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THE HANDLING OF RISK ASSESSMENTS IN NRC REPORTS

A Report to the Governing Board
National Research Council

by the

Governing Board Committee on the Assessment of Risk

March 1981

Notice: The activity that was the subject of this report was an internal review of procedures and practices applicable to the conduct of NRC studies involving risk and risk assessment. As such, this report was not reviewed by an independent group and is not intended for public distribution or comment.

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CONTENTS

Tables

Appendices

PREFACE

In the summer of 1979, the Governing Board called for a study of the NRC's experience in conducting assessments of risk and established a committee for the purpose. Risk assessment as its practice has evolved is a rubric covering a broad range of analytic activities including: the identification of hazard, the estimation of probabilities of occurrence of hazardous events of specified magnitude, the linkage of such events with various undesirable health, safety, environmental and other societal consequences, and the evaluation of risks by comparison with costs, with other risks, with benefits, with alternative ways of reducing risks, or with the risk of substitute activities. A complete risk assessment would involve most or all of these elements.

The committee met four times: in October 1979, in April and July 1980, and in February 1981. The committee was asked to survey the extent and content of recent NRC risk assessment activity, to identify generic problems in their conduct and presentation, and to suggest ways to improve the performance and presentation of the results of studies involving risk assessments. The committee did not evaluate the worth of past NRC studies nor did it seek to prescribe risk assessment methodologies.

In assembling the committee and its staff considerable effort was expended in bringing together three types of experience: leadership in Assemblies or Commissions in formulating charges and choosing committees; chairmanship of major risk assessment studies; and professional experience in some aspect of risk assessment. In addition it was desired that most committee members be members of the NAS, NAE or IOM, as part of the committment of their membership to provide oversight and review of the work of the NRC. As the committee was assembled it was recognized that additional perspectives from other areas of experience, e.g., law and insurance, would be desirable and these were added.

Of the 11 members of this committee 9 are members of the NAS, NAE and/or IOM. One is president of the IOM, another has served on the Governing Board, three have been chairmen of Assemblies or Commissions, and most have chaired important NRC committees that dealt with questions of risk. Disciplines represented on the committee include the natural and social sciences, economics, engineering, medicine, history of science, and law. Almost all members have experience in risk assessment in at least one important area of concern, e.g., air pollution, energy, food and drugs; and many are expert in the methodologies of risk assessment. In addition the committee had available the experience of the NRC's Committee on Risk and Decision Making the chairman of which, Howard Raiffa, served as a member of this committee as well.

The committee also benefited from the invaluable contribution of staff members Roy Widdus and Robert S. Chen, who organized and assembled the data and report samples, conducted much of the detailed analysis, and assisted in the drafting of this report. Both deal with risk issues in their regular NRC

staff activities. A number of members of the NRC senior staff were encouraged to attend the committee's meetings and otherwise keep abreast of its deliberations. Several Assembly and Commission Executive Directors, and the Director of the Office of Information, Howard Lewis, attended some of our meetings and made welcome contributions to our deliberations, as did Raphael Kasper and Micah Naftalin who, successively, served as staff director to the committee. The Executive Directors of Assemblies and Commissions or their deputies, and several committee staff officers, reviewed a draft of the report and met with members of the committee in February 1981 to discuss the recommendations of the report and approaches to their possible implementation. We owe special thanks to the Assembly of Life Sciences (ALS) and Assembly of Mathematical and Physical Sciences (AMPS), respectively, for making possible the contributions of Widdus and Chen.

Robert W. Kates, Chairman

INTRODUCTION

In the past five years, the NRC has been issuing reports at the rate of approximately 250 per year. Of that number, nearly one-half address topics in which risk plays a part, and one report in every five--upwards of 50 a year--involves the performance of an actual estimation or evaluation of one or more elements of risk.[1] The handling of issues involving risk is thus a very significant aspect of the Research Council's work. Indeed, considering the reputation for authority enjoyed by the Academy and the wide range of hazards that it addresses, it is clear that the NRC is a major and influential assessor of risk in the United States.

Questions referred to the NRC typically have appeared intractable to the modes of analysis applied to them prior to their referral. Risk assessments, in particular, lie at the frontiers of method where no general agreement as to approaches exists. To avoid artificial consensus a diversity of approaches is inescapable at this time. This situation, however, obliges the NRC to appraise continually the diverse approaches to risk assessment as a means of improving the quality of future studies.

Studies addressing well known risks to human health and the environment are naturally subject to high public interest, scrutiny and, often, controversy. This is especially so given the usually wide range of uncertainty surrounding the findings due to lack of data, limitations or ranges of error intrinsic to models or procedures, and/or the incompleteness of such models or analyses. It thus follows that the NRC's reputation for credibility and probity can be significantly affected by the ways in which it addresses questions involving risk.

In view of the NRC's prominent role, the Governing Board felt that thorough evaluation of the NRC's risk assessment activities was needed. We chose to use as a data base the reports issued by the NRC in the years 1974 to early 1979--1,377 in all. We made a preliminary analysis of a randomly selected 20 percent sample (273 reports, including 63 (23%) Transportation Research Board (TRB) reports), and a more detailed review of 20 reports chosen

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[1]Although the risk associated with actions and policies is a concept that plays an important role in evaluating decisions, no agreed upon definition of it exists. Most of us use the word "risk" in an informal way, counting on the context to suggest our meaning (see, for example, any NRC report in which the word is used or almost any issue of the New York Times). Common usage makes clear that risk has something to do both with the magnitude or severity and the likelihood of untoward consequences, but exactly how the nature of the evil and its probability distribution are to be quantified and combined is not yet agreed upon by students of decision making. In some cases risk refers to a very small probability of a very disastrous event, such as an accidental nuclear explosion or a major earthquake in a metropolitan area. In other cases, it refers to a relatively high probability of a fairly minor event, from the society's viewpoint, but which is catastrophic to single individuals, such as the increased cancer deaths due to some small increment in background radiation. In still other cases it refers to major financial losses, such as that of a house to an individual or a billion dollars to Chrysler. Sometimes risk concerns isolated events; other times, it refers to highly repetitious events in which case the risk of each occasion is far different from the cumulative risk.

from among the major risk assessments. The review of the sample indicates that nearly one-half (49%) of all NRC reports address topics in which risk plays a part (41% if TRB reports are excluded).[1] Approximately one in every five reports involves the actual performance of some element(s) of risk assessment--either estimates of hazardous events or harmful consequences, the comparison of these with other risks, costs or benefits, and alternative ways of reducing risks. The balance of the studies and their reports included in the 49% involved a risk-related topic but did not do a risk estimation or assessment. Appendix A lists some of the variety of topics with which risk assessments or risk related reports from the NRC have dealt. They include air quality, antibiotics, abortion, dams, germplasm resources, grizzly bears, radiation, radioactive wastes, vibration and voice identification.

