

Department of Defense Response to Questions for All Agencies Potentially Affected by the Draft OMB Risk Assessment Bulletin – July 2006

1. The Department of Defense (DoD) appreciates the opportunity to respond to the questions posed by the National Research Council's Committee chartered to review the Office of Management and Budget's (OMB's) proposed Risk Assessment Bulletin. The Committee was tasked to determine if the proposed guidance will meet OMB's stated objective to "enhance the technical quality and objectivity of risk assessments prepared by federal agencies."

2. A wide variety of risk and hazard assessments are performed by many different offices and organizations across DoD with varying missions ranging from basic research to civil works. These include risk assessments performed for:

- Developing DOD environment, safety and occupational health (ESOH) standards.
- Assessing site-specific human health and ecological risks from environmental contamination.
- Assessing ESOH risks from operating weapons systems and military platforms (e.g., community noise level from aircraft operations; risks to military personnel from weapons firing).
- Assessing materials being considered for use in weapons systems and platforms.
- Assessing the risks of infectious diseases to DoD's operating forces.

3. The responses below focus primarily on risk assessments performed in the functional areas of environmental protection, human safety and health and facilities/civil works. Due to time constraints for developing responses and the sensitive or classified nature of certain national defense programs, the responses do not cover such areas as military operations/threat assessments, munitions, or all areas of weapons systems development and acquisition.

DoD Responses to Questions

1. General questions about current risk assessment practices

a. Please provide a brief overview of your current risk assessment practices.

Risk assessment methods and characterization of uncertainty are dependent upon and tailored to the specific purpose or function being assessed. There are some common approaches prescribed within functional areas, but no over-arching approach for all types of risk assessments.

The following provides some examples of the types of risk assessments performed by DoD and the approach used.

Occupational Health Risk Assessments:

DoD develops internal exposure limits for occupational hazards when a regulatory standard is not available, or when DoD determines the regulatory standard does not

sufficiently reduce the risk to DoD personnel or operations. In the development of such internal standards, a comprehensive health risk assessment would normally be prepared.

Environmental Risk Assessments:

Site-specific risk assessments for releases of hazardous substances, pollutants, and contaminants resulting in environmental contamination are conducted under the Defense Environmental Restoration Program following the process set forth in the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the Resource Conservation and Recovery Act (RCRA). The majority of the human health assessments conducted by DoD follow the methodology outlined in the Environmental Protection Agency's (EPA's) *Risk Assessment Guidance for Superfund (RAGS), Volume I, Human Health Evaluation Manual, Parts A through E*. The EPA's *Ecological Risk Assessment Guidance for Superfund (ERAGS)* is used for conducting ecological risk assessments. The Department is currently developing a methodology to assess the hazards associated with military munitions and explosives of concern in collaboration with EPA.

The Department occasionally conducts risk assessments pursuant to RCRA authorities. For example, at installations that have hazardous waste combustion facilities or activities, RCRA assessments are usually conducted. The human health portion of RCRA assessments follow the methodology outlined in the *Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities*. These types of risk assessments are almost exclusively screening in nature, but often the results are used to make permitting decisions.

Health Hazard Assessments:

Health hazard assessments are conducted following a formal approach or standard operating procedure for various programs within the DoD. The assessments are completed by a team of professional subject matter experts (e.g., industrial hygienists, toxicologists, acoustic engineers, physicians, epidemiologists, etc.) as warranted by the specific assessment. The results of these assessments are documented in a formal health hazard assessment report.

A hazard assessment may use multiple inputs to assess the significance of a hazard including:

- Benchmark system design standards (e.g., military standards, industry standards, consensus standards);
- Established risk criteria (e.g., Occupational Safety and Health Administration's Permissible Exposure Limits, American Conference of Governmental Industrial Hygienists Threshold Limit Values, other military unique criteria); or
- Experience from previous systems, safety assessments, human factor assessments, operational requirement documents, management documents, test documents, user manuals, and field observations.

Examples of the application of health hazard assessments follow:

- The control of health hazards associated with the life cycle management of new and modified equipment to identify potential hazards early in the life cycle and eliminate hazards in the design phase.
- The evaluations of materials being considered for various applications, such as use aboard submarines.

