PROPOSED RISK ASSESSMENT BULLETIN

OFFICE OF MANAGEMENT AND BUDGET

RESPONSE PREPARED

BY

RISK ANALYSIS CENTER

INSTITUTE FOR REGULATORY SCIENCE

AND

POTOMAC INSTITUTE FOR POLICY STUDIES

RISK ANALYSIS CENTER

The Risk Analysis Center (RAC) was formed with the stated purpose to promote Best Available Science (BAS) in risk assessment, risk management, and risk communication. The RAC was formally established in 1999 by the Institute for Regulatory Science, and in 2006 became a joint center of the Institute for Regulatory Science and Potomac Institute for Policy Studies. Members of RAC who were responsible for preparation of this response are:

A. Alan Moghissi, Chair
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In addition, Betty R. Love oversees the day-to-day operation of RAC. Biographical summaries of these individuals are attached to this response.

Risk Assessment, risk management, and risk communication are the three essential elements of risk analysis. Each of these requires special skills and appropriate approaches to use risk in societal decision processes. As the validity of risk assessment is directly related to the quality of the scientific information that is used in its derivation, independent peer review constitutes an important prerequisite for the acceptability of its results.

RAC has identified rules that govern risk assessment. These rules are attached to this response. Similarly, RSI has an extensive description on the requirements of Best Available Science (BAS). A brief description of BAS is also attached to this document.

INTRODUCTION

The Office of Management and Budget (OMB) has traditionally provided guidance to federal agencies on a variety of subjects. The Proposed Risk Assessment Bulletin the Office of Management and Budget (RA Bulletin) continues this tradition and addresses detailed requirements for performing risk assessment. One of the recent activities of OMB with immediate impact on the RA Bulletin is the Information Quality Bulletin for peer review (OMB 2005).

There are a number of organizations performing risk assessment. These include various agencies of the federal government; certain state and local agencies; industry; and academia. The RA Bulletin includes a significant number of references supporting the need for the development of the RA Bulletin and the reasoning for the chosen path. A significant number of these references deal with activities of the U. S. Environmental Protection Agency (EPA), which performs more risk assessments than other federal agencies. In addition, many other references deal indirectly with environmental issues. Consequently, this response contrasts EPA's approach to the approach described in the RA Bulletin.

Risk Assessment vs. Risk Management

By far the most important aspect of the issue addressed by OMB is the respective roles of risk assessment and risk management. A key problem of the current approach used in risk assessment is the confusion between risk assessment and risk management, particularly the inclusion of risk management subjects in risk assessment.

According to the RA Bulletin, risk assessment "refers to a document that assembles and synthesizes scientific information to determine whether a potential hazard exists and/or the extent of possible risk to human health, safety, or the environment. It defines risk assessment as "a scientific and/or technical document that assembles and synthesizes scientific information to determine whether a potential hazard exists and/or the extent of possible risk to human health, safety, or the environment."

Consistent with the definition of the National Research Council (NRC 1983), the RA Bulletin indicates that the RA Bulletin definition applies to documents that could be used for risk assessment purposes, such as an exposure or hazard assessment that might not constitute a complete risk assessment. Furthermore, the RA Bulletin indicates that documents that evaluate baseline risk as well as risk mitigation activities are included in risk assessment.

In its definition, the RA Bulletin states: "influential risk assessment [is] a risk assessment [that] the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions. The term 'influential' should be interpreted consistently with OMB's government-wide Information Quality Guidelines and the Information Quality Guidelines of the relevant agency. A risk assessment can have a significant economic impact even if it is not part of a rulemaking."

Consistent with the NRC (1983) recommendation, the RA Bulletin defines risk management by describing how risk assessment is used. "Risk assessment is a useful tool for estimating the likelihood and severity of risks to human health, safety and the environment and for informing decisions about how to manage those risks." The numerous documents appearing subsequent to the publication of the NRC report indicate a reasonable consensus within the scientific community, regulated industry, academia, and virtually all who are involved in various aspects of risk assessment, risk management, and risk communication that the definitions provided by the RA Bulletin are reasonable and valid. Note that numerous documents published by the EPA (e.g. EPA 2004; EPA 2005) rely heavily upon NRC's definition.

