

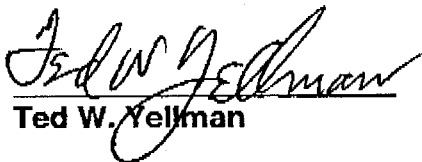
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June 13, 2006

Office of Management and Budget  
Office of Information and Regulatory Affairs

Subject: Proposed Risk Assessment Bulletin, OMB, draft released  
January 9, 2006

Attached are my personal comments on the subject draft. They do not necessarily represent the opinions of any other person or organization.

Sincerely,

  
Ted W. Yellman

June 13, 2006

## A REVIEW OF THE PROPOSED OMB BULLETIN ON RISK ASSESSMENT RELEASED JANUARY 9, 2006

**REFERENCE:** Proposed Risk Assessment Bulletin, Office of Management and Budget, draft released January 9, 2006

### GENERAL COMMENTS

#### OVERALL FORMAT AND ORGANIZATION

- (1) Are all 26 pages of the Reference intended to be a draft for a Risk Assessment Bulletin (as indicated on page 1 by "Proposed Risk Assessment Bulletin"), or only pages 23 through 26 (as indicated on page 23 by "**RISK ASSESSMENT BULLETIN**")? How is it possible for a document to have supplementary information which precedes the core information and outweighs it by a factor of 5?
- (2) The draft can be divided into three parts: (1) A 7 1/2 page stand-alone section starting at the beginning of the *Supplementary Information* section, followed by (2) a 14 3/4 page section which goes on to the end of the *Supplementary Information* section, followed by (3) a 3 1/2 page **RISK ASSESSMENT BULLETIN** section which tracks almost exactly the topics in (only) the last 14 3/4 pages of the *Supplementary Information* section. How was this scheme arrived at? It is confusing and seems to have resulted in pointless duplication.
- (3) Documents like this need a proper Table of Contents. Without one, it is difficult to understand how a document is organized. So I have created a Table of Contents for the document as it is currently organized (*not* for a document organized as I would *like* to see it organized). In case somebody might find it helpful, I have placed my Table of Contents at the end of this review.
- (4) Documents like this also need a proper References section. In this draft, the information which is given about References is incomplete and scattered through the body of the draft. People should be able to determine what the several predecessors to this document have been, and what the other documents are which bear directly on this one.
- (5) Apparently, some significant difference is intended between what are called "goals" and what are called "standards". I can't understand what that difference is. Why, for example, is *completeness* of assessments a "goal", whereas *objectivity* of assessments is a "standard".
- (6) A litany of terms intended to denote various "desirable attributes" of risk assessments is spread randomly (and in many cases repeatedly) throughout the document. That is harmless enough. However, it would be helpful if somebody would explain what they mean. For example, does "transparent" mean the same thing as "clear"?
- (7) The draft reads a lot as if it were written by a committee—thoughts appear here and there throughout the document with, in many cases, little evidence of an attempt to organize them logically.
- (8) The draft does not distinguish between first-level uncertainties—that is, *probabilities* (which some academics call *aleatory uncertainties*) and second-level uncertainties (which some academics call *epistemic uncertainties*). Most people simply call the latter *uncertainties* with no modifier. They in turn are often divided into completeness, conceptual-model, and parameter uncertainties. In a document which is so focused on problems with uncertainties, it would be useful for this document to provide people with practical information about what "uncertainty" actually is.

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- (9) The major *types* of losses which are of interest in risk assessments are not clearly identified. They are losses of human life or well-being, property losses, and damage to the natural world. Identifying those three basic types of losses would help things in better perspective. (Characterizing "safety" as a loss type, for example, is imprecise.)

## DEFINITIONS

The document is rich with undefined terms, which is a bane of good engineering practice. Examples of undefined terms which either *have* been used or *could* profitably be used in the document include risk, risk assessment, likelihood, probability, hazard, loss event, loss value, severity, human well-being, expected loss, uncertainty, influential risk assessment, reproducibility, quality, objectivity, utility, integrity of information, data, presentation, risk management, acute risk, chronic risk, type-1 uncertainty, type-2 uncertainty, risk communication, risk perception, risk reduction, residual risk, baseline risk, dose-response risk, systems risks, rats (wait, maybe you don't have to explain that one), engineered systems, variability, probabilistic risk assessments (sometimes unfortunately called "qualitative risk assessments"), non-probabilistic risk assessments, completeness, reliability, unbiasedness, transparency, population, exposure, sensitivity analysis, assumption, negligence, model uncertainty, data uncertainty, statistical uncertainty, injury, illness, mitigation, stringency, and benefit-cost analysis.