Civil Works:

The Army Corps of Engineers (COE) is expanding the use of risk assessment in dam safety including a screening level portfolio risk assessment. Currently, the Louisiana Coastal Protection and Restoration (LaCPR) study is proposed to include a multifaceted risk assessment, the incorporation of large uncertainty scenario drivers, and a risk-informed decision process. The National Research Council (NRC) reviewed the Army Corps of Engineers risk assessment approach to flood damage reduction and published their findings in 1999. Generally, NRC thought the approach was a great improvement but identified some issues for further consideration. The continuing need for risk assessments was reinforced by the events surrounding hurricane Katrina.

The COE also uses risk assessments in evaluating the appropriate options for the disposal of dredged material during the maintenance and construction of the nation's waterways. The COE has developed a variety of guidance manuals and procedures for the evaluation and testing of dredged material. Some of the COE work in this area was reviewed previously by the NRC (e.g., *Contaminated Sediments in Ports and Waterways: Cleanup Strategies and Technologies*, 1997).

b. Specifically, do you conduct probabilistic risk assessment?

Probabilistic risk assessments may be performed within DoD for past or predictive effects on health, although rarely in support of baseline risk assessments conducted for the Defense Environmental Restoration Program. Probabilistic techniques have been explored but dismissed in a number of cases because of lack of scientifically defensible technical information; lack of acceptance by the regulatory community; difficulty in communicating the results to the public; and/or significant time, resource, and cost restraints. Probabilistic risk assessments are not always needed to adequately inform the decision-makers and stakeholders about the risks and hazards present and should be performed if necessary to aid decision making.

Markov Chain Monte Carlo Analysis has been used for chemical specific risk assessments in conjunction with the development of pharmacokinetic models.

c. Is there a common approach to both risk assessments and uncertainty analysis? How do you currently address uncertainty and variability in your agency's risk assessments?

There is a common approach to the conduct of DoD risk assessments depending on the functional area and purpose for which the assessment is being done (e.g., environmental site assessments follow EPA RAGS and ERAGS guidance as addressed above).

There is not a common approach for uncertainty analysis for the diversity of risk assessments that DoD conducts. Typically, uncertainty and variability are addressed in risk assessments either qualitatively or quantitatively. The uncertainty analyses performed in individual risk assessments vary by the type of assessment produced and time/resource constraints. Levels of effort are not consistent; some uncertainty sections in some risk documents are very detailed, others are not. Variability is often addressed by statistical approaches and spatial analyses.

Below are some specific comments related to uncertainty analyses found in DoD risk assessments:

- Within the uncertainty sections of the assessment, specific areas may be examined (e.g., for ecological risk assessments, area use factors (AUFs) are typically considered).
- While cancer risks and hazard quotients are generally summed across chemicals and exposure pathways, there is usually no discussion regarding the underlying scientific uncertainty of this approach.
- It is common practice to direct environmental sampling in a biased manner (e.g., directed to wastewater outfalls). This biased approach is consistent with most regulatory guidance and attempts to ensure human health protection. This practice incorporates a wide margin of safety to account for uncertainty as to the exact exposure point and variability in types of exposure. However, the uncertainty is not captured by current site attribution methods. It is common practice to use this type of biased sampling data in comparison to ambient/background for the purpose of attributing contamination to the entire site.
- In the face of scientific uncertainty associated with site characterization, it is common practice to use either the maximum detected concentration or if sufficient data are available, the 95th upper confidence limit (UCL) of the mean concentration as being representative of the site. The associated uncertainty and variability is rarely included in the risk characterization, although it is sometimes discussed in a qualitative manner.
- Although the scientific uncertainty associated with chemical-specific/toxicological risk assessment (e.g., IRIS risk assessment) is carried into each site-specific chemical risk assessment, risk characterizations rarely discuss the uncertainty associated with the safety and uncertainty factors assigned to toxicity criteria found in IRIS.

d. Please identify any substantial scientific or technical challenges that you may encounter when conducting risk assessments for your agency.

Listed below are some of the substantial/scientific challenges DoD encounters when conducting risk assessments.