RAC Rules on Risk Assessment and Risk Management

As stated above, rules governing risk assessment and risk management developed by RAC are attached as an appendix to this document. Briefly, risk assessment is defined as follows:

Risk Assessment is a scientific process entirely free of societal objectives. The level of protection, consideration of specific segments of the population, and all other societal objectives are the domain of risk management

This rule is consistent with the RA Bulletin: "Risk Assessment must be scientifically objective, neither minimizing nor exaggerating the nature and magnitude of risk". The methods that are described in the RA Bulletin are consistent with the RAC rule as stated above, and the requirements of Best Available Science (BAS) included in this statement as attachment I. Furthermore, RAC subscribes to the notion that risk assessment must meet three key attributes: "utility, objectivity, and integrity" as required by the RA Bulletin.

In contrast to RAC and the RA Bulletin, EPA (2004 p.22) clearly indicates its approach by stating: "At EPA risk assessment (evaluation of the science) and risk management (decision making, setting of policy) are not necessarily separate." EPA further explains the need for interaction between those who perform risk assessment and risk managers. The explanation excludes a description of the respective roles of the two functions. Similarly, EPA (2005 p. 5-2) correctly identifies the need for interaction between risk assessors and risk managers during the risk assessment process. Again here, because of the mixing of the functions of risk assessment and risk management, it overlooks the fact that the objective of this interaction should be to inform the risk manager of the intricacies of the risk assessment process. The purpose of the discussion on various default assumptions and other scientific data should be to enlighten the risk manager, who may or may not have a scientific background, on details of the process.

Interpretation of Legal Mandates

In defending its approach, EPA (2004] quotes various laws and suggests that they mandate different approaches in risk assessment. EPA quotes these mandates as follows:

"Apparent inconsistencies in risk assessment practices across EPA can stem from differences in statutory language. For example, individual statutes identify varying risks to evaluate and protect against (e.g., establish a margin of safety; protect sensitive resources; reduce overall risk) and mandate different levels of protection (e.g., protect public welfare; prevent unreasonable risk; reduce overall risks; function without adverse effects). Examples among major EPA program offices illustrate some of the different Congressional mandates regarding risk assessment and risk management practices:

a) In the case of threshold effects . . . an additional ten-fold margin of safety for the pesticide chemical residue shall be applied for infants and children . . . (OPPTS; FFDCA §408 (b)(2)(C))

b) The Administrator shall, in a document made available to the public in support of a regulation promulgated under this section, specify, to the extent practicable:

1) Each population addressed by an estimate of public health effects;

2) The expected risk or central estimate of risk for the specific populations;

3) Each appropriate upper-bound or lower-bound estimate of risk . . . (OW; SDWA §300g-1 (b)(3))

c) The Administrator shall . . . [add] pollutants which present, or may present, through inhalation or other routes of exposure, a threat of adverse human health effects . . .or adverse environmental effects through ambient concentrations, bioaccumulation, deposition, or otherwise but not including releases subject to regulation under subsection (r) of this section as a result of emissions to air . . . (OAR; CAA §112(b)(2))

d) . . . Provide an ample margin of safety to protect public health or to prevent an adverse environmental effect (OAR; CAA §112(f)).”

The “differences in statutory language” is based on the confusion between the respective roles of risk assessment and risk management. In examples described above, this confusion can be readily demonstrated as follows:

a) The ten-fold margin of safety is a congressionally mandated risk management process. The task of the risk assessor is to provide the actual risk value(s). Subsequently, the risk manager must use the factor of 10 in justifying the risk management decision

b) The simplest approach to follow this mandate is to perform a probabilistic risk assessment.

c) This is a detailed description of certain pathways need to be included in the risk assessment.

d) The inclusion of ample margin of safety is a risk management process. To be sure, the risk assessor must provide scientifically defensible approaches and computations for various levels of “ample margin of safety”. However, the selection of the level of safety is the domain of risk management.

EPA further states “Similarly, individual statutory requirements regarding the appropriate level of protection can have a significant impact on the focus (the purpose and scope) of a risk assessment, which can lead to the appearance of inconsistency in risk assessment practices. Such requirements vary across Agency programs, for example:

a) . . . To assure chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment (OPPTS; TSCA §2(b)(3)).

b) . . . Function without unreasonable and adverse effect on humans health and the environment (OPPTS; FIFRA §3).

c) . . . Necessary to protect human health and the environment (OSWER; RCRA §3005 as amended).

d) . . . Provide the basis for the development of protective exposure levels (OSWER; NCP §300.430(d)).

e) . . . Adequate to protect public health and the environment from any reasonably anticipated adverse effects (OW; CWA §405(d)(2)(D)).”