Consider, for example, the quite-similar-but-somewhat-different definitions for risk assessment on pages 1 and 23. Risk assessments do not in fact seek to determine whether *potential* hazards exist, nor the extent of *possible* risks. A person embarks on a risk analysis precisely because he or she *already knows* that one or more "potential hazards" exist—and therefore also "possible risks". Risk-assessment processes are about (however effectively they may do it) identifying *actual* hazards and determining *actual* risks.

It would make sense to gather all such definitions in one place. As the draft stands, there are not nearly enough definitions and the ones which do exist are (1) poor, and (2) in many cases duplicated. A great service to the risk-assessment community could be rendered by providing, for the first time, a broad and generally-agreed-to set of definitions applicable to the risk-assessment disciplines generally.

I will suggest a few definitions here as an example of what might be done. They came out of the engineered-systems risk-assessment discipline, and thus may (or may not) need to be altered a bit to accommodate other risk disciplines. In any case, if a document is supposed to educate people about how to do risk assessments, shouldn't people at least agree about what terms like "risk" actually mean?

**Tragic event:** An event which includes loss of human life or well-being, substantial property or monetary loss, and/or substantial damage to the natural world. (The point at which loss or damage becomes "substantial" is a matter of judgment.)

**Accident:** A sequence of events which includes one or more tragic events.

**Hazard:** A hazardous event, meaning a condition or a change in condition which if it arises significantly increases the probability of a subsequent tragic event. (The point at which such a probability becomes "significantly increased" is a matter of judgment.)

**Near-tragic event:** A hazard which if it arises greatly increases the probability of a subsequent tragic event. (The point at which such a probability becomes "greatly increased" is a matter of judgment.)

**High-impact event:** Either a tragic event or a near-tragic event.

**Incident:** A sequence of events which includes one or more near-tragic events but no tragic events.

**Mishap:** A sequence of events which includes one or more tragic events or near-tragic events.

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**Experiment:** A sequence of events which are related to each other.

**Risk:** A measure of the exposure of an experiment to unpredictable losses caused by the possibility of one or more particular hazards arising. Risk consists primarily of an expected-loss value—that is, an estimated per-experiment average loss value. Risk may or may not be extended to include numerical or non-numerical information about (1) the estimated variability of unpredictable losses from experiment to experiment, and (2) the uncertainty which is believed to exist about the accuracy of a stated expected-loss value. The word "risk" is also sometimes used casually when "hazard" is meant, and "risky" when "hazardous" is meant.

#### **AT WHOM IS THE DOCUMENT AIMED?**

The **SUMMARY** section states that the document is intended to improve (1) *information disseminated by the federal government to the public* and (2) *risk assessments produced by the federal government*. However, on page 5 of the draft, it is pointed out that risk assessments are often prepared by *contractors to the government*. These assessments may be performed by private organizations either because (1) the assessments are required by a federal agency to allow it to certificate or otherwise approve a product, or (2) the assessments have been contracted to the private sector by a government agency in order for it to meet a requirement for such an assessment. So is the limitation implied in the **SUMMARY** real or not? Logically, why would the material in this document *not* apply to *all risk assessments submitted to federal agencies by private organizations*? Wouldn't the quality of those assessments be of at least equal concern to the federal government?

Extensive manufacturer-originated and Federal-Aviation-Administration-originated criteria already exist for the safety of commercial airplanes. If an attempt is made to "overlay" the "standards and goals" in this draft over the extensive protocols for commercial-airplane safety-risk assessments which have evolved for large commercial airplanes over the last fifty years, the result could be chaotic. Whatever the scope of the document in this respect is and isn't needs to be much more clearly stated.