In order to get a sense of the variety of risk assessments undertaken in the Research Council, we examined in some detail six exemplars: on ionizing radiation, safe drinking water, pesticide information, halocarbons, saccharin, and risks of nuclear power. We did this, in the first two meetings, based largely on staff-prepared excerpts, briefings by participants in the respective studies, and by reviewing the respective report summaries and extracts. Moreover, the staff prepared a profile of each of the reports in the broader random sample according to a set of questions developed by the committee, e.g., was risk involved in the study and was an element of risk assessment undertaken; were hazards to humans, animals, the biosphere and/or the socio-economic system identified and, if so, by some organized technique such as modeling, monitoring or screening; were uncertainties explicitly discussed; were risks compared to other risks, to benefits, to costs? The questionnaire is provided as Appendix B.

Early in our deliberations, we anticipated that certain generic issues, i.e., characteristics common to studies of risks, might usefully be identified and that we might wish to draw some inferences about them. Examples of such generic issues ranged from matters of committee organization--e.g., did the charge to or makeup of the committee influence the result in predictable or unforeseen ways--to the use of a variety of methods of analysis, including regression analysis, decision analysis, risk or cost-benefit analysis, and various approaches to the problem of extrapolation, e.g., from animal data to humans, or from models to physical processes.

Another kind of issue that we anticipated might be of concern involved matters affecting the presentation of the findings of a study in its report. Did the study committee's procedures for deliberating encourage the widest possible use of the respective expertise and specialties resident in the study committee membership and, if so, how well did its report reflect or handle the balance between the needs of quantitative and qualitative analysis and findings, and how well, i.e., how explicitly, did the report alert the reader to the degree and character of uncertainty. The results of this review are reflected later in this report.

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[1]Unless otherwise noted all further statistics quoted on the risk assessments identified in the random sample excludes TRB.

STUDY METHODS

Survey of the Treatment of Risk in NRC Studies: 1974-1979

In order to make a statistically valid assessment of the frequency with which NRC studies have involved risk, the staff attempted to ascertain the total output of the Academy complex in the period 1974-1979. This turned out to be extremely difficult. However, the most complete list is that maintained by the library which includes:

- Major reports generated by committees
- Proceedings of conferences
- Authored research or position papers, e.g., from the Academy Forum, Transportation Research Board, Institute of Medicine
- Reports of visits, e.g., to China or to evaluate a natural disaster
- Letter reports (from committees or individuals)
- Articles published in professional journals, e.g., from the Medical Follow-Up Agency, Assembly of Life Sciences
- Reports of research conducted under international programs.

Notifying the library of the issuance of a document, and thus its inclusion in the library's list, is dependent upon action by the staff officer responsible for the report. No certainty exists that the library is informed of all documents, letter reports, etc. that are produced. In theory all reports containing evaluative judgments will pass through the Report Review Committee (RRC) and the offices of the NRC Senior Editor and the NRC Reports Offices. However, no permanent listing of such reports is kept by these offices. Thus, the committee found it difficult to be sure of the total output of documents during the period under study.

The staff screened the library's list of documents produced from 1974-1979 to eliminate the nonevaluative ones such as brochures, directories, translations, and periodic administrative reports. From the remaining 1,377, a sample of 273 documents (20%) was selected randomly for further study. All 273 reports were reviewed and those containing some aspect of risk assessment were further examined. A questionnaire (Appendix B) designed by the committee for its own use was applied to these reports. The frequency with which particular facets of or approaches to risk assessment occurred in these reports was calculated (also given in Appendix B). The percentages derived from the sample should approximate the actual proportions in the entire set of 1,377 documents from 1974-1979 (plus or minus 3% at the 95% confidence level).

Examination of Selected "Major" Studies Involving Risk

Using the list of 1,377 documents from 1974-1979, the staff examined those which from their titles could be construed as dealing with risk. Evaluative reports generated by a committee, which devoted a substantial proportion of their contents to risk assessment, were listed as "major risk assessments." The directors of Assemblies and Commissions were asked to nominate the major risk assessments from their divisions in the period under study. Using their suggestions and with further examination of the reports on the list of major risk assessments, 20 reports were chosen for detailed study. The selection of the 20 reports was made to parallel the distribution of risk assessment studies among the respective sections of the NRC. Additionally, an attempt was made to match topics so that the treatment of a similar topic by more than

one NRC division could be compared. Most of the other major reports were examined cursorily for the manner in which they treated particular issues. The staff then prepared a paper for the committee illustrating the variety of ways in which NRC reports treat facets of risk assessment. In all, approximately one-half of the reports dealing with risk in the covered period received some level of examination by the committee and/or its staff.

The questionnaire previously applied to the random sample of reports, and a new set of questions (Appendix C), arising out of the committee's subsequent deliberations, were applied to the 20 major risk assessments and the results discussed by the committee.

Questionnaires applied to reports were intended to test as methodically as practicable certain hypotheses that evolved from the committee's review of the case studies at its first two meetings. The coding of answers to the questions for each report was validated by the use of parallel, independent evaluations.

Case Studies

At its first two meetings, the committee met with the staff officers and some committee members from certain significant recent NRC risk assessments and discussed with them the conduct and outcome of the studies with which they had been involved. The committee thus studied the NRC activity leading to the following reports: The Biological Effects of Ionizing Radiation (ALS); Drinking Water and Health (ALS); An Evaluation of the Carcinogenicity of Chlordane and Heptachlor (ALS); Saccharin: A Technical Assessment of Risks and Benefits (ALS) and Food Safety Policy (IOM); and Risks Associated with Nuclear Power (COSPUP).

