

September 29, 2008

Office of the Assistant Secretary for Policy
U.S. Department of Labor
Room S-2312
200 Constitution Avenue, NW
Washington, DC 20210
Attention: Risk Assessment Policy

Re: RIN 1290-AA23 – Requirements for DOL Agencies’ Assessment
of Occupational Health Risks Notice of Proposed Rulemaking (73 FR
50909), August 29, 2008

Dear Sir/Madam:

ORC Worldwide (ORC) welcomes this opportunity to provide comments on the Department of Labor (DOL) notice of proposed rulemaking (NPRM) on Requirements for DOL Agencies’ Assessment of Occupational Health Risks.

ORC is an international management and human resources consulting firm whose Washington, D.C. office has for more than 35 years specialized in providing a wide array of occupational safety and health consulting services to business organizations. Currently, more than 140 large (mostly Fortune 500) employers in diverse industries are members of ORC’s Occupational Safety and Health networks. The focus of these networks is to promote effective occupational safety and health programs and practices in business and to facilitate constructive communications between business and government agencies responsible for establishing national occupational safety and health policy. The activities of ORC’s Occupational Safety and Health networks are based on the premise that providing safe and healthful working conditions is the mutual concern of employers, employees and government agencies.

It should be noted that companies that are members of ORC’s Occupational Safety and Health networks have provided information, opinion and advice to ORC in the development of its comments. However, these comments are solely those of ORC and may differ from the views and comments of individual member companies.

ORC offers the following general comments:

DOL has not established the need for a new regulation prescribing agency risk assessment procedures.

The purpose of this rulemaking, according to the preamble to the DOL's NPRM, is "to compile its existing best practices related to risk assessment into a single, easy to reference regulation, and to include two requirements to establish consistent procedures for conducting risk assessments that promote greater public input and awareness of the Department's health rulemakings." What is notable and puzzling is the utter failure of the DOL to justify or explain in the proposal why the issuance of a *regulation* is a necessary or appropriate means for achieving any of these three goals. In other words, why is a regulation, as opposed to some other non-regulatory alternative, the only or even the best way to 1) "compile best practices related to risk assessment into a single easy to reference" document, 2) "establish consistent procedures for conducting risk assessment," and 3) "promote greater public input and awareness" of health rulemakings?

A fundamental precept of modern regulation, especially in this administration, has been that there must be a demonstrable need for a rule and that there are no alternatives to a regulation that would effectively accomplish the same purpose. And while the DOL asserts that the Regulatory Flexibility Act does not apply to this rulemaking (73 FR 50910), the principle of establishing a need for a rule should not be ignored. For example, there is no evidence presented in the NPRM to indicate that procedures in the referenced OMB/DOL guidance documents are not sufficient or are not being followed, or that interested parties believe that opportunities for participation in health rulemakings are lacking in some way. As is discussed in more detail below, ORC believes that rulemaking is not an appropriate vehicle for achieving the basic objectives described in the proposal.

The "art and science" of risk assessment is evolving and dynamic and should not be "frozen in time" in this overly-simplistic and confusing proposal.

Improving the organization, accessibility and credibility of DOL risk assessment best practices is a worthwhile goal and, in fact, a "single, easy to reference" source for risk assessment best practices used by DOL agencies might be useful. ORC would be supportive of DOL compiling (or at least summarizing) "*existing* risk assessment best practices" used by the agencies. However, it is a breathtaking leap to suggest that the best or even a reasonable means to do this is through a new regulation. Regulation seems a particularly inappropriate way to address the issue of risk assessment "best practices" – a regulation could, indeed, capture "existing" DOL practices, but risk assessment is an evolving and dynamic field, involving the development of new techniques and approaches as our scientific understanding of how toxic substances and harmful agents affect the human body and how to extrapolate and interpret data improve over time. Almost by definition, a regulation is ill-suited to prescribe "best practices" that will surely change, perhaps rapidly, in the coming years. It makes little sense to "freeze" today's risk assessment practices in a regulation that may have to be amended with some frequency in order to allow for the continual improvement of agency best practices in the ever-evolving art and science of risk assessment.

It should also be noted that there have been frequent modifications to OMB regulatory guidance documents over the past 30 years as administrations change and new policies are adopted – these

changes to the regulatory management process are an acknowledged prerogative of a President and basic regulatory management processes should not be “locked in” at an agency level, so that they may become inconsistent with future administration policy.

Finally, even assuming that a compilation of risk assessment best practices in some form is a laudable goal, this document does so only in a very superficial way (see examples below) that is not helpful to participants in OSHA and MSHA rulemakings who may not be familiar with agency methodology. In addition, the proposal is not at all clear as to what extent and how the referenced OMB documents are applicable vis a vis OSHA and MSHA case law and longstanding agency policy and practice. In the end, the public may be left more confused than enlightened.

ORC has the following comments regarding specific sections of the NPRM:

The definition of significant risk is incomplete and is not a useful description of what constitutes “significant” risk for health standards-setting purposes.

An understanding of the parameters of what constitutes “significant risk” for health rulemaking purposes is fundamental to the application of risk assessment practices by the DOL. The only “definition” provided in the NPRM is in §2.9(b), *Definition. Significant risk*. The term significant risk, the subject of more than 25 years of judicial precedent, is in fact, not defined or described meaningfully at all in this paragraph. Instead, DOL only reminds itself that before promulgating a health standard pursuant to the Occupational Safety and Health Act, it must establish that “there is a significant risk that can be eliminated or lessened by a change in practices....” This supposed “definition” provides no useful guidance to the reader with respect to critical threshold issues, e.g., what are the basic parameters of “significance” of a risk (the preamble discussion at pages 50912-13 is likewise not helpful) and what is the basic nature of the “risks” that the agencies can regulate. With respect to the latter point, there is no mention anywhere in document of the critical concept of “material impairment of health or functional capacity,” without which there can be no adequate discussion of “significant risk.”