#### **WHAT ARE THE PURPOSES OF THE DOCUMENT?**

It is not clear just what this document is intended to do. Is it supposed to be a means of urging people to produce higher-quality risk assessments, to give inexperienced people a sense of what risk assessments can be about, to fulfill a federal mandate, some other things, or some combination of those things? Among other things, the document fails to distinguish between *chronic risks* and *acute risks*, and to recognize that very different conceptual and mathematical models are used by people with very different backgrounds to analyze them. As seems to be common with "guidance" of this type, the draft seems to have been written mainly as if it were trying to inform people who *already understand* the problems it is trying to address. Of at least equal importance should be people and organizations who do *not* understand those problems, or at least do not understand them very well.

#### **COMMENTS ON SOME SPECIFIC SECTIONS**

##### **SUPPLEMENTARY INFORMATION/Introduction section (Page 1)**

The statement is made that *risk assessment is a useful tool for estimating the likelihood and severity of risks*. The primary products of risk assessments are determinations of *expected (all-experiment-averaged) loss values* caused by various identified hazards (that is, hazardous events). Estimates which are made of the *likelihoods* (usually expressed as probabilities) and *expected severities* of various losses are made to *determine* those loss values. However, neither likelihoods or severities are the *primary product* of risk assessments. And while it is true that *risk assessment* can refer to a document, it can also refer to the *process* used to create that document.

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The Bulletin is said not to address in any detail.....*risk management* and *risk communication*. Apparently, narrow meanings have been assumed for these terms. In my view, risk assessment is a subset of risk management—with the other parts being *risk reduction* (whether, how much, and how risks need to be reduced) and *risk communication* (including primarily how information about risk is conveyed to the public, but also to some degree how and how well the reasoning in the risk assessment itself is explained). All three terms (*risk management*, *risk reduction*, and *risk communication*) are of course subject to definition. This draft, unfortunately, does not step up to the plate in that respect.

The scope of the document is said *not* to encompass how federal agencies should *manage or communicate risk*. The document should not be directed at how federal agencies should go about trying to *reduce* risk. However, a subsequent paragraph states that risk assessments *can* be used for informing the public and other audiences. Isn't that "communicating risk"? Again, a lack of definitions is causing confusion.

#### **SUPPLEMENTARY INFORMATION/Uses of Risk Assessments/Priority Setting (Page 4)**

The statement is made that a 1990 EPA assessment of environmental hazards demonstrated that the "environmental risks of greatest concern to the public often were not ranked as the greatest risks by agency managers and scientists". What is the message here? Does this statement imply that risk assessments *should* concentrate on risks perceived as most significant by the public? If so, wouldn't that conflict with "objectivity"? Whatever message this statement is intended to carry needs to be clarified.

Does "potential hazard is not of concern" here mean that a "potential hazard is determined not to cause enough risk to be analyzed as an actual hazard....."?

"The purpose of the screen is to determine....."whether a risk could exist, and whether the risk could be sufficiently serious to justify agency actions". What seems to be meant by this is "whether an actual hazard exists". That is borne out by the fact that it is "hazards", not "risks", which the rest of the paragraph speaks to.

#### **SUPPLEMENTARY INFORMATION/Uses of Risk Assessments/Informing Risk Management Decisions (Page 4)**

"if so, to establish the appropriate level of stringency" could be stated in plain English as "if so, how much to reduce it".

The two sentences starting with "A wide set of standards...." could be condensed to "In some cases, acceptable risk levels will be based upon statutes, regulations, or case law."

It is excellent to point out that risk assessments can provide technical inputs to benefit-cost analysis. However, this point is important enough that it deserves more than a passing reference. It should be explained how these two types of analyses relate to each other.

#### **SUPPLEMENTARY INFORMATION/Uses of Risk Assessments/Informing the Public (Page 5)**

The two paragraphs in this section seem to be limited to "inducing changes in the behavior" of the public. Such an activity constitutes *risk communication*, and is certainly part of *risk management*. However, I do not think it is *risk assessment*. Such communications may be *based on* a previous risk assessment or assessments, but projects done solely "to inform the public through education and informational programs", are not *risk assessments*.

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**SUPPLEMENTARY INFORMATION/Types of Risk Assessments (Page 5)**

This would also be a good place to point out that there are two quite different basic types of risk assessments: those addressing chronic risks and those addressing acute risks. (The next three titled sections address chronic risks, and the one after that addresses acute risks).