Using the three sources of information described above--the reports identified in the random sample, the selected 20 major risk assessments, and the case studies--it is possible to describe the risk assessment process in the NRC.

FINDINGS, CONCLUSIONS, AND RECOMMENDATIONS

General Findings

Studies that the National Research Council undertakes that address risk issues typically involve ambiguity in the definition of the hazard, or paucity of data, or controversy as to physical, biological and social processes. Were it not so the agencies would not need to request NRC judgment. Given these circumstances, the NRC commonly addresses questions that are difficult to answer or appear intractable and for which the modes of analysis are not well established.

We note that the risk assessment reports often are on the frontiers of method and experiment with new concepts. There is no general agreement among them as to approaches. This diversity is healthy in the face of ill-defined and rapidly changing thinking about risk assessment. It should be encouraged. However, it also places a special obligation upon the NRC as a whole to appraise the various efforts and to draw from them whatever lessons may benefit the next studies.

The statistical findings of the screening of the random sample are included in Appendix B. The distribution of risk assessments between

Assemblies and Commissions is shown below in column B of Table 1, reflecting that the Assembly of Life Sciences, Commission on Sociotechnical Systems/ Transportation Research Board, and the Commission on Natural Resources are the NRC units most involved with risk assessment.

TABLE 1
Risk Assessment by NRC Unit

Origin of Report	A % of Random Sample (273 Reports)	B % of Identified Risk Assessment Reports in Random Sample (59 Reports)	C % of Risk Related Reports in Random Sample Not Doing a Risk Assessment (75 reports)	D % of NRC Units' Reports Involving a Risk (B and C)*
Assembly of Behavioral and Social Sciences	2.2	1.7	2.6	50
Assembly of Engineering	5.8	—	9.3	46
Assembly of Life Sciences	16.3	34.0	13.3	69
Assembly of Mathematical and Physical Sciences	18.3	8.5	5.3	18
Commission on Human Resources	2.6	—	—	—
Commission on International Relations	6.2	1.7	4.0	24
Commission on Natural Resources	6.8	14.4	—	46
Commission on Sociotechnical Systems (CSS)	9.9	3.4	17.3	56
CSS/Transportation Research Board	23.0	31.0	41.3	76
Institute of Medicine	3.3	—	2.6	22
National Academy of Engineering	4.0	5.1	2.6	45
National Academy of Sciences	1.5	—	1.3	25

*Care should be taken in interpretating some of these values because percentages are based on small sample sizes, e.g., ABASS had 6 reports in the random sample.

Generic Issues

The Scope and Extent of the Study: Its Relationship to the Charge

Almost all NRC risk assessment studies deal only with a specific aspect of a problem involving risk, rarely entirely appraising a risk, but rather consisting of only one or a few components of a complete appraisal. The frequency with which reports contain some component of a risk assessment or deal with a topic involving risk is shown in Table 2. Sixty-three of the 273 reports in the random sample were TRB reports of which 49 fell into categories A and B of Table 2. TRB reports were judged to be a particular type of risk report. We chose to use the 41 reports identified as risk assessments in the random sample not coming from TRB as the basis of subsequent calculations of the frequency of various facets or techniques of risk assessment.

TABLE 2
Involvement of Risk in NRC Studies

Total Reports Examined	210* (273)
A. Reports doing some part of a risk assessment	20% (22%)
B. Reports dealing with a topic involving risk not included in category A	21% (27%)
C. Reports on topics not involving risk	59% (51%)

*Numbers in parentheses include TRB reports.

Of reports in categories A and B of Table 2, nearly 90% had some explicit or implicit constraint on their scope. Often this was that the charge did not specifically call for a risk assessment but was related to a

specific technological or managerial question. Such restrictions on the scope of a study are rarely given prominence or discussed: most reports merely reiterate the charge to the committee in their preface. Similarly, renegotiation of the charge to a committee rarely occurs.

The surveys and screenings highlighted the fact that NRC committees are rarely called upon for full risk assessments. Only a few examples could be found in which such assessments were requested, e.g., Saccharin: A Technical Assessment of Risks and Benefits (ALS); Risks and Benefits of Recombinant DNA Research (ALS); Considerations of Benefit/Cost Analysis for Activities Involving Ionizing Radiation Exposure (ALS).

We had anticipated a consistent tendency to broaden or narrow the scope of a study in comparison to its contracted charge, a change that might affect the reception of the report. The study of the 20 major risk reports revealed a trend for reports to narrow the focus of their deliberations more often than broadening them, but this was not a marked tendency. Typically reports would focus upon what they judged to be the critical questions within the scope of the charge.

Analysis of the randomly selected sample of reports for each of the years 1974-1979 did not reveal any striking trend in the proportion of studies dealing with risk (Table 3). It is worth noting, however, that in the 1955-65 period the proportion of reports involving risk was below 20 percent. By 1970, this had risen to 26 percent. As Table 3 reflects, the proportion had doubled, to approximately 50 percent, by the mid-1970's.

TABLE 3
Involvement of Risk in NRC Studies by Year
(20% Sample)

Year	Number of Reports	Percentage		
		Contains Part of a Risk Assessment	Report Topic is Risk Related but no Risk Assessment was done	Topic is not Risk Related
1974	48	29%	27%	44%
1975	43	23	26	51
1976	67	22	32	46
1977	53	17	30	53
1978	47	17	19	64
1979*	15	20	27	53
Total	273	22	27	51

*Not all reports issued in 1979 were available at the time of the survey.

The fact that almost all NRC studies are narrow in scope is not in itself an issue. Possibly committees function best both scientifically and in timely fashion when the required judgment or analysis is quite specific and the committee's charge is narrowly drawn. Also, narrowing the concern may promote the comfort of committee members. But narrowness can also defeat the purpose of the study--to contribute to understanding a risk--and is, in any case, a frequent source of misunderstanding. Such reports are likely to be read as aspiring to achieve an overall assessment or as implying that other key

aspects of the risk or total problem are unimportant or inconsequential, e.g., The Long-Term Worldwide Effects of Multiple Nuclear Weapons Detonations (AMPS); The Effects of Herbicides on South Vietnam (ALS).