Again here, the “differences in statutory language” is based on the confusion between the respective roles of risk assessment and risk management.

a) Again here the decision on the “unreasonable risk of injury to health and environment” is a risk management decision. Much like item 1.d, the risk assessor must provide scientifically defensible approaches and computations for various levels of “unreasonable risk of injury to health and environment” for consideration by the risk manager.

b) and c) The mandate applies to risk management. Risk assessment should be identical regardless of the required level of protection.

d) This mandate emphasizes exposure. However, the risk assessment is unaffected by the mandate. The risk manager is to be provided data indicating potential impacts of various levels of exposure. However, the decision on the chosen level rests with the risk manager.

e) The RAC interprets this mandate as requiring a probabilistic risk assessment. The risk assessor must provide the risk manager with the impact of various levels of “reasonably anticipated adverse effects”. However, the decision on what constitutes “reasonably anticipated adverse effects” is risk management.

EPA continues by stating: “Even the statutory language used for different statutes administered within one major office, EPA’s Office of Air and Radiation (OAR), shows differences:

a) . . . Protect public health with an adequate margin of safety (OAR; CAA §109).

b) . . . Provide an ample margin of safety to protect public health or to prevent an adverse environmental effect (OAR; CAA §112(f)).

c) . . . Protect the public welfare from any known or anticipated adverse effects (OAR; CAA §109).

d) . . . [Not] cause or contribute to an unreasonable risk to public health, welfare, or safety (OAR; CAA §202(a)(4)).

e) . . . Protect sensitive and critically sensitive aquatic and terrestrial resources (OAR; CAAA §404 (Appendix B)).

f) . . . Reduce overall risks to human health and the environment (OAR; Title VI of CAA).

g) . . . Actions to mitigate environmental and health risks (OAR; SARA Title IV).”

As stated above, all of these mandates deal entirely with risk management and do not require different approaches in risk assessment. Each of these mandates is discussed as follows:

a), b), c), d). All of these mandates deal with the level of protection. As stated in previous sections, the risk assessor must provide scientifically defensible approaches and computations for various levels of protection for consideration by the risk manager.

d) This risk deals with "critically sensitive aquatic and terrestrial resources". The task of risk assessor is to perform a risk assessment dealing with potential candidates of "critically sensitive aquatic and terrestrial resources". The decision on what level of exposure is acceptable to protect that "critically sensitive aquatic and terrestrial resources" is the task of the risk manager.

The information included in this section clearly indicates that legal mandates do not require different risk assessments. In fact, if EPA would agree to perform probabilistic health and environmental/ecological risk assessments, the contradictions identified by the EPA disappear.

Application of Science-Based Risk Assessment

As covered by the RAC rule and stated by the RA-Bulletin, risk assessment is a scientific process and ideally void of societal objectives. On numerous occasions, EPA has stated that the objective of its risk assessment is to be protective. Two basic documents published by EPA (EPA 2004, 2005) demonstrate the point:

1. EPA (2004 p.16) states that "Since uncertainty and variability are present in risk assessment, EPA usually incorporates a "high-end" hazard and/or exposure level in order to ensure an adequate margin of safety for most of the potentially exposed, susceptible population, or ecosystem. EPA's high-end levels are around 90% and above — a reasonable approach."

2. EPA (2004 p.19) states "When exposure data or probabilistic simulations are not available, an exposure estimate that lies between 90^{th} percentile and the maximum exposure in the exposed population be constructed 'by using maximum or near-maximum values for one or more of the most sensitive variable, leaving others at their mean values'."

3. EPA (2004 p.62) states that "Our risk estimates are designed to ensure that risks are not underestimated which means that a risk estimate is the upper bound on the estimated risk."

4. EPA (2005 p.5-2) states: "While it is an appropriate aim to assure protection of health and the environment in the face of scientific uncertainty, common sense, reasonable applications of assumptions and policy, and transparency are essential to avoid unrealistically high estimates."