- Assigning Risk Assessment Codes (RACs) for health hazard assessments

When assigning RACs for life cycle management of new and modified equipment and other safety analyses, variability is introduced because of the subjective, professional judgment used in assigning severity and probability values. While risk assessments may use state-of-the-art techniques, they have inherent limitations based on the capabilities of current technologies to predict ESOH effects (e.g., limitations in laboratory toxicology studies to predict human health effects related to new materials).

- Consistency and satisfying the various regulatory agencies in regards to transparency

The degree to which a risk assessment is considered minimally or not transparent to one agency may be considered efficient preparation to another. Setting a minimal standard for transparency would facilitate more efficient production of risk assessments. In addition, the various federal and state program offices with which we interact often have different interpretations of the same guidance documents or the same regulations. Consequently, the risk assessment “target” is constantly moving, making it difficult to effectively produce a risk assessment that meets all regulatory requirements.

- Effectively communicating complex and highly technical risk assessment information

Stakeholders unfamiliar with the risk assessment process or individuals who have emotional attachment to the issue present a challenge for risk communication. Mandatory performance of even more complex risk assessments, such as probabilistic risk assessments, can amplify this challenge. Standardizing the types of risk assessments and more clearly defining when and how each type of risk assessment is to be conducted would be a significant improvement.

- A lack of scientifically defensible and/or agreed upon input information.

Toxicity data, especially for the acute portion of the risk assessments and for the dermal pathways, is absent for many of the chemicals included in our risk assessments. Likewise, fate and transport data are often unavailable, as are scientifically defensible exposure inputs and statistical distributions for these exposure inputs. Consequently, this absence of information has hindered the use and performance of probabilistic risk assessments. Targeting research to fill these information gaps would allow risk assessors to produce more comprehensive and technically defensible products.

- Calculating risk for intermittent exposure(s)

From an applied perspective, exposures being assessed may be intermittent and the risk assessment model and associated toxicity data are not sufficiently refined to account for intermittent exposures. Consequently, exposures may be averaged over some exposure

duration, resulting in an underestimation or overestimation of risk, depending on the chemicals involved. Further development of the existing model or development of a new model, specific for intermittent exposures, would be a good first step to removing this challenge. Toxicity data representative of intermittent exposures would also need to be developed.

- Over-estimating risk

The current approach to ensuring health protection in the face of scientific uncertainty was devised almost 30 years ago. That approach is to multiply a default factor of up to 10 for each of four types of uncertainty assumed to act independently. Uncertainty factors are applied for inter-human variability/sensitivity, animal to human extrapolation, LOAEL to NOAEL extrapolation, and sub-chronic to chronic extrapolation. Today, many health risk assessors believe that multiplying default uncertainty factors overestimates risk. When coupled with the use of non-peer reviewed toxicity values, the approach may lead to significantly overestimated risk values and thus overly conservative cleanup levels.

- Evaluating the vapor intrusion pathway

Regulators frequently require DOD to evaluate the vapor intrusion pathway under residential scenarios. This is problematic because: 1) the methodology remains technically complex and controversial among risk assessors; 2) residential indoor air is not regulated; and, 3) standards for residential indoor air have not been established.

- Lack of toxicity values for emerging contaminants

Regulators frequently request that DOD conduct risk assessments on contaminants for which toxicity values have not been established and for which inadequate toxicological information exists.

The following is a list of subjects identified by DoD risk assessment professionals as lacking policy or guidance, or consistency in policy or guidance.

- Consistent and reasonable policies and practices on the use of background data (anthropogenic and naturally-occurring background) and quantifying and accounting for background.
- Guidance for identifying and characterizing genetic polymorphisms (genotype-environment interactions) and inter-individual differences in susceptibility to toxicants.
- Consistent policies and practices on evaluating ecological habitats.
- Guidance for estimating exposure concentrations of contaminants in soil and groundwater in human-health risk assessments.
- Policy or requirements for defining the extent of site characterization required to inform a risk management decision for a site.
- Guidance for determining home ranges for receptors being evaluated in ecological risk assessments.

