

To: Office of Management and Budget

Office of Information and Regulatory Affairs

From: Scott Farrow Date: June 12, 2006

Subject: Comment regarding: Proposed Risk Assessment Guidance

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I am submitting these comments in response to the call for public comments on the Proposed Risk Assessment Guidance Bulletin.

I am in an odd position of being both an advocate for the application of risk analysis and increased guidance from OMB. Hence I find OMB's attention to the subject good and the attempt at guidance useful but I strongly recommend that substantial revisions be made or the guidance project restarted. This recommendation is based both on my academic work on risk issues and on my recently completed term as Chief Economist of the GAO which provided an unusually broad cross-agency perspective on risk issues. I first present major comments, each followed by a recommendation, then technical comments.

Major comments:

- OMB's adoption of the framework of environmental and health risk assessment, and limiting the application of the guidance to that area omits appreciation for other risk based framings, some of which are also of major importance such as Homeland Security. The OMB limitation can also provide an appearance of selective application that is not justified in the draft guidance document.
 - Recommendation: Review alternative risk assessment and risk management frameworks (such as the COSO commission; OMB's budgetary guidance in A-11, Part 7, Section 300; and the U.S. Government Accountability Office which I believe is developing an analyst's guide on risk assessment and management, a version of which can be found in Appendix I of GAO-06-91.)
 - o Recommendation: Change the focus to provide generic, technical guidance on risk assessment that is suitable across all agencies. OMB may then wish to supplement that core guidance with modules on the typical terminology and framing used in a specific domain such as homeland security or the environment, health, or safety.
- OMB's guidance focuses on public information although if the purpose is to improve the quality and consistency of risk informed decisions, there is no reason of which I'm aware to limit the application to public documents. For instance, OMB currently requires a risk assessment and a separate alternatives evaluation

for capital purchases as part of budget submissions (see A-11, Part 7, Section 300). Shouldn't these risk assessments be held to the same quality and subject to the same guidance as are public documents? They too can involve hundred million or billion dollar decisions.

- Recommendation: make guidance applicable to internal and external (public) documents.
- OMB's draft document has elements of alternatives analysis and risk assessment. In the absence of a government wide model of risk management (which may or may not include risk assessment), the alternatives portion of the guidance lacks coherence with other alternative evaluation frameworks generally advocated by OMB such as benefit-cost analysis. In the alternatives analysis of A-11, 7/300, benefit-cost analysis is the preferred method of evaluation as it also seems to be through Executive Order 12866 for regulation. GAO has also treated the alternative analysis as a separate phase from risk assessment (GAO-06-91, Appendix I, A Risk Management Framework presents a generic model and then descriptions that are tailored for Homeland Security).
 - o Recommendation: For guidance across all agencies, consider what framework OMB wishes all agencies to follow. To the extent that the alternatives discussion can highlight the usefulness of one type of analysis (risk) feeding into OMB's existing recommendations on alternatives, that would be useful.
- OMB defines risk assessment but not risk. To the extent that risk is viewed as a possibility of an adverse consequence (sometimes there are also risks of beneficial consequences), then the guidance should be technically focused on methods to inform decision-makers about possibilities and consequences. While I agree that quantifiable approaches to risk typically represent a goal, the vast majority of governmental risk analyses of which I'm aware are of a more qualitative type.
 - Recommendation: Reshape the document as default technical guidance to be used across all agencies for the analysis and presentation of possibility and consequence information to decision-makers. This would entail substantially more attention to qualitative methods frequently used for IT and Security decisions among others.
- Risk is a large topic on which multiple professional organizations are involved. In the development of the National Income and Product Accounts that led to measurements such as GDP, multiple Government agencies worked with a large group of academics to develop measures and concepts over time.
 - Recommendation: coordinate a consortium of relevant Executive agencies to provide the "real world" context and feedback to professional and academics so that they may provide material for OMB to select from in its applications.

Technical recommendations (in order to be brief, the suggested recommendations are provided as suggested inserts or deletions.)

- P. 1: insert "used in decision-making and" following integrity of information on line 2 of Summary.
- P. 1, delete "to human health, safety, and the environment" in line 2 of the Introduction; also on page 8, last paragraph.
- Review of background as on p. 2 should be expanded beyond E, H, S risk approaches, see for instance, first major comment above.
- P. 3, para. 4; the distinction between risk management and risk assessment is not universally held across applications, and even in EHS the line has become blurred.
- P. 4: priority setting, I suggest you consult with the Department of Homeland Security and their guidance on benefit-cost analysis, a document that I think confuses benefit-cost and other approaches under the same name.
- P. 4: Informing risk management decisions; the link to alternatives evaluation as generally recommended by OMB and to benefit-cost analysis could be strengthened.
- P. 6/7: examples of human, experimental, etc emphasizes the EHS aspect; what about security risks, education risks, economics risks? Similar limitation on p. 9 for influential risk assessments; what about port security, risk of failing to graduate from high school, economic risk to industry or others?
- P. 9: Applicability; include what are generally considered internal government documents such as budget submissions under OMB circular A-11.
- P. 10: Goals could be developed in a way that puts risk assessment in the context of risk management sequence of analysis and actions.
- P. 15; section 7, insert after second sentence, "A risk assessment should also be integrated with any benefit-cost or cost-effectiveness analysis carried out."
- P. 16, section 1; integrate with other alternative analyses (such as EO 12866 or A-11, 7/300).
- P. 16, section 5, end of first line, insert after include, "a characterization of the distribution at least including"
- P. 19, section 6; could also discuss risk conditional on variability factors such as might result from a regression analysis.
- P. 20, start of section 7, I note that this is the closest to a definition of risk that is provided. If this definition were made more central, then the document would be more a technical guidance on assessing possibility and consequence in whatever domain it occurs.
- Section IX: consultation should include the budget side of OMB that already has some guidance on risk.

- Risk Assessment Bulletin, page 23: add a section 4 that defines risk.
- Page 23, section II; delete "available to the public" (Why should internal assessments not meet similar standards for quality and objectivity?)
- P. 23; section IV: "needs" are not knowable...key pieces of information?; remainder of the section is an example for EHS but should be broadened.
- P. 24, section 3; should expand considerably on qualitative guidance as this is a major gap in the guidance; on quantitative, replace "a range" with "information about the statistical distribution at least including the mean and the range"
- P. 23, 7(a), replace with "a risk based evaluation of alternative options consistent with guidance provided for EO 12866, clearly establishing the baseline risk as well as the risk reduction alternatives that will be evaluated, noting that this is not a substitute for benefit-cost or cost-effectiveness analysis where such analyses are called for."
- Page 24, 7(e): replace "a range" with "a characterization of the distribution including at least the mean and the range"
- Insert IV7(f): Information sufficient to link risk information to cost information
- P. 25: "qualified" scientific organization may be difficult to determine, define?