**SUPPLEMENTARY INFORMATION/Types of Risk Assessments/Actuarial Analysis of Real-World Human Data (Page 6)**

This is almost a random litany of various hazards. Does "actuarial" mean something different than "statistical"? Why is the title restricted to "human data"? Some motor vehicle accidents, for example, are caused wholly or in part by mechanical failures, and there have certainly been studies done on such risks. What world other than the "real world" would data come from? Does "real world" mean "outside a laboratory"?

**SUPPLEMENTARY INFORMATION/Types of Risk Assessments/Dose-Response Analysis Using Experimental Data (Page 6)**

Are rats and mice the only creatures which serve as surrogates for humans in experiments? If a rat dies of old age during an experiment, why was his "short lifetime" a benefit? Isn't there a parallel in the "engineered systems" world to using rats when failure-rate data are used from components which are different than the components in the system being analyzed? Isn't there a broader message here which the reader will be unaware of?

This rat material may be of some interest to people who have had no contact with rats—but it will be of little if any benefit to people who actually work with rats.

**SUPPLEMENTARY INFORMATION/Types of Risk Assessments/Failure Analysis of Physical Structures (Page 7)**

This title of and the material in this paragraph are much too narrow. A more general and appropriate title would be "Engineered Systems". There are many engineered systems for which the hazards of interest are not restricted to structural failures.

**SUPPLEMENTARY INFORMATION/Legal Authority (Page 7)**

Is this draft a direct response to direction given the OMB in Public Law No. 106-554, § 515(a). If so, that should be clearly stated. It's not just authority which is significant here, it's also responsibility.

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin (Page 8)**

It is a little late in the draft to state (again) that the bulletin addresses quality standards for risk assessments. Surely readers will have noticed that by now. I am also puzzled that the material falling under the sub-heading "**The Requirements of This Bulletin**" also fall under the broader heading **SUPPLEMENTARY INFORMATION**. Such information doesn't seem "supplementary" to me at all.

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section I: Definitions (Page 8)**

Why has "Section I: Definitions" changed to italics? That is inconsistent with previous sections. Does a section on definitions properly fall under "Requirements of this Bulletin"? Also, this material is largely duplicated on page 23. Is there a point to that?

The only technical definition offered here is for "risk assessment", and I previously commented on problems with that definition.

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What happened to "property" as a category of loss, as mentioned previously? The term "risk mitigation" is often erroneously substituted for "risk reduction"—and that has been done here. "Mitigation" means reducing the *severity* of a loss GIVEN that one occurs. There is never a point in having two words for the very same thing in a technical document.

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section II: Applicability (Page 9)**

The statement is made that "every quantitative (meaning "probabilistic") risk assessment should provide a range of plausible risk estimates, when there is scientific uncertainty or variability". It's not clear whether this statement is attempting to make a distinction between variability and uncertainty or not—it reads as if the two terms are considered synonyms for each other. They are not. Recognition of both (1) variability of the values of losses which will occur from experiment to experiment and (2) uncertainty about the stated expected (average) values of losses, are fundamental to probabilistic risk assessment. There is some degree of uncertainty present in every risk assessment. Therefore, this section seems to be saying that a "range of plausible risk estimates" must be provided as a product of every risk assessment. As a general requirement, that statement is much stronger than it should be. In many cases, presenting an alleged "range of plausible risk estimates" will add no value to the decision-making process. Also, what "plausible" is supposed to mean is left completely to the imagination.

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section III:1. Goals Related to Problem Formulation (Page 10)**

This paragraph essentially states that risk analysts should keep in touch with their managers.

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section III:2. Goals Related to Completeness (Page 10)**

In the systems-analysis world, the word "complete" (often also described as "exhaustive") applied to a risk assessment means that the assessment has considered all the combinations (or sequences) of events which are *significant contributors to the probability of a tragic event of concern*. "Completeness" in the Reference draft, however, seems to mean something broader—the general "thoroughness" or "depth" of an analysis, including, for example, obtaining better numerical data to support event probabilities. Again, the document suffers from an ambiguity in definitions.