The committee suggests, therefore, that reports of all risk assessment studies include a clear prefatory statement delineating the scope and limitations of the report. For instance, it should orient the reader by describing what a complete risk assessment on the subject at hand would consist of, and why the NRC and/or the committee chose to address the specific aspect being reported on. Moreover, it should indicate, where possible, what other parallel activity or literature (inside or outside the NAS) address the other assessment components.

Committee Selection and Membership

There is no formal mechanism within the Research Council whereby studies on topics involving risk, risk estimation or risk assessment are identified as such at their outset. Thus, nominations for committees to study topics involving risk are normally subjected only to the same degree of scrutiny as those for other committees; no special treatment is accorded such studies to check if the committee experience is appropriate. Our early discussions identified instances where the relevant experience for some aspect of a risk assessment contained in a report was not obviously present on the committee that produced it.

To investigate this further a group of 5 simple tests matching the risk assessment content of the report to the apparent experience of committee members was applied to the 20 major risk assessments. Table 4 illustrates the results of the test. Some mismatches are apparent.

The results presented in Table 4 must be viewed in the light of the fact that incomplete information was available to the committee in some cases and that individuals with experience in risk analysis may be primarily regarded as authorities in other specialties. This is exacerbated for the public by the usual practice of only identifying organizational affiliations for committee members. However, unquestionable deficiencies in areas of committee expertise were apparent in certain studies.

An important justification for NRC activities rests on its ability to bring highly capable scientific talent to bear on consideration of scientific questions. The validity and credibility of NRC risk assessments (as with other studies) thus rests on the credentials of the committee members as scientists qualified to make fair, balanced, and, above all, expert judgments on the scientific aspects of the risk being assessed. This, of course, is well recognized in the NRC and much formal effort is devoted to identifying and selecting the best possible committee. It is disturbing therefore that we identified some deficiencies. We think the defect must lie in the initial committee selection process as we examined and rejected the hypothesis that the mismatch arises from a committee that is initially matched to the charge but then expands beyond it without adding the requisite expertise.

Remedies for the apparent mismatching seem readily available. It should be possible to design a simple check list (based on questions similar to those in Table 4) that can be used during the selection process as a reminder of the need to match the probable risk assessment components of a study to experience.

TABLE 4
Committee Experience and Report Content: 20 Major Risk Assessment Reports
(Asterisk* denotes potential mismatch problem)a

Does the Report:	Does the Committee include:	
Conduct or reject extrapolation of animal data to humans	Toxicologists or Biomathematicians	
	Yes	No
Yes	11	2*b
No	2	5
Assess human health hazard	Epidemiologist(s)	
	Yes	No
Yes	6	8*
No	0	6
Compare assessed risk to other risks	Professional experience in risk analysis	
	Yes	No
Yes	3	2*
No	2	13
	Experience in economic analysis, psychology or health care	
Discuss benefits	Yes	No
Yes	5	1*
No	2	12
	Experience in the analysis of risk perceptions or psychology	
Discuss public perception or acceptability of the risk	Yes	No
Yes	4	1*
No	5	10

[a] The absence of particular experience from a committee may also play a role in omissions from a report: this series of questions dealing with report content does not address this issue which would require a comparison of the committee's composition to the charge to the committee.

[b] These mismatches were due to lack of biomathematicians on the committee.

To respond to the need to provide evidence that a committee has been well selected to fulfill its charge, in particular, to deal in a satisfactory way with risk assessment, we recommend that the Assembly or Commission that created the committee include in a preface to the report: (1) A complete statement or accurate summary of the charge to the committee. (2) A description of the various intellectual considerations that went into the design of the committee, indicating the range of competencies required and the nature of the balance in viewpoints and concerns that was attempted, the types of additional experience provided by formal consultants to the committee, and (when appropriate) the reasons for what may be considered by some critics or commentators to be significant omissions in its composition. (3) A brief description of the relevant background, experience, and research activity of each member of and major consultant to the committee. We do not recommend that an explicit account be provided of how the particular membership actually fulfills the criteria; in general, this should be fairly obvious if the committee was well chosen and these three statements are well prepared.

A more subtle problem (and one not restricted to risk assessments) is the small pool of specific experience from which committee members are drawn. Among the biological sciences a small group in the total pool of biomathematicians has been consistently drawn upon for committees considering quantitative extrapolation of animal data to derive human risk. Consistent omission or shortage of experience for committees is evident in the paucity of behavioral and social scientists on risk assessment committees.

These shortages of or failures to draw upon expertise in areas comprising risk assessment are also reflected among the staff of the Academy. Of the 520 members of the professional staff we have identified only three or four who have contributed to the broad professional literature of risk assessment and perhaps as many as 10 who are regularly conversant with it. This compares to the 20-25% of NRC reports that contain some aspect of risk assessment.

Because of the relatively recent and specialized experience involved, we suggest that a serious effort be devoted to identifying the pool of individuals having experience in the various components of risk assessment. Individuals from this pool could be asked to serve on committees or to act as advisors to or reviewers of risk assessment studies.

We did not explore the issue of conflict of interest on risk assessment committees.

Methodologies and Techniques of Risk Assessment

A typical NRC risk assessment study assumes the existence of a hazard and attempts to identify the magnitude of the risk by some organized technique of data collection. Typically, the risk of concern is to humans (90% of reports) rather than to animals (29%), the biosphere (46%) or the socio-economic system (34%). Sixty-eight percent of the 41 risk assessment reports in the random sample attempt to represent numerically the magnitude of the risk they addressed.

Nearly one-half of the 20 selected major risk assessments presented their risk estimate in probabilistic terms. Nearly one-third of the 41 risk assessment reports identified in the random sample similarly used a probabilistic presentation of their risk estimate.

Most (16) but not all of the 20 major risk assessments discussed uncertainties in their evaluations or estimates but only 10 of the 41 risk assessment reports in the 20% random sample did so.

Data from studies on animals were used to judge human risk in 22% of the random sample of reports and 45% of the 20 major reports studied.