There are numerous problems in EPA's approach:

1. There is an appearance of arbitrariness in the scientific approach of EPA.
2. In EPA (2004), there is a quote from an American Chemistry Council document which states that risk assessment must not "intermingle policy judgments within the scientific assessment of risk" and "the choice of an appropriate margin of safety should remain the province of responsible risk-management officials, and should not be preempted through biased risk assessment"
3. By far the most important problem associated with EPA's approach is the appearance of misinforming the public. On numerous occasions, the media quotes as "true value" a risk value resulting from EPA's risk assessment. What is wrong with giving the public the true value? If there are uncertainties in the value, they should be so quoted and a justification given for choosing whatever value is chosen.

The Need for Probabilistic Health Risk Assessment

A key issue in certain risk assessments is the animal-to-human extrapolation. There is an extensive literature on problems associated with animal-to-human extrapolation. For example, Funget al, (1995) demonstrate that a large number of chemicals that are carcinogenic in an organ of mice are not carcinogenic in the same organ of rats; and equally important is the fact that a large number of chemicals that are carcinogenic in one of them are not carcinogenic in the other animal. Faced with such a problem and the need to perform risk assessment, it is imperative that biological parameters are considered in using the extrapolation from animals to humans. The same applies to extrapolating from high doses to environmental levels.

The objectives of the RA Bulletin and RAC rules appear to be similar if not identical. Although there is no reason to avoid performing probabilistic risk assessment, most regulatory agencies have resisted converting from a deterministic to a probabilistic risk assessment. The example of extrapolation from high-doses to low-doses and from animals to humans may be used to demonstrate the point.

The process of performing probabilistic risk assessment would consist of the following steps:

1. All animal experiments are included in the assessment.
2. Excluded are the results of falsified studies as are those that were experimentally flawed. For example, an experiment that used agents that were contaminated with interfering agents would fall into this category.
3. Negative studies (those with too few animals) are included with appropriate statistical modifications.
4. Each data point is converted to humans with appropriate conversion parameters.
5. The entire dataset is used to estimate the central as well as the upper and lower values of the risk.
6. If default factors are to be used, they should be in the mid point of potential values. If a decision is made to use higher than midpoint values, a reasonable upper and lower bound should also be used in the computation.
7. Once this process is completed, the upper and lower statistical values should be evaluated in terms of biological plausibility.

The results of this effort should be presented to the risk manager. The midpoint should be the point of departure. The risk manager should use the upper and lower values in justifying the chosen option.

The Need for Increased Use of Probabilistic Ecological Risk Assessments

Based on the current status of relevant science, certain types of ecological risk assessments are too complex to support meaningful applications of probabilistic methods. However, many other types involve data similar to the data used in health risk assessments and are well suited to a probabilistic approach. Ecological risk assessments for pesticides, for example, utilize quantitative exposure models and dose-response data that are closely analogous to models and data used in health risk assessments. In 1996, EPA's FIFRA Science Advisory Panel recommended that the agency develop and validate methods for probabilistic ecological risk assessment of pesticides. In response to this recommendation EPA commissioned a multi-stakeholder Ecological Committee on FIFRA Risk Assessment Methods (ECOFRAM) to review the available methods and recommend approaches for further development. The

recommendations from ECOFRAM, which were issued in 1999, have still not been implemented and EPA's Office of Pesticide Programs still relies primarily on deterministic risk assessments.

Probabilistic methods are also applicable, at least in principle, to many activities that EPA performs pursuant to the Clean Water Act and the Toxic Substances Control Act. Examples include the establishment of water-quality criteria, issuance of discharge permits, and regulation of chemical manufacturing. If probabilistic methods (including estimation of central tendencies and statistically based upper and lower bounds) were more widely used in these assessments, then the worst-case assumptions and safety factors that are frequently used to hide risk management decisions within assessment documents could be eliminated.

CONCLUSIONS

The RA Bulletin is a welcome document that, if implemented, would reduce or eliminate a large shortcoming in risk assessment. In particular, it would strengthen the scientific foundation of numerous societal decisions. The primary beneficiary of the implemented RA Bulletin would be environmental protection. The use of Best Available Science and elimination of societal objectives from the scientific foundation of environmental protection would be the prerequisite of sound environmental protection.