- Guidance, policy, or requirements for selecting toxicity values from a range of possible values.
- Guidance for determining the weight-of-evidence in carcinogen assessments.
- Policy or requirements for the appropriate use of screening concentrations in risk assessments.
- Guidance for addressing inconsistencies with statistical approaches for use in risk assessments.
- Guidance or standards for assessing risks of contaminants when analytical limits of detection or analytical capability may not be developed/available to meet existing public health goals.

e. What is your current definition of risk assessment, and what types of products are covered by that definition?

For different programs and different agencies within DoD, there are slightly different definitions that relate specifically to the type of assessment being performed. Some of the definitions are presented below:

Occupational Health Program:

Risk assessment is defined as a structured process to identify and assess hazards. An expression of potential harm, described in terms of hazard severity, accident probability, and exposure to hazard. Sub-definitions follow:

- Hazard Severity. An assessment of the expected consequence, defined by degree of injury or occupational illness that could occur from exposure to a hazard.
- Accident Probability. An assessment of the likelihood that, given exposure to a hazard, an accident will result. An accident receives a specific classification based on an established criteria scheme.
- Exposure to Hazard. An expression of personnel exposure that considers the number of persons exposed and the frequency or duration of the exposure.

Environmental Program:

Risk assessment is the collection and evaluation of scientific information for the purpose of determining potential adverse health impacts to human and/or ecological populations from exposure to substances (chemical or biological) released into the environment.

Health Hazard Assessment Program:

Risk assessment is an organized process used to describe and estimate the likelihood of adverse health outcomes from occupational or environmental exposures to hazards. It consists of four steps: hazard identification, toxicity assessment, exposure assessment and risk characterization.

In the Defense Environmental Restoration Program, a site-specific risk assessment is used in risk management decisions to determine the extent of risks at a site and the need for response actions.

Health hazard assessment is a methodical evaluation of the consequences of exposure to a hazard(s) with particular focus on potential adverse human effects. The HHA process may incorporate hazard identification, characterization, assessment and communication. It may be used to support a regulatory program or policy position and meet one or more of the following criteria:

- Focus on significant emerging issues
- Support major regulatory decisions or policy/guidance of major impact
- Establish a significant precedent, model, or methodology
- Support major regulatory decisions or policy/guidance of major impact
- Have significant inter-agency implications
- Consider an innovative approach for a previously defined problem, process, or methodology
- Satisfy a statutory or other legal mandate for peer review

Civil Works

The COE does not have risk "terms of reference" nor overall risk assessment standards. As the COE explores an appropriate approach to implementing the OMB bulletin, the necessary Engineering Regulations will be revised in accordance with the requirements of Section IV of the bulletin.

f. About how long (that is, from initiation of the risk assessment to delivery to the regulatory decision maker) does it take to produce the various types of risk assessments?

The length of time to produce a risk assessment varies greatly depending on the complexity of the subject and the type of risk assessment. Health hazard assessments, as addressed in this response, typically take 30 to 90 days from receipt of a complete package for review. Human health risk assessments for the Defense Environmental Restoration Program sites can vary from months for simple sites to five years or greater for complex sites.

The time needed to produce a risk assessment depends greatly on the amount of information available at the initiation of the risk assessment and/or the specific requirements for conducting the assessment. The time required can be significant in situations where (1) no sampling has been performed, (2) risk communication is just beginning, (3) toxicological information does not exist or has to be developed, and/or (4) the exposure/health effects are not known or well understood. In urgent situations, there may be a need to provide as accurate an estimate of risk as possible in a very short timeframe. In these cases, a risk estimate may be made in as little as a few hours.

2. Questions about OMB's definition of risk assessment and applicability

Using the definition of risk assessment described in the OMB Bulletin, are there work products that would now be considered risk assessments that were not previously considered risk assessments? If so, what are they?

The term “risk assessment” is a very broad term that the OMB Bulletin correctly recognized can involve many different methodologies in the varied disciplines that utilize the assessment of risks as a decision making tool. However, we do not believe that it will significantly change what products we consider risk assessments at this time.

The applicability of the OMB Bulletin requirements to some DoD activities some projects is somewhat unclear. For example, the second paragraph of Section II states, “[t]his Bulletin does not apply to risk assessments that arise in the course of individual agency adjudications or permit proceedings...” Additional confusion arises from the sentence, “[t]his Bulletin also shall not apply to risk assessments performed with respect to inspections relating to health, safety, or environment.” Therefore, it is possible that the Bulletin would not be applicable to some inspection work products.

