RESPONSE TO:

REQUIREMENTS FOR DOL AGENCIES' ASSESSMENT OF OCCUPATIONAL HEALTH RISKS

Notice Of Proposed Rulemaking: 29 CFR Part 2

RIN 1290-AA23

Prepared

by

RISK ANALYSIS CENTER

Potomac Institute for Policy Studies
Arlington, VA

Institute for Regulatory Science
Alexandria, VA

September 26, 2008

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 (moghissi@nars.org)
Dennis K. Mc Bride, Vice Chair (dmcbride@potomacinstitute.org)
Betty R. Love
Lawrence Barnthouse
Paolo F. Ricci
Fritz A. Seiler
Sorin R. Straja

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 proposed Risk Assessment Guide of the U.S. Department of Labor (DOL) addresses general requirements for performing risk assessment in response to a chain of events. It is structured in the tradition of risk assessment going back to the report of the National Research Council (NRC 1984) that identified the respective roles of risk assessment and risk management. Recognizing the importance of risk assessment in the regulatory process, the Office of Management and Budget (OMB 1995) provided general guidelines on various aspects of the risk. Recognizing the significance of risk assessment in the regulatory process, the OMB provided a draft bulletin (OMB 2005) substantially expanding the scope of its 1995 guidance. The Bulletin was subsequently revised and published (OMB 2006). This latter document was peer-reviewed by the National Research Council (NRC 2007). Based on recommendations of the NRC, the Bulletin was withdrawn and replaced by a general guidance (OMB 2007) outlining general principles of risk analysis.

In addition to the items described above, there are two potential legal mandates that are applicable to the DOL decision:

1. In 1980, the Supreme Court of the U.S (SCUS 1980) reversed a decision of the Occupational Safety and Health Administration (OSHA) that had reduced the Permissible Exposure Limit (PEL) of benzene from 10 ppm to 1 ppm. As discussed later in this response, that decision interpreted the legal authority of DOL in risk analysis. This decision is still valid and sets the stage for risk-based decisions by the DOL.

2. The OMB general guidance and its implementation by the DOL require compliance with certain sections of the Safe Drinking Water Act (SDWA 1996). That law mandates that "The Administrator shall, in a document made top the public in support of a regulation promulgated under this section, specify, to the extent practicable:

(i) each population addressed by any estimate of public health effects;
(ii) the expected risk or central estimate of risk for the specific populations;
(iii) each appropriate upper and lower bound estimate of risk; and
(iv) peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data."

IDENTIFICATION AND DISCUSSION OF RELEVANT ISSUES

Although the announcement of the DOL largely identifies and addresses relevant issues, the RAC members decided that it might be advantageous to discuss each issue.

Terminology

There appears to be confusion on certain terms used in risk analysis. In its 1995 memorandum, the OMB stated that it dealt with "policy on risk assessment, management and Communication. The principles are designed to define risk analysis, and to generally guide agencies as they use risk analysis in the regulatory context." This statement implies that risk analysis includes risk assessment, risk management, and risk communication. Shortly thereafter, in February 1996, the American Association of Engineering Societies (AAES 1996) reaffirmed this definition and provided some details on various aspects of these three components of risk analysis. Therefore,

risk analysis may not be used as if it were synonymous with risk assessment. It is essential to ensure that the terminology in unambiguous for scientific, legal and policy reasons.

Principles of Risk Assessment

The DOL has correctly identified the three principles of risk analysis, as defined above. All three components of risk analysis require transparency. Similarly, they also require consistency, although consistency in risk management requires some level of flexibility. Due to the place of risk assessment in the risk management process, the principle of reliability applies primarily to risk assessment.

Elements of Risk Assessment

The DOL announcement correctly identified the four elements of risk assessment as:

1. Hazard identification
2. Dose-response assessment
3. Exposure assessment
4. Risk characterization

Hazard Identification: The DOL correctly identifies hazard identification as whether a substance or a chemical is a health hazard. In addition, the DOL accepts the notion that an "event" or a practice may also require hazard identification.

Dose-Response Assessment: Again here, the DOL correctly describes the process. However, the DOL appears to confuse the respective roles of risk assessment and risk management (see under *Analysis of Uncertainty and Variability*).

Exposure Assessment: The DOL is correct to suggest that measurements of workplace exposures should be used in assessing the risk. However, the results of dose-response function should also be evaluated in the characterization process.