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section III:3. Goals Related to Effort Expended (Page 11)**

This section just says to expend the appropriate level of effort for the problem of concern.

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section III:4. Goals Related to Resources Expended (Page 11)**

This section says the same thing for "time and money"—which of course are pretty closely related to effort expended.

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section III:5. Goals Related to Peer Review and Public Participation (Page 11)**

Peer review and public participation in many cases should not just be *considered*—they are *essential*. That is particularly true for the "influential" risk assessments alluded to elsewhere in the draft. Will this material really be effective in ensuring that decision makers make good decisions about who gets to review risk assessments?

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**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section IV: General Risk Assessment and Reporting Standards (Page 11)**

How do all the other "desirable attributes" mentioned elsewhere in the draft relate to the three "key attributes" of "utility, objectivity, and integrity"?

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section IV: General Risk Assessment and Reporting Standards/1. Standards Relating to Informational Needs and Objectives (Page 12)**

This section basically says that the *reasons* for performing a risk assessment should be stated clearly. The last sentence, however, addresses its *actual scope*, so it belongs in the next paragraph.

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section IV: General Risk Assessment and Reporting Standards/2. Standards Relating to Scope (Page 12)**

Some risk assessments are not limited to analyzing a single hazard, so "the hazard of concern" should be changed to "the hazard or hazards of concern". And this time around, the term "completeness" is used in the narrow technical sense (as in "the pathways to an accident") which systems analysts normally use (which I explained previously). That usage is not consistent with the broader use of the term on page 10. I would also discourage the use of poetic terms like "pathways to accidents" when what is being referred to is better described by the standard term "sequences of events".

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section IV: General Risk Assessment and Reporting Standards/3. Standards Related to Characterization of Risk (Page 13)**

The first sentence distinguishes between risk analyses which "characterize risk" *qualitatively* versus those that characterize risk *quantitatively*. A better and more standard way to approach this would be to distinguish between *non-probabilistic* and *probabilistic* risk analyses. (Any given analysis is one or the other—never both, as the "and" in the first sentence implies. If probabilities appear in it, it is probabilistic. If not, it isn't.) The remainder of the first paragraph and all of the second paragraph then addresses the issue of *uncertainties* in the values determined in risk analyses for expected losses.

That issue is indeed critical—but misconceptions about dealing with uncertainties are common. When failure probabilities and rates used in engineered-systems risk assessments are established based on sparse real-life data ("small-samples"), it is possible to "characterize" (or even "correct for" and maybe "overcorrect for") the resulting uncertainties numerically by applying *confidence theory*. Such uncertainties are called "data uncertainties" or "statistical uncertainties". However, that is virtually the *only type* of uncertainty which it is practical to characterize *numerically* (or, if you prefer, *quantitatively*) in a meaningful way. That important limitation on "quantifying" uncertainties is not conveyed by the material in this section. It is also not clear what providing a *range of plausible risk estimates* means. Does it mean providing an *upper confidence limit* and a *lower confidence limit* for an expected-loss value? (In almost all practical problems, one is not concerned at all about "best-case" limits—only about things turning out *worse* than you expected.) Is this "quantitative characterization of risk" (actually, specifically of its *uncertainty* aspect) to be done at some particular confidence level, or at whatever confidence level an analyst might choose? Does *expressing multiple estimates of risk* mean the same thing as *providing a range of plausible risk estimates*—or does it mean something different?

Addressing statistical uncertainties as outlined in this section will be applicable to many risk assessments directed at health hazards. However, it will not be applicable to most risk assessments of engineered systems and subsystems—for example, airplane roll-control systems. Nevertheless, I think there is a danger that, based on this document, efforts will be made to impose "uncertainty science" on such assessments.



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**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section IV: General Risk Assessment and Reporting Standards/4. Standards Related to Objectivity (Page 14)**

It would be difficult to argue against clarity, completeness, unbiasedness, transparency, credibility, and reliability. Motherhood and apple pie are good too!

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section IV: General Risk Assessment and Reporting Standards/5. Standards Related to Critical Assumptions (Page 15)**

It is important to explain assumptions as clearly as is practical—especially assumptions which result in certain aspects of problems being neglected. As a practical matter, however, it will rarely be either desirable or possible to provide a "quantitative evaluation of reasonable alternative assumptions". One makes the most realistic assumptions that one can—and there is little point in making assumptions which do not meet that test because doing that will often just confuse the decision-making process. This statement could easily result in a lot of non-productive work which is nothing but hocus pocus.