The requirement for an ANPRM for every rulemaking is excessively restrictive and unsupported.

In §2.9(c) (1), DOL proposes requiring that an Advance Notice of Proposed Rulemaking (ANPRM) always be issued as part of every health rulemaking. While the fact is that many if not most OSHA health rulemakings conducted in the last couple of decades have included an ANPRM, it is an unnecessary restriction on Agency discretion to require this step for every health rulemaking. To be clear, ORC is not objecting to the use of ANPRMs as one tool for assuring the “open and vigorous exchange of information and ideas” around science and risk. But it is not the only tool, and indeed, historically not a particularly effective one. It has been primarily used simply to gather preliminary information around whether, in general, there is an adequate evidentiary basis to commence a rulemaking. Data and information is “dumped” into a docket and very little public discussion (“open and vigorous exchange”) actually ensues until the NPRM, if any, is published. An example of something that may actually work more effectively than an ANPRM in some situations is the informal circulation/publication of a “pre-proposal” draft

standard around which public meetings and discussions can be held. MSHA has used this tool effectively in the past. The point here is that there is no justification for a blanket requirement for an ANPRM, which may not always or even often accomplish the objective sought. ORC recommends that the Department establish certain “performance criteria” around the need for early (pre-proposal) information exchange and leave it to the agencies to decide in a particular situation how to achieve those objectives.

There is an inadequate explanation of why industry-by-industry working life exposure data has been singled out as an essential aspect of agency risk assessment.

In §2.9(c) (3), DOL states, “Risk assessments shall utilize the best available evidence, and the latest available scientific data in the field, *including industry-by-industry evidence relating to working life exposures.*” [Emphasis added.] ORC understands from earlier drafts of this proposal that there is apparently a “history” to this provision involving a preamble discussion (omitted from the final proposal) that described at some length recent working life patterns in various industry sectors. It appears that there is some concern on DOL’s part that, in at least some health standards rulemakings, OSHA has failed to collect “real world” working life exposure data on an “industry-by-industry” basis and factor those data into the risk assessment process. What the DOL fails to do in the NPRM is to assert, let alone prove, that this implicit “failing” has had some adverse impact on the standards in which it occurred. Put another way, why is this analysis so essential that it must be a mandated part of the risk assessment process? Because such a new requirement would limit OSHA’s traditional statutory and policy discretion, there should be a compelling reason to impose what amounts to a new substantive obligation on the agencies. It might make more sense for the DOL to remove the last clause, emphasized above, from the mandatory language in the text of the rule and instead state in the preamble that “utilizing the best available evidence should generally include, where feasible, an evaluation of industry-by-industry working life exposure information.”

By implying that the dose-response assessment step of a risk assessment always involves “an adverse health outcome” DOL at the very least creates confusion and at worst, seems to restrict rulemaking action to cases where there are demonstrated adverse human health outcomes.

In §2.9(c) (3) (ii) *Dose-response assessment*, DOL says the “. . . dose response assessment step examines the relationship between exposure to a hazardous substance and *an adverse health outcome.*” [Emphasis added.] This is another example (see significant risk definition) of poor, confusing and potentially conflicting draftsmanship. It is critical here to reference the operative statutory term “material impairment of health and functional capacity” and the decades of case law and policy determinations that have come to define that phrase. This key phrase has at its core the notion that prevention of work-related illness is a fundamental goal of OSHA and MSHA health standards. Although permissible exposure limits (PELs) are designed to prevent illness in most workers, many OSHA health standards also require actions such as monitoring and surveillance activities that are designed to detect individual changes in a worker’s biological systems that presage the manifestation of illness and are generally triggered by “action levels” that are set below a PEL. Identifying these early, often “sub-clinical” changes allows for the protection of

workers before serious disease occurs. DOL's use of the term "adverse health outcome" does not convey, and could be construed as in conflict with, both the key statutory term and this important function of health standards.

The public access provisions in §2.9(d)(1) and (2) are well-intentioned but can be accomplished by non-regulatory means.

ORC agrees with DOL's objective. In fact, making the kinds of documents referenced in the NPRM publicly available in the docket is not only a simple process but is currently standard practice at OSHA and MSHA as well. We note with some puzzlement that DOL did not follow its own prescription for transparency in its failure to post any supporting materials or background information in the docket for this rulemaking.


Summary and Recommendations

The NPRM has had the laudable effect of reviving discussion of appropriate use of science in the development of public policy, especially in occupational health rulemakings. ORC does not object to a compilation of best practices in risk assessment, with improved procedures for transparency. However, the DOL has failed to justify the need for a regulation to accomplish its objectives. In addition, the proposal is poorly drafted in significant ways that could lead at least to confusion and at worst to conflict with the Acts whose requirements the proposal purports to clarify.

A more supportable, adaptable and effective alternative means to achieve the DOL's objectives, and one that would address many of the concerns raised by the NPRM, would be the issuance of a guidance document instead of a regulation. Such a step would allow for the appropriate degree of flexibility and responsiveness needed for the continual improvement of risk assessment approaches and their application to DOL health rules.

ORC appreciates the opportunity to present these comments in response to the NPRM and would be happy to discuss any of these comments further with DOL staff.

Sincerely,

A handwritten signature in black ink, appearing to read "Frank A. White". The signature is written in a cursive, somewhat stylized font.

Frank A. White
Senior Vice President