REFERENCES

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ATTACHMENT I

INSTITUTE FOR REGULATORY SCIENCE

BEST AVAILABLE SCIENCE

The public is often provided with contradictory scientific information. The news media are often accused of selecting scientists who support their preconceived notions. Advocacy organizations, certain regulatory agencies, and even certain members of the legislative branch of the government seem to follow the same path. The result is confusion and mistrust of science, scientists, and many important societal institutions. Those frustrated with the current situation have coined words such as "sound science" and "junk science" to identify the acceptability of scientific information. Meanwhile, the phrase "Best Available Science" or BAS is increasingly used to describe the level of acceptability of scientific information. The BAS concept is based on three important elements as follows:

1. Status of science
2. Selection process
3. Science vs non-scientific objectives

STATUS OF SCIENCE

The status of knowledge can be categorized into three classes consisting of proven science, evolving science, and fallacious information, each having two subgroups as follows:

Proven Science

Class IA - Confirmed Science: This class is equivalent to scientific law. It is scientific information that has been unequivocally confirmed and generally accepted. Note that each scientific law or scientific fact has its limitations and conditions for its validity. For example, the validity of the law of gravity has been well established, including the fact that it does not apply to atomic nucleus. Similarly, the speed of light is known with a given accuracy. The differences in its measurement are within the generally-accepted accuracy.

Class IB - Applied Science: This class consists of application of scientific laws to various branches of commerce and industry. Engineering and other applied sciences fall into this class.

Evolving Science

Class IIA- Extrapolation: This class includes scientific information obtained by extrapolation from observations beyond its scientific validity. Most predictive models and a large segment of contested scientific information fall into this class. These include predicted changes in the global climate, and cancer assessment as performed by the U.S. Environmental Protection Agency (EPA). Data resulting from exposing rodents to high levels of chemicals (occasionally so high that a fraction of animals die of acute poisoning) are extrapolated by EPA to humans for exposure levels that are sometimes a million-fold lower.

Class IIB - Scientific Judgment: In many cases, decisions must be made without having the needed scientific information. The methodology for expert judgment is reasonably well developed and consists of asking a number of individuals to give answers to specific questions and statistically assess the results. However, in absence of this rigorous system, the scientific judgment is no more than an educated guess.

Fallacious Information

Class IIIA - Speculation: This class consists of information that cannot meet the standards of scientific acceptability. Ethical consideration dictates that the nature of the information be clearly indicated. This requirement is mandatory for any scientist who engages in speculation. Furthermore, it is imperative that the scientific community develop unambiguous rules of conduct to ensure that speculation is identified as such.

Class IIIB - Pseudo-science: Sometimes called "junk science" or "politically processed science", this information has the sole purpose of promoting someone's ideology. The champion of this class of science was Lysenko, a Soviet geneticist who claimed a new form of genetics. The result of implementation of his system was the destruction of genetics research in the Soviet Union and disastrous agricultural production in that country. Pseudo-science is by no means limited to the past or the Soviet Union. A large segment of information disseminated by certain advocacy groups can be classified into this category. Often the dissemination of pseudo-science is justified on the basis that it is necessary to exaggerate or scare people in order to move the democratic system. What is being overlooked is the long-term damage that misinformation causes.

SELECTION PROCESS

There are rational and reasonable uncontested methods to resolve scientific controversies. Briefly, scientific information is divided into the following four distinct categories:

Group 1 - Personal Opinions: Expression of views by individuals regardless of their training, experience, and social agenda, are included in this group. Personal opinions are seldom—if ever—BAS. At best, this category can be used to initiate the study of a scientific issue. Note the standard process of news media is reliance upon this category in its reporting of scientific issues.

Group 2 - Gray Literature: Written information prepared by government agencies, advocacy groups, and others that has not been subjected to an independent peer review is included in this category. This is the favorite category of government agencies, advocacy groups, and individuals who want to promote an idea. In fact, this category is the more organized and written form of personal opinions. Again here, at best, this category should be used to initiate a study. Experience shows that in the overwhelming majority of cases this category does not meet the requirements of scientific acceptability.

Group 3 - Peer-Reviewed Science: Information subjected to an independent peer review constitutes this category. Peer review is the foundation of scientific acceptability. There are numerous requirements for acceptability of peer review. Briefly, the individual who is chosen as a reviewer must be a "peer" to the author of the study, and must have no conflict of interest. In addition, the author of the study must respond to the criticism by the peer to the satisfaction of an uninvolved person or organization.