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section IV: General Risk Assessment and Reporting Standards/6. Standards Related to Executive Summary (Page 15)**

This section seems to be aimed at communicating risk to the public, rather than to executives as the title implies.

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section IV: General Risk Assessment and Reporting Standards/7. Standards Related to Regulatory Analysis (Page 15)**

"Mitigation" is used when "risk reduction" is intended.

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section V: Special Standards for Influential Risk Assessments/1. Standard for Reproducibility (Page 16)**

Why has the document switched at this point from the previous "Standards" (plural) to "Standard" (singular)? Why would a re-analysis using identical data and identical methods generate anything but similar results? There will rarely if ever be a need to re-analyze exactly the same problem, so this "standard" is apparently a surrogate for some other attribute or attributes. What are they?

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section V: Special Standards for Influential Risk Assessments 2. Standard for Comparison to Other Results (Page 17)**

Relevant previous studies should of course be considered. Good point.

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section V: Special Standards for Influential Risk Assessments/3. Standard for Presentation of Numerical Estimates (Page 17)**

This seems to be essentially a repeat of material on page 13, and only one of many forays throughout the document into a single general subject—uncertainty.

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section V: Special Standards for Influential Risk Assessments/4. Standard for Characterizing Uncertainty (Page 17)**

Yet more material on uncertainty. In my view, all the discussions about uncertainty spread through the document should be covered in a single section of the document. The statement "When model uncertainty is substantial, the central or expected estimate may be a weighted average of the results from alternative models" is an exact repeat of material on the previous page. It should also be realized that if you should follow that "weighted average" advice, you are de facto doing nothing more than creating a new probability

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by blending the probabilities of various alternative event sequences. And of course it is easy to talk conceptually about "weighting" alternatives—but not so easy to establish the values you will use for those weightings. Some advice about that would be helpful.

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section V: Special Standards for Influential Risk Assessments/5. Standard for Characterizing Results (Page 19)**

This advice is almost identical to that under *Standard for Comparison to Other Results*.

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section V: Special Standards for Influential Risk Assessments/6. Standard for Characterizing Variability (Page 19)**

This "variability" seems to be largely about accounting for how health risks can vary based on differences in risk factors among populations of people known to be different from each other—for example, children versus elderly people. This is yet another interpretation of "variability"—one which doesn't involve randomness. If "variability" is to be used in so many different ways, then its various possible meanings should at least be explained. And as with "uncertainty", the third facet of risk, I think it would be profitable to locate discussions about this "second facet of risk" in a single area of the document.

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section V: Special Standards for Influential Risk Assessments/7. Standard for Characterizing Human Health Effects (Page 20)**

I am unconvinced that there is any practical difficulty in distinguishing between adverse events and non-adverse events. In any case, risk is always and only about adverse effects—never non-adverse effects.

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section V: Special Standards for Influential Risk Assessments/8. Standard for Discussing Scientific Limitations (Page 20)**

"Scientific limitations" here seems to mean almost exactly the same thing as the limitations in "Efforts Expended" and "Resources Expended" discussed on page 11.

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section VIII: Deferral and Waiver (Page 22)**

Deferrals are discussed here, but waivers are not.

**SUPPLEMENTARY INFORMATION/The Requirements of This Bulletin/Section IX: OIRA and OSTP Responsibilities (Page 22)**

I would prefer to see such abbreviations written out in a title, but that's just me.

**RISK ASSESSMENT BULLETIN**

As I indicated previously, everything in this section tracks, and in most cases repeats, what somebody apparently considered to be "highlights" of the material starting on page 8 entitled **The Requirements of This Bulletin**. Therefore, I will forgo comments on the **RISK ASSESSMENT BULLETIN** section. It has most of the same problems I already previously identified in the **The Requirements of This Bulletin** section.

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OFFICE OF MANAGEMENT AND BUDGET  
RISK ASSESSMENT BULLETIN, JANUARY 9, 2006 DRAFT**

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June 13, 2006