A variety of other risk estimation techniques were used, including epidemiology, qualitative inference of cause for concern occasioned by the results of animal tests, quantitative extrapolation of such tests (repudiated by some committees), combined human exposure-animal potency evaluations, and inference from short-term mutagenicity tests. A variety of types of mathematical modeling (of dose-response curves, of chemical systems, of atmospheric models) have been used in NRC reports as would be expected. Multiple regression analysis is rarely used. Further data on the frequency with which reports contain particular components of risk assessment will be found in Appendix B.

A broad risk assessment almost always involves diverse kinds of analysis often developed by disciplines employing different assumptions, standards of reliability and acceptance of uncertainty. For example, in a recent risk assessment--the one dealing with ozone depletion[1]--epidemiology, dose-response extrapolation, chemical modeling and atmospheric modeling, were employed in sequence in order to estimate the potential increase in ultraviolet light-induced skin cancer and malignant melanoma possibly resulting from continued release of chloroflurocarbons. The problems involved in compounding the uncertainties by combining theoretical simulation models, laboratory reactions, clinical observations, and epidemiological correlations have not been really examined by the risk assessment literature and is an important research task for risk analysts.

Another problem, somewhat more studied, but still one on which there is little consensus, involves the appropriateness of the various techniques for risk evaluation, i.e., the comparison of the assessed risks either with other risks, or with imputed benefits, or with the costs of alternate means of reducing the risks, or with the risk (and subsequent costs) of substitute activities or technologies. Attempts at such comparisons can be found in some recent reports but only infrequently.[2] In the 20 major risk assessments studied the only risk comparison observed was between "man-made" and "natural" background radiation.

Comparisons of risk and benefit pose serious problems. Neither individuals nor society enter into an action entailing risk unless there is thought to be some associated benefit from that action, and usually the analysis of the choice is incomplete without a characterization of the

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[1] Protection against Depletion of stratospheric Ozone by Chlorofluorocarbons (AMPS/CSS).

[2] Considerations of Health Benefit/Cost Analysis for Activities Involving Ionized Radiation Exposures and Alternatives (ALS); Polychlorinated Biophenyls (CNR); Saccharin: Technical Assessments of Risks and Benefits (ALS); Protection Against Depletion of Stratospheric Ozone by Chloroflurocarbons (AMPS).

benefits. (In some cases they may be sufficiently well known that no explicit mention is needed, but usually the problem is sufficiently complex that the benefits should be dealt with explicitly.) Once the benefits are brought in, various tradeoffs must be discussed, including how the risks change with changes in the amounts of the benefits, the sorts of substitutions that are available and how they alter the risks, and how the groups of individuals involved vary.

Notwithstanding the need to weigh both risks and benefits, such analyses are complex and cannot readily be provided for a number of reasons. One is the fact that the measures associated with the risks are almost always quite different from those associated with the benefits, and the attempts to recast both in a common measure (often money) tend to be artificial and misleading. Another is that the person or persons at risk may differ from those who are the beneficiaries of the action. Sometimes the risk and/or the benefits are clearly targeted; other times one or the other group is quite diffuse or ill defined. Still another problem arises when the probability structure of the problem is ill understood and one is not really working with a known or estimatable probability distribution. This occurs when a mechanism is very poorly understood, as with earthquakes or with human errors in flying or running a nuclear power plant, and when the decisions of other human beings affect the outcome, as with terrorists causing a major catastrophe or other businessmen affecting a business decision.

Efforts have been under way for some years to formulate various general classes of risk-benefit situations and to offer methods to analyze them. Although there has been both theoretical and empirical progress, there is no satisfactory general formulation that can be recommended for use in NRC reports.

It will probably prove helpful to include either as a member or on the staff of a committee that will be dealing with risk in a major way someone experienced in risk-benefit analysis. The reason is that while no general schema exists, those with some experience in the area can help the committee to avoid the more obvious errors, omissions, and pitfalls and bring to its attention examples of procedures that seem to have been helpful elsewhere.

Uncertainty of Probability or Other Risk Estimates

While most (80%) of the 20 selected major risk assessments discussed uncertainties in their risk estimates 74% of the risk assessments identified in the 20% random sample did not. In presenting risk assessments it is crucial that the reader be provided with clear documentation of the uncertainties involved in the risk estimates. This has not been true of most NRC reports. This appears to have been better done, but still not universally adequate, in the "major" risk assessment reports. The absence of documentation or discussion of the various uncertainties due to, a) lack of data, b) limitations or ranges of error intrinsic to models or procedures, and c) the incompleteness of models or analyses appears quite high. This was the major unexpected and disturbing finding of our review. It was unexpected because the documentation of these three sources of uncertainty is essential to the good practice of science and reviewers are specifically encouraged to check for it by the Report Review Committee. It is especially disturbing because a common anecdotal observation in the NRC is the failure of sponsors,

the media or the public to "understand" the qualifications of assessments due to uncertainty. There is surely failure to understand in the absence of its documentation.

Our recommendation is a simple one: No risk assessment should leave the NRC without adequate documentation of the various types and degree of uncertainty inherent in the assessment.

Committee Interactions and Process

Almost universally the scientific judgments expressed in reports are the result of round table discussions to achieve consensus where possible. In all the reports studied only one instance, described below, was identified where an alternative method was used. Impressions on committee functioning were gathered from discussions with staff officers and the broad experience represented on our committee. However, no attempt was made to examine the ultimate effects of particular chairmen or committee members in the process on the final report. Committees and hence reports varied in the degree to which they ventured into evaluative judgments.[1]

NRC reports infrequently contain minority reports or statements. Only two of the twenty major risk assessment reports and none of the randomly selected sample contained minority statements. This finding is discussed later.

The central task of a risk assessment committee, once adequate data are assembled and reviewed, is to make judgments, to assay the scientific information relative to a specific source or type of risk. Two extremes of judgment can be distinguished in theory: scientific findings, susceptible to demonstration, replication and verification; and policy judgments as to the specific ways in which the risk under consideration should be managed. Connecting these two extremes is a bridge of values, some characteristic of the sciences, others of various components of society, and all potential subjects of dispute. Inevitably, as one moves from scientific findings toward policy prescriptions there is movement away from the relatively common ground of scientific expertise toward issues more likely to be in dispute.