Risk Characterization: Again, the process described by DOL is consistent with commonly used practices.

Best Available Evidence

Much of the scientific foundation of the proposal is included in the section with the above title. Section C. "Best Available Evidence: DOL's Internal Guidance in Information Quality" subsection (a) discusses "Best available peer-reviewed science and supporting studies conducted in accordance with sound objective scientific practices". We urge the DOL to use "Best available scientific information and supporting studies conducted in accordance with sound objective scientific practices" As Attachment II to this response indicates, the term "Best Available Science" or BAS implies certain practices that go far beyond the intention of this section.

Section b (ii) of the same section raises questions related to consistency with the BAS concept. Unless testimony of individuals is based on peer-reviewed information, care is required to ensure the reliability of information provided by these individuals.

As the section *Analysis of Uncertainty and Variability* indicates, we are strongly endorsing the practice described under part 2 of this section.

Analysis of Uncertainty and Variability

The Risk Assessment Bulletin of OMB (2006) required that characterized risk would provide central estimate of risk along with high ends and low ends of the risk. The report of the NRC (2007) was extremely critical of the OMB approach by asking "central estimates of what?" The NRC correctly identified two sets of distribution consisting of uncertainty and variability. Let us discuss each separately.

Uncertainty: Uncertainty is based on lack of knowledge. The knowledge on the true model of a dose response is limited and often conjectural. However, the rule that generally governs uncertainty indicates that the more available data, the less the uncertainty. There are appropriate models that are applicable to animal-to-human and high-dose to low-dose extrapolations including models that are applicable to a large number of animal species. Consequently, all applicable animal data should be used. Those who claim that it would be difficult to obtain values other than the upper limit overlook the fact that uncertainty analysis provides central point as it does the upper or lower levels.

Variability: In contrast to uncertainty, variability is an inherent property of a system under consideration. In an occupational setting, the ventilation rates of a factory, a mine, or a laboratory are measurable and potentially known. However, they vary from place to place. Therefore, establishing a central, an upper, and a lower value would not necessarily accommodate the need of a risk manager. We do not argue that the variability should not be assessed. Instead, we contend that both the legal system and the voluntary process have recognized the problem of variability, and have remedied it by using safety factors. A very large number of regulatory decisions use a safety factor such as 10 in numerous standards to accommodate the variability.

Mixing Uncertainty and Variability: We share the view of the NRC (2007) that mixing variability and uncertainty leads to confusion. Often the statistical upper bound becomes so high that it loses any relationship to reality. Consequently, the statistical evaluation of data should rely upon uncertainty and use safety factors to accommodate variability.

Risk Assessment vs. Risk Management

In its announcement, the DOL references the Supreme Court in implying that risk assessment may use conservative assumptions. According to the Supreme Court "Thus, so long as they are supported by a body of reputable scientific thought, the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than under protection." This statement does not imply that the conservative assumptions are to be made in risk assessment. The statement could be easily applied to risk management.

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

The neutrality in this definition suggests that risk Assessment must be scientifically objective, neither minimizing nor exaggerating the nature and magnitude of risk. The mixing of the functions of risk assessment and risk management does not necessarily improve the interaction between risk assessors and risk mangers. What is being overlooked is 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.

We do not advocate that conservative assumptions should not be used in the regulatory decision process. It is imperative that the regulatory process use appropriate assumptions in protecting the workers and the general public. However, the determination of the level of safety or an acceptable risk is not a scientific process. If that were the case, there would be no need for OSHA, Mine Safety and Health Administration (MSHA), the Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and other regulatory agencies. One would set up scientific panels that would decide the level of safety. The legal system, at least in the U.S., has recognized that determination of level of safety or acceptable risk is not the domain of the science. Consequently, there are numerous legal mandates including those quoted in the DOL announcement that clearly and unambiguously assign that responsibility to the regulatory agencies including OSHA and MSHA in DOL as well as EPA, FDA, and many other regulatory agencies.

OPPOSITION TO THE DOL ANNOUNCEMENT

We have observed with a great deal of interest the opposition to the DOL announcement. This opposition can be categorized into three groups as follows:

1. Those who were concerned that the document was not made available to the public prior to its publication.
2. Those who are inherently opposed to "sound science" peer review and have repeatedly argued that regulatory processes are more appropriately decided by stakeholders.
3. Those who sought for extension of the deadline to have time for a thorough evaluation of the issues included in the announcement.

