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Subject: Comments on Draft Guidelines

NUCLEAR REGULATORY COMMISSION'S COMMENTS ON DRAFT GUIDELINES

In general, we commend the overall direction that OMB is taking in the draft guidelines. We believe that standardized approaches to regulatory analysis, both within and across agencies, to the extent feasible and appropriate, can provide a more uniform reporting format and methodology, as well as a structure to improve the overall quality of federal regulatory analyses. Though the NRC promulgates very few rules that would be "significant" under E.O. 12866, and though the draft Guidelines are aimed mainly at "significant" rules, the NRC expects to be able to carry out regulatory analyses in accordance with this new OMB guidance. We are pleased, nonetheless, that the draft guidelines recognize that the degree of complexity of a regulatory analysis should be commensurate with the complexity and significance of the rulemaking. In fact, the draft might usefully include more guidance on how complex analyses should be, in order to ensure that agencies expend appropriate levels of effort, particularly in analyzing uncertainties.

We understand from the Federal Register notice that, after receiving comments on the proposed guidelines, OMB will coordinate an interagency review of the guidelines. We look forward to participating in that review. The final guidance will be a matter of great importance to us, and the NRC has a great deal of experience in risk assessment, cost-benefit analysis, and cost-effectiveness analysis.

We offer the following more specific comments, which suggest that some aspects of the draft need to be clarified, in part to achieve the desired comparability across rules and agencies. (Web addresses for two of the NRC-related documents we mention in our comments are listed at the end of our comments.)

1. Precautions in Current Risk Assessment Procedures --

OMB asks for "ways in which 'precaution' is embedded in current risk assessment procedures through 'conservative' assumptions in estimation of risk, or through explicit 'protective' measures in management decisions as required by statutory requirements as well as agency judgments." 68 Fed. Reg. 5499. One of the chief ways in which precaution is embedded in the NRC's procedures is the NRC's regulatory philosophy of "defense-in-depth." This philosophy calls for multiple layers of protection to prevent and mitigate accidents. In the context of risk-informed, performance-based regulation, the agency looks to see whether the defense-in-depth it is considering requiring is commensurate with the risk and uncertainty associated with the estimate of risk. See the NRC's "Risk-Informed Regulation Implementation Plan" (August 2001), especially Part 1. Also, the NRC is required by statute not to use costs as a deciding factor when determining minimum safety requirements (see *Union of Concerned Scientists v. NRC*, 880 F.2d 552 (D.C. Cir. 1989)). However, the agency is permitted to calculate the costs and benefits of any safety measure.

2. Benefit-Cost Analysis and Cost-effectiveness Analysis --

The first two sections of Appendix C are well written and add much useful perspective for conducting effective regulatory analysis. Also the description in Section III of the complexities of benefit-cost analysis (BCA) and cost-effectiveness analysis (CEA) provides useful insight. Cost/Effectiveness Analyses can help agency decision making and public understanding of regulatory actions. The draft guidance about monetizing health and safety benefits and costs is also useful, and takes into account practical difficulties agencies face in obtaining relevant data.

However, some aspects of Section III need clarification. First, the differences between the uses of BCA and the uses of CEA need to be more clearly defined, especially the differences in the relative importance they assign to qualitative factors and factors that can be measured in monetary units. Second, though the last paragraph on page 5516 provides some useful insights into comparing qualitative values and monetary values of benefits, the discussion needs to be clarified. An example would help.

Third, we would welcome clarification on the use of CEA for public health and safety rules when the primary benefit categories -- in our case, radiation exposure avoided -- are expressed in monetary terms. The draft seems to give conflicting advice on the use of CEA in such a situation. At one point, the draft says that a CEA should be prepared for all major rulemakings for which the primary benefits are improved public health and safety. 68 Fed. Reg. 5516, column 1. But the draft also says that, where we can assign a reasonable monetary value to all benefits, we will be doing BCA but not CEA. *Id.*, column 3. In both places, the draft seems to be thinking of CEA as non-monetary. See also *id.*, column 2. Our practice in fact looks both to net benefit and to cost-effectiveness, but not to the non-monetary sort of CEA the guidance at one point urges. Historically, the NRC relied almost exclusively on a monetary form of CEA; we compared actions on the basis of how many dollars they cost to avert a "person-rem," a measure of exposure. However, because CEA cannot establish whether cost-effective alternatives are also net beneficial, the NRC replaced its monetary CEA with BCA based on a \$2,000 per person-rem conversion factor. Generally speaking, an action is net beneficial if it costs no more than \$2,000 per person-rem of exposure avoided. With both costs and benefits being thus presented in commensurate units, the agency can make both a net beneficial determination and a monetary cost-effectiveness determination. See section 4.3.4 of the NRC's Regulatory Analysis Guidelines, NUREG/BR-0058, rev. 3. It is not clear what any non-monetary sort of CEA would contribute in this case. As noted above, the draft seems in one place to agree, and yet in another place urges doing CEA (non-monetary) for every safety rulemaking. Hence our suggestion that the guidance be clarified.

3. Discount Rates --

Although the section on discount rates -- sub-section IV.C -- contains many useful distinctions, the section requires clarification to help ensure that the appropriate rate is used for each particular application. The choice of a discount rate can completely alter the conclusions of a regulatory analysis. The discussion regarding the rationale for use of discount rates is confusing, and leaves open too many options for setting a "realistic discount rate" for various purposes. OMB's previous guidance recommended 7% for base case calculations and 3% for sensitivity analysis purposes. Since many of the NRC's actions concern projects with very long lives, the NRC has often used real discount rates less than 7% for its best estimates, reserving

3% and 7% for sensitivity analyses. See section 4.3.4 of the NRC's regulatory analysis guidelines, NUREG/BR-0058, rev. 3. But OMB's draft guidance seems to attach equal weight to the 3% and the 7% rates. This suggests to us that the base case or best estimate would now be presented as a range of values based on a range of discount rates. It is not clear why it is necessary to vary the discount rate for the base case, given that there will still be a need to present upper and lower bound estimates to account for uncertainties and other sensitivities. Moreover, such variation in the base case removes the clearly defined frame of reference there was in past practice and thus tends to diminish clarity in the benefit-cost results. The discussion on page 5522 regarding the discounting of benefits or costs that are health-related is especially open-ended and particularly relevant to the NRC's interests.

4. Uncertainties --

We believe that, during the interagency review, a number of agencies may want to focus closely on the treatment of uncertainties. The NRC employs a specific methodology for assessing risks and probability and has ongoing efforts to improve the treatment of uncertainties in the application of probabilistic risk assessments. Uncertainties are complicated for health effects, particularly radiological health effects, which are of interest to the NRC, EPA, DOE, HHS, and other agencies.

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REFERENCES --

The NRC's Regulatory Analysis Guidelines (NUREG/BR-0058, rev. 3) --
<http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0058/r3/index.html>

The NRC's Risk-Informed Regulation Implementation Plan --
<http://www.nrc.gov/what-we-do/regulatory/rulemaking/risk-informed/ririp.pdf>

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