3. Questions about type of risk assessment (tiered structure)

a. In your agency, is there currently a clear demarcation between risk assessments used for regulatory analysis and those not used for regulatory analysis? Is this clear at the outset of the risk assessment?

Typically, there is usually a clear distinction between risk assessments used for regulatory analysis and those that are not (i.e., used for internal DoD purposes). Many of the environmental risk assessments are site-specific and are performed to meet statutory (e.g., CERCLA) and regulatory requirements. Whereas chemical-specific toxicological risk assessments are done to determine reference doses or concentrations and typically have the potential to impact the state of the science, the published values may be used by other agencies for regulatory purposes. These are typically done by DoD for military-specific chemicals.

Other risk assessments may be done to answer military-specific, force protection, or threat assessment questions.

b. In your agency, is there currently a clear demarcation between “influential risk assessment” used for regulatory purposes and other risk assessments used for regulatory purposes? Is this clear at the outset of the risk assessment?

There is no clear demarcation between “influential risk assessment” used for regulatory purposes and other risk assessments used for regulatory purposes.

4. Questions about impact of the Bulletin on agency risk assessment practices

a. If applicable, please specify provisions in the Bulletin that can be expected to have a substantial positive effect on the quality, conduct, and use of risk assessments undertaken by your agency.

The general framework provided by the Bulletin will be useful to DOD for improving scientific rigor for its risk assessment procedures. Below are some specific improvements that will likely be realized:

- Increased transparency of the science and assumptions in the risk assessment.
- Improving the scientific defensibility of risk assessments as a result of the provisions listed in Section IV: “General Risk Assessment and Reporting Standards.”
- Defining the central tendency (CT) as an “expected effect” and the requirement to express risk as a range should produce more realistic risk management decisions. However, it would be beneficial if the OMB Bulletin provided examples of when it may be appropriate to regulate using the expected effect vice the most conservative estimate.
- A more comprehensive characterization of the sources of uncertainty via use of quantitative approaches will be included in risk assessments performed. We consider this extremely important and beneficial for chemical-specific risk assessments (whereas this may not be as necessary for more routine, site-specific risk assessments). Perhaps more importantly, is the recognition and use of this uncertainty information in risk management decisions.
- More detailed discussion(s) of the full range of uncertainty will be generated by modeling of data (the strengths and weaknesses associated with various assumptions/modeling). This is frequently lacking in health risk assessments. These modeling assumptions include those associated with dose-response curves and point-of-departure (POD); dose ranges and associated likelihood estimates for identified human health outcomes.
- More detailed discussions of variability (the range of risks reflecting true differences among members of the population due to, for example, differences in susceptibility) and uncertainty (the range of plausible risk estimates arising because of limitations in knowledge) will have a positive effect on the outcome of the risk assessment. Failure to characterize variability and uncertainty thoroughly can convey a false sense of precision in the conclusions of the risk assessment.
- For cancer health risk estimates, quantitative estimates of the POD corresponding to central, upper-bound, and lower-bound estimates; the use of different plausible POD values; different plausible mathematical functions fit to the observed epidemiological data, where available, and different assumptions for estimating historical exposures among human subjects (epidemiological data), when applicable, should significantly improve the risk assessments.

- For non-cancer health risk estimates for chemical-specific risk assessments, characterization of the uncertainty associated with fitting a dose-response relationship to the available data and selection of a POD. Where applicable, it should be acknowledged that the information available remains insufficient to support a meaningful point estimate.

b. If applicable, please specify provisions in the Bulletin that can be expected to have a substantial negative effect on the quality, conduct, and use of risk assessments undertaken by your agency.

The adherence to the provisions listed in Section V: “Special Standards for Influential Risk Assessment” and in Section IV: “General Risk Assessment and Reporting Standards”, the performance of risk assessments will be more labor and resource intensive.

