin only instructs agencies to discuss the distinction between adverse and non-adverse effects, and conduct a sensitivity analysis based on the distinction; it does not contain a directive to base risk estimates on adverse effects. Agencies not infrequently derive risk estimates from a non-adverse biological effect, an early molecular event, or a biomarker of exposure. At times, such an approach is justified on the basis that the effect/event is, on the basis of scientific knowledge or judgment, on the causal pathway to an adverse effect. Nevertheless, the choice of an effect that precedes an adverse effect represents a disguised policy (conservative) policy choice embedded in the risk assessment, and is a bias. The whole point of a risk assessment should ultimately be to estimate the risk of an adverse effect.

9. Standard for Addressing Significant Comments (pp. 20-21, 25)

Instead of stating that it is "typically useful" to prepare a response-to-comments document, this section should state that the agency "shall" prepare such a document. Otherwise this is not a "standard".

Sec. VI: Updates (pp. 21, 25)

The language concerning when a risk assessment should be updated based on newly available scientific data is far too discretionary in view of the importance of updating/revising. Continued dissemination of an important but inaccurate risk assessment could be highly damaging. The current language states only that an agency "should . . . consider" updating after taking into account resources, priorities, and the importance of the document. A distinction should at least be made for "influential" risk assessments (and this section apparently should be the 10th additional requirement for "influential risk assessments). We believe this section should state that in the case of "influential" risk assessments, "the agency shall, if it is determined that resources and priorities allow, update, and consider revising, a risk assessment in conformance with the other requirements of this bulletin, if new scientific data is brought to its attention, through an IQA petition for correction, that would be likely to alter materially the current risk assessment."

This section should also address what should be done to update currently outstanding risk assessments (particularly "influential" risk assessments) that do not conform to the new guidance. Many such risk assessments would be considered inadequate and misleading (or deficient with regard to objectivity and/or utility) when reviewed in light of the new guidance. At a minimum, agencies should be required to develop plans, with OMB oversight, for revising such risk assessments, particularly influential risk assessments, through an orderly process.

Sec. VIII: Deferral and Waiver (pp. 22, 26)

This section should provide for agency notification of OMB if this provision is exercised, and give OMB oversight authority to review the rationale and either overrule the agency or set a timeframe for issuing a complete risk assessment that complies with the new guidance.

Sec. X: Effective Date (pp 22, 26)

This section is ambiguous as to whether the new guidance applies to risk assessments that were developed prior to one year following promulgating of the new guidance but are still being disseminated when 12 months have passed following publication of the new bulletin. Assuming that what is meant is that the new guidance applies only to final risk assessments that are disseminated for the first time after 12 months have passed following publication of the bulletin, the recommended changes above under sec. VI (Updates) should be incorporated into, or merged with, this section.

Sec. XI: Judicial Review (p. 22, 26)

Although this disclaimer is unlikely to have any legal effect, it is inaccurate and inappropriate and should simply be removed. The bulletin is clearly not intended just to improve the internal management of the Executive Branch; it is intended to improve risk assessments that are disseminated to, and greatly influence, public choices and agency regulatory decisions. In addition, the guidance will be issued in compliance with a Congressional mandate to issue such guidance, not as a matter of administrative discretion. Whether final agency action that is not in accordance with the bulletin, other IQA guidance, or the IQA itself is subject to judicial review under the Administrative Procedure Act is a matter that will be determined by the federal courts, not by OMB.

Implementation Measures

The bulletin should contain specific measures to ensure its expeditious and complete implementation. The bulletin should specify that all agencies should take the following implementation measures:

(1) Agencies shall use the one year before the bulletin becomes effective to review their internal guidance to ensure that it conforms to the bulletin, and, if necessary, issue new guidance documents.

(2) Agencies shall announce their specific plans for review and possible revision of internal guidance documents in the next Regulatory Agenda after the bulletin is issued and shall invite public comment on both what should be revised and their plans for revision of specific guidance documents. Information on these actions shall be posted by agencies on their information quality websites.

(3) Agencies shall designate at least one, but not more than three, risk assessments to be reviewed by OMB for conformance with the OMB guidance under the GPRA/PART procedures.

(4) Agencies shall submit an annual report to OMB on new risk assessments that have been issued in conformance with the OMB guidance, any previously conducted risk assessments to which the OMB guidance has been applied, and any agency guidance documents that have been revised to conform to the OMB guidance.

Issuance of Final Guidance

There is nothing radical about the proposed guidance. To a great extent it represents a restatement and consolidation of agreed-upon best practices for addressing issues that have been discussed for many years but have never been incorporated into consistent guidance.[14] In essence, the proposed guidance is designed to ensure that the quality standards mandated by Congress and previously promulgated by OMB -- especially the basic standards of objectivity, transparency, and utility -- are applied to this very influential category of information. It is time to issue final guidance as soon as possible to "ensure and maximize" the quality of this type of information.

Respectfully submitted,

/s/

William G. Kelly, Jr.

[14] More than ten years ago, in testimony on proposed enactment of the PRA, the Administrator of OIRA during the Clinton Administration, Sally Katzen, stated that the Administration actively supported the goals of ensuring that risk assessments contain "'the most scientifically objective and unbiased information concerning the nature and magnitude of health, safety, and environment risk . . . in order to provide for sound regulatory decisions and public education . . . [and to] allow for public scrutiny and [to] promote quality, integrity, and responsiveness of agency decisions.'" Hearings on H.R. 830 before the Subcomm. on National Economic Growth, Natural Resources, and Regulatory Affairs of the House Comm. on Gov. Reform and Oversight, Feb. 7, 1995, at 15-16, and see also at 18 (88-696 CC, GPO 1996).