This contrast may be exemplified by the following excerpts drawn from a recent report.[2] Scientific findings are typified by verifiable statements such as:

> CFMs [chlorofluoromethanes], after release at the surface of the earth, mix with the atmosphere and rise slowly into the stratosphere, where they are decomposed by the sun's ultra-violet radiation. Chlorine atoms (Cl) and chlorine oxide (ClO), produced directly or indirectly by this decomposition, then react to remove ozone (catalytically), reducing the total amount of ozone and somewhat shifting the distribution of ozone toward lower altitudes.

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[1]Contrast Drinking Water and Health (ALS) with An Evaluation of the Carcinogenicity of Chlordane and Heptachlor (ALS).

[2]Halocarbons: Environmental Effects of Chlorofluoromethane Release (AMPS).

Clearly a policy prescription is the statement:

> We recommend that legislation be enacted requiring labelling of all products containing CFMs F-11 and F-12 and not intended to remain under seal during use.

Bridging these two extremes is a statement based on underlying value judgments:

> The various uses of CFMs are of very different magnitude and of very different importance to human life, including human health. Home refrigeration of food, at one extreme, is important to human health and accounts for less than 1 percent of all releases. CFM use in aerosol sprays, at the other extreme, are mainly replaceable by other dispensing techniques or by other propellant substances, at some loss of convenience, efficiency or safety, and amount to about three quarters of all releases. (Some aerosol uses, including some for medical purposes, deserve special consideration.)

In general unless policy recommendations are part of the charge of a risk assessment committee, committees do not contain the requisite expertise to make such recommendations. We do recognize that there is a need to bridge the gap between assessment and policy decisions because the scientific assessment does not automatically translate into the information required to make policy judgments. Thus we encourage explicit discussion in the report of the implications of scientific findings for policies when possible. But in any event an effort should be made to distinguish clearly between scientific finding and judgment based on personal knowledge or values.

Regardless of the type of judgment reached, how it is elicited is a related concern. In general, the committee process of judgment formation can be described as interactive and consensual. Seldom, we understand, are committee members formally polled as to their individual judgment early in the study; typically, positions emerge in the discussion process within the committee meeting, in later response to the minutes of the meeting, and in the reviewing of successive drafts of the report. Social psychologists who study these matters would be quick to point out how these common procedures tend to anchor judgments to an illusory collective mean, to the strong influence of an outspoken colleague, or to the wording of a draft statement (often prepared by staff or a single, designated member, rather than the members collectively). These procedures, while helpful in achieving consensus, may actually work to obscure real and important differences held by one or more members. At the very least there is no guarantee that all or even most of the individual judgments of a committee specifically selected to provide a range of judgments has been brought to bear on the questions in doubt.

Alternatives do exist for elicitation of committee members' viewpoints, as exemplified in their novel and convincing application in the report on The Environmental Impact of Stratospheric Flight (see Appendix K of that report, pp. 308 and 326) in which the collective judgment of committee members, with respect to their expert judgments on the probability of the correctness of a range of uncertain key values--

"key links in the causal chains"--was elicited by means of a questionnaire that asked them to select the respective values and, at the same time, rank their relative expertise in respect to each value estimated. With the aid of the computer, a consolidated range of judgmental estimates was produced, thus more accurately capturing each expert's individual estimate, as distinguished from the more typical reporting style of summarizing the consensus of a roundtable discussion. Other methods of elicitation, not so ellaborate, are also available. Committees should be made aware of, and encouraged to experiment with, alternative approaches to the elicitation of judgment within the committee process.

The finding that minority reports are infrequent should be interpreted with caution, as disagreement may not have arisen or may have been treated adequately within the text.

Risk assessments on the frontier of knowledge will often evoke differential scientific judgments. Consensus in a risk assessment is desirable but should not be achieved by following committee practices that fail to recognize such differences or that "paper-over" them when they occur. When unanimity of view, as to findings and judgment, or recommendations, does not develop naturally, then the report should carefully formulate both the areas of agreement and the nature of the differences in terms that are acceptable to all committee members. Here the consensus is to the nature of the areas of agreement and disagreement, not total agreement of view. It may or may not be appropriate to identify individuals holding each view. If this cannot be done then, as a last resort, the report should include minority statements that constitute formulation of a disagreement or view that are acceptable only to a subsection of the committee.

Finally, a very large but related issue is posed by contradictory judgments found between NRC committees. These are occasionally cited as evidence for the unreliability of NRC risk assessments. We discovered a dramatic example of such disagreement in our review of the major risk assessments: of seven recent reports,[1] three rejected quantitative extrapolation of animal carcinogenicity to predict human cancer risk, three adopted such extrapolation, and the seventh did so while expressing strong skepticism of its value. Of the seven reports none contains substantive discussion of the reasons for disagreement with other NRC reports.

This would seem, on first impression, to be an unacceptable outcome of NRC reports on what is surely an important science and policy issue. Much of our committee effort was expended discussing this concern, including the careful examination of case examples to determine whether this seemingly contradictory outcome was due to the specific charge to

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[1] Regulating Pesticides; An Evaluation of the Carcinogenicity of Chlordane and Heptachlor; Interim Report of the Diesel Impact Study Committee; Drinking Water and Health; Kepone, Mirex and Hexachlorocyclopentadiene; Chloroform and Other Nonfluorinated Halocarbons; Saccharin: A Technical Assessment of Risks and Benefits.

the study committee or to some biased disciplinary or individual make-up in committee membership. Some evidence was found for both cases--in cases where the charge strongly encouraged such extrapolation it appeared forthcoming; also, certain disciplines appear to find the making of such extrapolations more congenial than do others.

On balance, however, the existence of such contradictory judgments appears to be a true reflection of the fact that profound uncertainty exists in our understanding of the subject of these reports, i.e., carcinogenesis. In such a state of affairs, differences of opinion should be expected as the normal function of science. What is less acceptable is that these contradictory judgments be rendered in seeming ignorance of, and independent of, other judgments on similar questions. We expected, and here recommend, that NRC reports should carefully cite other related reports, describe how those committees came to other conclusions and why the present committee differs from those conclusions.

Presentation of Study Findings

As noted above, approximately 68% of the reports identified as risk assessments in the random sampling attempted to represent numerically the magnitude of the risk under study, nearly one-third in a probability estimate. Those studies that did not attempt to quantitate the risk they studied were generally dealing with an environmental impact, e.g., the impact of sewage disposal on the environment, which was difficult to express in a single or even a collection of figures. The appropriate balance between quantitative and qualitative descriptions of risk is discussed below.