Additional labor will be required to:

- Collect the necessary information and data to characterize risk as outlined in the OMB Bulletin.
- Negotiate with regulatory authorities about the scope of the risk assessment. When deciding specific inputs, there will now be a wider range of choices, rather than one or two choices.
- Communicate the results to people unfamiliar with the risk assessment process, due to the increased complexity of the risk characterization portion and the increase in the amount of material requiring explanation.
- Increase the level of expertise needed to perform quantitative uncertainty analysis for completing a risk assessment. Finding the expertise in a timely fashion may present challenges.
- Review products due to increased time associated with more complex risk assessments.

c. If your agency followed the procedures described in the Bulletin, would it affect the time course for production of the risk assessment (that is, the time required from initiation of the risk assessment to delivery to the regulatory decision maker)? If so, please explain why?

The time required will vary depending on the organization and type of risk assessment being conducted. No expected change is anticipated for some risk assessments while a significant increase in time may be required for others. Some organizations within DoD believe that adherence to the provisions listed in Section V: Special Standards for Influential Risk Assessments and in Section IV: General Risk Assessment and Reporting Standards may impact the ability to meet critical and/or regulatory prescribed deadlines unless the allowable timeframes are extended to accommodate the expanded assessments.

d. One of the Bulletin's reporting standards states the need to be scientifically objective by "giving weight to both positive and negative studies in light of each study's technical quality." Please give an example of how this would be implemented by your agency or department.

A requirement to give weight to both positive and negative studies in light of each study's technical quality would generally be a beneficial change. The key point in the question is "in light of each study's technical quality." DoD upholds the principles of scientific objectivity and consideration of all peer-reviewed literature, with an emphasis on appropriate and technically relevant study design for the research.

The ability to be able to select site-specific exposure assumptions and toxicity parameters based upon the latest science, vice the default values required by some regulatory agencies, would be very beneficial. Risk assessors should have the option to evaluate the various studies and discuss in the risk assessment the justification for deviating from the standard default value(s). Currently, some agencies are reluctant to allow the use of site specific exposure assumptions.

The EPA's Final Cancer Guidelines state that well-conducted human studies that fail to detect a statistically significant positive association may have value and should be judged on their own merit. However, it may be difficult to have EPA consider negative studies of "equal weight" with positive studies, particular since the Cancer Guidelines also have a default assumption that states when cancer effects are not found in an exposed human population, this information, by itself, is not generally sufficient to conclude that the chemical poses no carcinogenic hazard to potentially exposed human populations.

Deciding whether to give weight to both positive and negative studies in site-specific risk assessments could be determined by the complexity of the risk assessment necessary for a scientifically sound decision and the benefits, if any, of conducting such an evaluation, since this may significantly increase the time and resources needed to conduct the assessment. If the requirements of the risk assessment include the development of parameters for use in the risk assessment, both positive and negative studies are likely to be used. If parameter development is not required, one may choose to use default parameters.

e. Does your agency use risk assessments conducted by external groups? Would it be helpful to you if risk assessments submitted to your agency by external groups, such as consultants and private industry, met the requirements proposed in the OMB Bulletin?

Products produced by external groups are occasionally used and frequently reviewed by DoD. Risk assessments from external groups are often used when there is a lack of existing regulatory guidance. Contractors frequently conduct human health and ecological risk assessments as part of the DoD Installation Restoration Program. DoD also considers risk assessments published in open scientific literature when examining chemicals for which no regulatory standards exist. Although it would result in an increased contract requirement, it would be beneficial if contractors and private industry met the OMB Proposed Bulletin requirements. Potential benefits include:

- More consistent DoD risk assessments,

- More rapid quality analysis/quality control (QA/QC) review(s),
- Increased transparency when using products prepared by others, and
- Better information on which a risk manager can base a decision.

The use by federal agencies of risk assessments submitted by external organizations, such as consultants and private industry, may increase the pace of such risk assessments and increase the number of toxicity benchmarks available by removing the burden for all toxicity benchmark development from EPA. The use of credible and scientifically defensible risk assessment by external groups would allow EPA to focus on those chemicals of national importance.

Assuming a “zero-sum” game in most programs, the aforementioned requirements may result in additional costs per assessment and thus fewer assessments may be conducted. The value of additional information and analysis would have to be considered along with the importance and impact of the assessment and the effects on overall programs.