Group 4 - Consensus-Processed Science: This category consists of information resulting from a process used to resolve scientific disputes. The prerequisite for this process is the formation of a group of peers under the auspices of an organization that is uniquely qualified to do so. Professional societies are primary candidates for this activity. There are, however, certain limitations to such an approach as follows:

1. Professional societies are qualified to manage the consensus process in their respective disciplines. For example, engineers cannot authoritatively speak on medical practice, and chemists cannot judge the validity of issues related to electrical engineering.

2. Management of the consensus process must exclude parochial interests of the profession represented by the professional society. Many professional societies represent their parochial interests and should disregard these interests during the consensus process.

3. Organizations established by Congress for the purpose of reaching scientific consensus must meet certain requirements. For example, the National Research Council (the research arm of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine) is uniquely qualified to evaluate interdisciplinary scientific issues. In contrast, the National Academy of Public Administration is qualified to address administrative issues, and the National Council on Radiation Protection and Measurements is qualified to evaluate issues related to radiation.

SCIENCE VS NON-SCIENTIFIC OBJECTIVES

There is ample evidence indicating that the intrusion of non-scientific objectives would jeopardize the objectivity and consequently the acceptability of scientific information. It is true that scientific investigation is performed because society wants to solve a problem or otherwise enhance the knowledge of humanity. In effect, the initiation or continuation of scientific activities is based on a societal objective. However, the inclusion of ideology, beliefs, or any other non-scientific objective in assessing the validity of scientific information is inconsistent with the foundation of BAS. Scientists have no monopoly on deciding what is good for society. Consequently, once the science is evaluated using the peer review or consensus process, members of other professions such as lawyers, accountants, or book sellers are as qualified to decide what is good for society as are members of the scientific community.

Attachment II

RISK ANALYSIS CENTER RULES GOVERNING RISK ASSESSMENT

Despite the abundance of information including peer-reviewed articles and reports resulting from consensus of credible panels, there appears to be a lack of clear rules governing various aspects of risk assessment. The following rules are derived from generally available and credible information.

Rule 1: Truth in Risk Assessment

This rule requires that the risk assessor clearly indicate the choices, assumptions, and other decisions and justify them. For example, for human health risk assessment the risk assessor must indicate why one set of animal tests was chosen and what would have happened if all animal sets had been used. Similarly, what options were available for high-dose-to-low-dose and rodents-to-human extrapolations? Subsequently, the risk assessor must provide actual computations to compare the results. In effect, the risk assessor must essentially analyze all options and indicate which one of them would be preferable and why. Applying a probabilistic approach will result in conclusions that rely on the central trend (e.g., average, median) and are unlikely to be significantly affected by the outliers.

Rule II: Honesty in Communication

The risk assessor must include the values resulting from the risk assessment in a common statistical form. The risk assessor must provide the central trend (e.g., average, median) together with the usual (e.g., 66%, 90%, 95%) confidence intervals (as specified by their lower and upper limits).

ATTACHMENT III

BIOGRAPHICAL SUMMARIES

Lawrence Barnthouse is the President and Principal Scientist of LWB Environmental Services. His scientific activities include ecological risk assessment; applied population biology; aquatic ecology; environmental toxicology; environmental modeling; regulatory support; CERCLA/RCRA assessment; natural resource damage assessment; risk-based corrective action; NPDES permits; and pesticide registration. Formerly, he was Manager of the ChemRisk office in Oak Ridge, TN. His activities included ecological risk assessment; environmental toxicology and modeling; product life cycle assessment; and regulatory negotiations. He was previously at Oak Ridge National Laboratory in its Environmental Sciences Division. There he performed CERCLA baseline ecological risk assessments for a number of DOE facilities; population studies and quantitative ecological risk assessments for fish and benthic communities in the Tennessee Valley; and studies of the impacts of coal mines and coal fired power plants on aquatic biota. Dr. Barnthouse served as Chairman of the National Research Council Workshop on Ecological Risk Assessment, and as a member of four committees of the National Research Council. He has authored or co-authored more than 80 publications. He is a Fellow of the American Association for the Advancement of Science; the Hazard/Risk Assessment editor of *Environmental Toxicology and Chemistry*; Chair of the Applied Ecology section of the Ecological Society of America; and a member of the Advisory Board of the Society for Risk Analysis. Dr. Barnthouse received an A.B. in Biology from Kenyon College, and a Ph.D. in Biology from the University of Chicago.