The RAC disagrees with the first two groups. It is imperative that societal decisions are based on BAS. We recognize the shortcomings of risk assessment and its inherent uncertainties. However, much like the democratic system of government, there is no other acceptable process to respond to societal needs.

We recognize that certain groups, including exceptionally relevant and distinguished organizations, need additional time to thoroughly evaluate such a complex subject. In our case, the RAC has dealt thoroughly with issues addressed in the DOL announcement since its inception and thus was able to meet the required deadline.

CONCLUSIONS

The DOL announcement 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 certain societal decisions. We urge the DOL to apply principles of BAS, including the rules

governing the risk analysis process. In particular, the use of BAS and elimination of societal objectives from the scientific foundation of risk assessment would be the prerequisite of sound occupational protection.

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ATTACHMENT I

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. Reliability of scientific information
2. Classification of scientific information
3. Areas outside the purview of science

1. ASSESSMENT OF THE RELIABILITY OF SCIENTIFIC INFORMATION

In the BAS concept, scientific information is divided into several distinct categories in ascending level of reliability as follows:

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.

Group 2 - Gray Literature

Written information prepared by government agencies, advocacy groups, and others that have not been subjected to an independent peer review is included in this category. This category often consists of an organized and written form of personal opinions.

Group 3 - Peer-Reviewed Science

Information subjected to an independent peer review constitutes this category. The peer review is the only mechanism to assess the validity of a scientific claim. Consequently, peer review remains the foundation of scientific acceptability. There is a voluminous amount of literature describing the peer review process. Note that at least three peers must review a study to qualify as peer-reviewed.

There are three criteria for the acceptability of the peer review process: 1) the peer reviewer must be qualified; 2) the reviewer must be independent as demonstrated by the lack of conflict of interest; and 3) the process must be transparent.

Group 4 - Consensus-Processed Science

This category consists of information resulting from a process used to resolve scientific disputes, particularly those in contested areas of science. The prerequisite for this process is the formation of a group of individuals to reach a consensus on a specific scientific subject. Members of this group must meet the qualifications and independency criteria described for peer review.

2. CLASSIFICATION OF SCIENTIFIC INFORMATION

Based upon the identified need, we developed a classification for the assessment of the level of maturity of scientific information. The final outcome of our process identified the following classes:

Class I – Proven Science

This class is the equivalent to scientific laws in the classical process. In the BAS system, it consists of scientific laws—sometimes called scientific principles—and their application.

Class IA - Confirmed Science: Scientific laws and all other information that have been unequivocally confirmed and are generally accepted constitute Class IA. We recognize that each scientific law or scientific fact has its limitations and conditions for its validity.

Class IB - Applied Science: This class consists of application of scientific laws to various branches of commerce and industry. The only prerequisite for information to be placed into this class is the correct interpretation of scientific laws. Much of the Engineering disciplines and a large segment of other applied sciences fall into this class.

Class IC – Virtually Proven Science: This class consists of information whose reliability has been uncontested, yet there is insufficient proof to be placed in the proven science class.

Class II – Evolving Science

This class has no counterpart in the classical process. The overwhelming scientific advances in virtually all disciplines are evolving science.

Class IIA – Reproducible Evolving Science: Reliable information dealing with a subject that is not completely understood constitutes the core of this class. The key factor in placing information into this category is reproducibility. An example of this class includes a large part of medical information.

Class IIB – Rationalized Science: The scientific foundation of information placed in this class is derived from proven or reproducible evolving science. However, it uses assumptions, extrapolations, and numerous similar processes in deriving its results and conclusions. In order to reproduce information in this class, the investigator must have not only proper skills and the necessary equipment, but must also accept the asserted scientific foundation, assumptions, choice of mathematical processes, default data, and numerous other prerequisites. Risk assessment, many predictive models, and a large segment of contested scientific information fall into this class.

Class III – Borderline Science

As the title implies, this class is not necessarily science. The closest part in the classical process to this class is hypothesis.

Class IIIA - Scientific Judgment: On occasion, information is provided to the society that lacks scientific foundation. Similarly, often decisions must be made without having the needed scientific information including basic principles, the necessary data, and other scientific requirements. The methodology for expert judgment is reasonably well developed and consists of asking a number of presumably knowledgeable individuals to give answers to specific questions and statistically assess the results. However, this class is often an educated guess.