Science is strongly biased towards numbers, for when numbers can be justly employed they denote authority and a precise understanding of relationships. Because this is so, there is an equally important responsibility not to use numbers, which convey the impression of precision, when the understanding of relationships is indeed less secure. Thus while quantitative risk assessment facilitates comparison, such comparison may be illusory or misleading if the use of precise numbers is unjustified.[1] Therefore, the choice of the degree of quantitation in expressing risk is at once the selection of a presentation device and an important scientific judgment of its own.

A major problem in presenting any risk assessment is to convey adequately the uncertainties encountered. In general, we feel it better to provide some indications of the interval involved rather than to present a point estimate with an error band. If a single, well designed experimental or observational study is the basis of the findings, then a statistical confidence interval (e.g., were the study to be repeated many times, in 95% of the cases the answer would lie in the interval from x to y) can be reported. If the

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[1] A report worth consulting in this regard is Recommendations on Quarantine Policy for Mars, Jupiter, Saturn, Uranus, Neptune and Titan. The committee was called upon to calculate the probability of contamination of these planets by terrestrial organisms. They fulfilled the charge but because of the lack of a firm experimental basis for some necessary assumptions, they also qualified the calculations they had made.

literature includes a number of studies each of which provides a point estimate, it may well prove best to state the range of the estimates. Whether one wishes to provide additional information depends on the situation; often one should show the histogram of estimates, especially if it is oddly skewed, bimodal, or there appears to be an outlier that greatly extends the range. In some cases no empirical literature exists and the results are based on extrapolation (e.g., from animals to humans, from massive dosages to small ones), modeling, or simulation. Here extreme caution is needed both to establish some plausible range of uncertainty and, at least as important, to make clear the assumptions built into the calculation and the sources of risk that have been omitted. A few suggestions thus emerge from our review:

1) Express numbers with their qualifiers and ranges of uncertainty. Do not use highly specific numbers in summaries or press releases if they need to be qualified in important ways. Only use them when they can be explained in context. They may well be taken out of context but we should not inadvertently encourage doing so.

2) When significant uncertainty exists, as it almost always does in risk analyses, interval expression is preferable to point expression.

3) Avoid using evaluative descriptions of probabilities such as large, weak, significant, moderate, etc. Wherever possible provide numerical estimates with the appropriate caveats concerning their quality; in particular, estimates of ranges of uncertainty should be provided.

4) Because untrained individuals have difficulty in appreciating numbers such as 10^{-8}, judicious use should be made of comparisons with familiar events of the same magnitude. Care must be exercised not to seem to trivialize the risk nor to mislead about the uncertainty of the estimate.

The reason for comparing a probability with some presumably known or experienced probability is the well documented fact that most people do not have an effective subjective dynamic range of more than 10^3 or 10^4, whereas we often need to discuss probabilities of 10^{-6} or smaller. There are, however, very great dangers in trying to make probabilities vivid by comparing them to some familiar event, among them the following. First, the case at hand may involve far more uncertainty than the comparison, which usually is something involving a very large sample size. An example is comparing the chance of a catastrophic earthquake in Los Angeles with some familiar event such as the chance of a commercial plane crash. Second, the nature of the untoward outcome may be radically different in the two cases, as it was in the example just given. This may have the unintended effect of making the committee appear to equate the consequences when all that was intended was to equate the probabilities. Third, the comparison event, although statistically well understood, may be seriously misperceived by a large fraction of the public and so, to that extent, provides a misleading comparison. An example is the comparative estimates of accidental versus disease-related mortality where a lay group impression (in one experiment) was overestimated by a factor of 15. Despite these difficulties, some of us believe that it is helpful to use judiciously selected comparisons, to characterise the range of probabilities involved, or to indicate that the probability in question is smaller or larger than a known probability by some simple factor (2, 10, 100, or 1000).

Post-Study Follow-Up:

Once the report is issued and the committee disbanded, we found, there are two related problems that may be characteristic of non-risk-related reports as well. Particularly in the case of controversial issues or recommendations, the credibility of our work is often judged not only by the quality of the report but by the quality of our response to critiques of it. Questions or issues often arise many weeks, or even months, after the publication of the report. Secondly, it appears to us that the usefulness of an NRC report can often be enhanced by a variety of follow-up activities performed by the committee and its staff, e.g., reviewing an agency's response, participation in Congressional hearings, or formal briefings of sponsors and public constituencies of the report's subject matter. Moreover, we found a decided lack of good records and/or institutional memory available to facilitate evaluating the ultimate usefulness and follow-up of our reports. While it was not the function of this committee to develop post-report, follow-up strategies for the NRC, we do cite the matter as one worthy of further consideration.

SUMMARY OF RECOMMENDATIONS

We here lay out our principal recommendations in a sequence which, as far as is possible, parallels the activities in the formulation of a committee and the production of a report. Further discussion of the basis for these recommendations and additional observations which may be helpful in improving the quality of risk assessment reports are found in the foregoing text.

We recommend that:

> The assembly or commission that created the committee include in the preface to the report (i) a complete statement or accurate summary of the charge to the committee, (ii) a description of the various intellectual considerations that went into the design of the committee, inidicating the range of compentencies required and the nature of the balance in view points and concerns that was attempted, the types of additional experience provided by formal consultants to the committee and (when appropriate) the reasons for what may be considered by some critics or commentators to be significant omissions in its composition, (iii) a brief description of the relevant background, experience and research activities of each member of and major consultant to the committee.

We do not recommend that an explicit account of how the particular membership fulfills the criteria be provided: this should be obvious if the committee is well chosen and these three statements well prepared. We were led to this recommendation by our observations that the selection of a balanced and credible committee to address issues involving risk seems to require especial attention to selecting individuals expert in one or more of at least five specialties, e.g., the ability to handle the extrapolation of animal data to humans, to assess epidemiologically human health hazards, to make relevant comparisons to other risks, to address benefits, and to assess or discuss the public perception or acceptability of risks. Both the inclusion and exclusion of specialists in these areas can affect significantly the credibility, and often the results, of risk studies. Additionally such specialized knowledge or experience is not always apparent from the names and titles of committee members.