Betty R. Love is currently Executive Vice President of the Institute for Regulatory Science. In that capacity, she is responsible for the management of day-to-day operations of the Institute, and for administration of several projects. She is the Administrative Manager of a large-scale peer review program in collaboration with the American Society of Mechanical Engineers for a number of organizations including the U.S. Department of Energy. Her current research activities center around the development and implementation of a systematic approach to stakeholder participation, notably in scientific meetings. Previously, Betty Love was Director, Department of Training and Information within the Office of Environmental Health and Safety of Temple University in Philadelphia, PA. During that period she was instrumental in the development of a "Handbook of Environmental Health and Safety". She also developed and implemented a large-scale training program not only for the faculty and staff of the University but also for others. Betty Love is currently Managing Editor of *Technology*. She has published several papers in peer-reviewed journals; has edited a number of compendia; and is the primary author of *Manual for Public and Stakeholder Participation*. Betty Love received a B.S. degree in Business Administration from Virginia State University in Petersburg, VA, and an M.S. degree in Developmental Clinical Psychology from Antioch College in Yellow Springs, OH.

Dennis K. McBride is the President of the Potomac Institute for Policy Studies, located in Arlington, VA. Potomac is a non-partisan, not-for-profit, academic think tank providing expertise to the Congress, Administration, inter-governmental concerns, and the judiciary. The Institute specializes in science and technology, the impact of innovation, and the challenges of security. McBride is a retired Captain (O-6), U.S. Navy (Medical Service Corps) with extensive experience in wide domains of science, technology, and policy leadership. Earning his gold wings, Dr. McBride was a designated Naval Aerospace Experimental Psychologist. From bench scientist to national leadership levels, McBride served at five laboratories in aviation engineering and biomedical sciences. He was Program Officer for Biomedical Science at the Naval Medical

Research Institute/Office of Naval Research, where he was awarded the Legion of Merit for his scientific leadership; Chief Scientist for modeling and simulation at the Naval Research Laboratory; Chief Scientist, Manned Flight Simulator Laboratory, Naval Air Test Center; Head, Manned Systems Laboratory, Pacific Missile Test Center; and Chief, Engineering Psychology Division, Naval Aerospace Medical Research Laboratory. Dr. McBride was Program Manager, modeling and simulation, at the Defense Advanced Research Projects Agency, where he earned the Defense Superior Service Medal for his technological leadership. On retirement after 20 years as a Naval Officer/Scientist, McBride was selected on a national search as Executive Director, the Institute for Simulation at the University of Central Florida, where faculty elected him to Professor, with appointments in engineering and in psychology. Dr. McBride is currently affiliated professor at the Georgetown University Public Policy Institute, where he teaches four courses (including evaluation methodology) and supervises graduate research. He is also appointed to the faculty of the Krasnow Institute (interest in human biology), George Mason University. Professor McBride has served/led numerous national and international panels and committees. Among his National Academies contributions, he chaired the National Research Council Panel on Engineering of Complex Systems—Pioneering Revolutionary Technology; he chaired the NASA moon-to-Mars portfolio review; and has led numerous technical studies at Potomac Institute. Co-Editor-in Chief of the peer-reviewed journal, *Technology,* Professor McBride serves on several academic editorial boards. He has produced over 150 papers in experimental, differential and evolutionary psychology, ergonomics, engineering, economics, medicine, and public policy. McBride's academic preparation was from formal enrollment at the University of Georgia, the University of Southern California, and the London School of Economics, inter alia. He earned a Ph.D. in experimental psychology, M.S. in systems, M.S./MPA in public administration, and he championed "nano-economics" at LSE. McBride is a graduate of the Student Flight Surgeon School, Naval Aerospace Medical Institute; Flight Test Engineer Program, University of Tennessee Space Institute; and he was a summer scholar at the Santa Fe Institute.