Class IIIB - Speculation: This class consists of information that cannot meet standards described in any of the above classes. It is often based on the intuition of an individual who wants to stimulate a discussion or initiate a research project.

Fallacious Information

This class of information falls clearly into the purview of science but is inconsistent with the three classes identified above. Those who desire to promote specific political, ideological, or other goals disseminate some of the information in this class. Their opponents often call this information "pseudo science", "junk science", or "politically-processed science". Often the dissemination of fallacious information is justified on the basis that it is necessary to exaggerate a problem in order to move the population to accomplish a noble goal. What is being overlooked is the long-term damage that misinformation causes.

AREAS OUTSIDE THE PURVIEW OF SCIENCE

The concept of BAS deals with classification of scientific information and evaluation of scientific assertions. It specifically excludes areas that are outside of science. Although the areas that are outside the purview of science are extremely large, for the sake of simplicity these are placed into two categories:

Faith

Faith is based on a belief of individuals or a group of individuals. It deals with areas that science cannot address. One of the key characteristics of faith is the inability of science to prove or disprove various assertions of faith. How can science prove the existence or the lack of existence of God; or a world beyond the physical world; or the interaction between God and an individual?

Societal Goals

The inclusion of ideology, beliefs, or any other non-scientific objectives in assessing the validity of scientific information is inconsistent with the foundation of BAS. There is ample evidence indicating that the intrusion of societal objectives in the scientific process 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. However, the initiation or continuation of scientific activities is based on a societal objective that is the domain of elected and appointed officials of the government.

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

and panels. He is a member of a number of professional societies including the American Society of Mechanical Engineers and is past chair of its Environmental Engineering Division. He is also an academic councilor of the Russian Academy of Engineering. Alan Moghissi received his education at the University of Zurich, Switzerland, and Technical University of Karlsruhe in Germany, where he received a doctorate degree in physical chemistry.

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

performed a wide variety of measurements, data evaluation, and statistics, as well as theoretical modeling and systems simulation. Later, he joined IT corporation and continued and expanded his previous activities. For a one-year period, Dr. Seiler was a Vice President with the Institute for Regulatory ScienceCa not-for-profit organization involved with the application of best available science, including peer review to societal decisions. Dr. Seiler is Fellow of the American Physical Society and has been designated Distinguished Technical Associate of IT Corporation. He is a member of the Society of Risk Analysis; the Health Physics Society; the American Nuclear Society, (Member of NCRP Liaison Committee); and the American National Standards Institute. He has published more than 120 scientific papers in the areas of physics, risk assessment, and risk management. Fritz Seiler received a Baccalaureate in Economics from the Basel School of Economics, and a Ph.D. in Physics from the University of Basel, Switzerland.

Sorin R. Straja is currently Vice President for Science and Technology of the Institute for Regulatory Science. He has over 25 years of expertise in mathematical modeling and software development as applied in chemical engineering and risk assessment. Previously he served as Assistant Professor of Biostatistics with Temple University, Philadelphia; as Director of the Department of Occupational Health and Safety of Temple University, Philadelphia; and as a chemist with University of Maryland at Baltimore. Sorin Straja has extensive experience in the chemical industry where he worked as a senior R&D consultant with the Chemical and Biochemical Energetics Institute, and as a plant manager with Chemicals Enterprise Dudesti and Plastics Processing Bucharest from Romania. He was an Assistant/Adjunct Professor of Chemical Engineering with the Polytechnic Institute Bucharest. Sorin Straja is the co-author of three books and over 50 scientific papers published in internationally recognized and peer-reviewed journals. He was an editor of *Environment International,* and currently is a contributing editor of *Technology*. Sorin Straja received a Certificate of Appreciation for Teaching from Temple University, the "Nicolae Teclu" Prize of the Romanian Academy, and a Certificate of Appreciation from U.S. Department of Agriculture for significant volunteer contributions. He is a Fellow of the Global Association of Risk Professionals, and a member of the American Chemical Society and of the American Institute of Chemical Engineers. Sorin Straja holds a M.S. in Industrial Chemistry and a Ph.D. in Chemical Engineering both from Polytechnic Institute Bucharest.