A. Alan Moghissi is currently President of the Institute for Regulatory Science (RSI), a non-profit organization dedicated to the idea that societal decisions must be based on best available scientific information. The activities of the Institute include research, scientific assessment, and science education at all levels—particularly the education of minorities. Previously, Alan Moghissi was Associate Vice President for Environmental Health and Safety at Temple University in Philadelphia, PA and Assistant Vice President for Environmental Health and Safety at the University of Maryland at Baltimore. In both positions, he established an environmental health and safety program and resolved a number of relevant existing problems in those institutions. As a charter member of the U.S. Environmental Protection Agency (EPA), he served in a number of capacities, including Director of the Bioenvironmental/Radiological Research Division; Principal Science Advisor for Radiation and Hazardous Materials; and Manager of the Health and Environmental Risk Analysis Program. Alan Moghissi has been affiliated with a number of universities. He was a visiting professor at Georgia Tech and the University of Virginia, and was also affiliated with the University of Nevada and the Catholic University of America. Alan Moghissi's research has dealt with diverse subjects ranging from measurement of pollutants to biological effects of environmental agents. A major segment of his research has been on scientific information upon which laws, regulations, and judicial decisions are based—notably risk assessment. He has published nearly 400 papers, including several books. He is the Editor-in-Chief of *Technology: A Journal of Science Serving Legislative, Regulatory, and Judicial Systems*, which traces its roots to the *Journal of the Franklin Institute*—one of America's oldest continuously published journals of science and technology. Alan Moghissi is a member of the editorial board of several other scientific journals and is active in a number of civic, academic, and scientific organizations. He has served on a number of national and international committees

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Paolo F. Ricci is currently both an Honorary Professor at the University of Queensland, Australia, and Professor of Environmental Science at the University of San Francisco. He teaches epidemiology, risk assessment and management; and decision analysis applied to environmental choices under uncertainty. He advises on environmental law, toxicity torts, and complex scientific issues. Additionally, Paolo Ricci is conducting statistical and probabilistic epidemiological and toxicological assessments of the risks associated with public and occupational exposures to benzene and other chemicals, as well as bacteriological and viral agents in air and water. He has taught graduate courses in statistics; risk assessment; a special course in legal theory; and tort law. He was also a partner with Ricci & Molton, and Senior Consultant for Arthur D. Little. He was involved with developing long-term projections of water supply, demand, and quality. He has reviewed national water guidelines, in the context of the Federal Drinking Water Guidelines for 1995, for the Australian Federal Government. Paolo Ricci is a member of the American Association for the Advancement of Science. He served on the Australian National Medical Research Council—the key federal Australian committee that governs medical and health scientific research for Australia—and participated by chairing sections and presenting papers at national and international conferences dealing with air and water pollution. He was Guest Editor of the American Society of Civil Engineers' *Journal of Energy Engineering*, *Environment International,* and the *Journal of Hazardous Waste Management*. Paolo Ricci has written and edited five books published by Prentice-Hall and other major publishing houses. He has authored more than 100 scientific publications in journals such as *Science; Environmental Science and Technology; Environment International; Environmental Research; the Journal of the Air and Waste Management Association; the Medical Journal of Australia*; and several other international peer-reviewed journals. He has also published several law review articles. Paolo Ricci holds an M.A. degree in Economics from Temple University in Philadelphia, PA; an LLM degree from Leicester University, UK; an MPA degree from the Kennedy School of Government at Harvard University; and Ph.D. and M.Sc. degrees in Engineering and Sciences from Drexel University, Philadelphia, PA.

Fritz A. Seiler is currently President of Sigma Five Consulting—a company devoted to the application of computer technology to solve environmental problems. He has over 30 years experience in research involving physics and risk assessment, with a broad background in nuclear physics, health physics, toxicology, uncertainty analysis, and risk management. He was a faculty member at the University of Basel, Switzerland where he conducted research in nuclear physics, including: experimental and theoretical studies reactions between light nuclei (fusion reaction) and studies on neutron interactions; neutron activation analysis; prompt gamma measurements; and similar topics. In addition, he accepted an appointment as Staff Officer for Nuclear-Biological-Chemical (NBC) Warfare Defense on the Swiss Army Command. In this capacity, he assessed and minimized NBC risks to military and civilian populations. Subsequently, he assumed an additional appointment as Commanding Officer of the Swiss Army's 37 radiation laboratories coordinating sampling; data collection; risk evaluation; and risk management. Subsequent to immigration to the United States, Fritz Seiler joined the Lovelace Inhalation Toxicology Research Institute. In that capacity, he was involved in risk assessment of chemical and radiological agents, cost-risk-benefit analysis emphasizing economics, and uncertainty analysis. He was also involved in the study of nuclear radiation dosimetry; environmental dispersion; chemical and radiological materials transport; and new sampling methods. He

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