In addition to a statement of the charge in the preface we recommend that each report include a

clear prefatory statement delineating the scope and limitations of the report. For instance, it should orient the reader by describing what a complete risk assessment on the subject at hand would consist of, and why the NRC and/or the committee chose to address the specific aspect being reported on. Moreover, it should indicate, where possible, what other parallel activity or literature (inside or outside the NAS) address the other assessment components.

We arrived at this recommendation from our observations that NRC reports usually address only one limited aspect (i.e., risk estimation) of a total risk assessment and that if left unexplained this begs misunderstanding as an implication that other components of the total evaluation of the risk are unimportant. In such a prefatory statement the committee may wish, if appropriate, to explain approaches to the total risk assessment, e.g., assessment of benefits, cost-effectiveness evaluation, cost-benefit assessment, which it chose not to employ.

The art of risk assessment and the application of its methods to the conduct of science and technology policies studies, is still very much an emerging field.

It will probably prove helpful to include either as a member or on the staff of a committee that will be dealing with risk in a major way someone experienced in risk-benefit analysis.

Because of the relatively recent and specialized experience involved, we suggest that a serious effort be devoted to identifying the pool of individuals having experience in the various components of risk assessment. Individuals having experience in the various components of risk assessment. Individuals from this pool could be asked to serve on committees or to act as advisors to or reviewers of risk assessment studies.

Concerning the conduct of studies we have two recommendations:

Committees should be made aware of, and encouraged to experiment with, alternative approaches to the elicitation of judgment within the committee process.

and

Consensus in a risk assessment should not be arrived at by following committee practices that fail to recognize differential scientific judgments. When uninamity of view as to findings or judgments does not develop then the report should carefully formulate both the areas of agreement and disagreement in terms acceptable to all committee members. If this cannot be achieved then the report should include minority statements that constitute formulations of a disagreement or view acceptable only to a subsection of the committee.

The former recommendation is made to ensure that full use is made of the diversity of experience that was drawn together for the committee. The recommendation on consensus building is made because risk assessments on the frontiers of knowledge where uncertainties abound will often evoke difference of opinion and that the credibility of science and the NRC will not be served by avoiding explicit mention of such divergence of opinion or by attempts to paper them over in the interests of presenting a weak consensus.

Concerning the content of reports we would recommend that:

no risk assessment should be issued without adequate documentation or discussion of the various types and degree of uncertainty inherent in the assessment.

We regard it as fundamental to the good practice of science that the sources of uncertainty be documented. Our survey of NRC risk assessment reports brought to light some deficiencies in this area which are discussed in the foregoing text.

With regard to content we would additionally recommend:

reports should carefully cite other related reports from the NRC, and if necessary describe how those committees came to other conclusions and why the present committee differs from those conclusions.

We found unexpectedly that this was not done and believe that while total unanimity of view cannot be expected especially in a rapidly advancing field explanation for divergence of view is essential for the NRC's continuing credibility. In order to facilitate the implementation of this recommendation we suggest that the Library establish a computerised system of indexing studies and reports with a retrieval capacity to be based on search keywords generated by the staff officer responsible for the study.

Finally, we have made a series of suggestions (rather than recommendations) as to the complex issues of presenting study findings, particularly: the issue of quantitative versus qualitative expression, the expression of uncertainty and the use of comparisons in expressing probabilities.

A SAMPLE OF TOPICS INVOLVING "RISK" WHICH THE NRC STUDIED: 1974-1979

Air Quality
Ocean Pollutants
Sewage Disposal
Herbicides in Vietnam
Stratospheric Flight
Halocarbons and Ozone
Ionizing Radiation
Non Ionizing Radiation
Toxicology of a myriad of individual compounds and classes
Food Safety
Antibiotic "Misuse"
Recombinant DNA Research
Dam Safety
Road Surface Safety
Road Lighting
Crash barriers
Earthquake prediction
Water quality, microbiological
Water and heart disease
Germ plasm resources
Tropical Forrests
Grizzly bear management
Quarantine for the Outer Planets
Ecological Effects of a Sea Level Canal (Atlantic Pacific)
Toxic substances in livestock water
Outer Continental Shelf Oil Drilling
Individual Privacy Violation
Voice Identification
Human Error
Legalized Abortion
Sleeping pill misuse
Phototherapy
Radiotherapy
Agricultural Production
Radioactive Wastes
Coal mine wastes
Strip mining
Criteria for Environmental Pollutants
Criteria for Index Pollutants
Hazardous Cargoes
Obesity
Noise
Coal Mining
Liquefied Natural Gas
Vibration
Odors
Construction Safety
Fire
Genetics

SURVEY OF NRC RISK ASSESSMENTS: QUESTIONS AND RESULTS

		Percentage Reports Positive	
		All reports identified in random sampling	20 Major Risk Assessment
1a.	Is there a risk estimation or a risk assessment?	100	100
1b.	Is no r.a., could there have been one if the committee chose to include one?	N/A	N/A
1c.	If no r.a., does the report recommend one?	15	15
1d.	Were there external constraints on the performance of the r.a.?	17	90
2a.	Does the r.a. assume the existence of a hazard?	90	85
2b.	Does the r.a. identify hazards by some organized technique, such as monitoring, screening, etc.?	80	100
2c.	Do the hazards identified include risks to humans?	90	90
2d.	Do the hazards identified include risks to animals?	49	45
2e.	Do the hazards identified include risks to the biosphere?	46	55
2f.	Do the hazards identified include risks to the socio-economic system?	34	35
2g.	Are other hazards identified (e.g., aesthetic)?	20	20
3a.	Does the r.a. provide quantitative estimates of the risk?	68	75
3b.	Does the risk estimation procedure involve extrapolation from animals to man?	22	45
3c.	Does the risk estimation procedure involve modeling?	22	60
3d.	Does the risk estimation procedure involve multpile regression analyses?	0	0
3e.	Does the risk estimation procedure calculate probabilities?	29	45
3f.	Does the risk estimation procedure attempt to place an economic value on losses?	15	30
3g.	Does the risk estimation procedure involve other analytical techniques?	37	50
3h.	Are uncertainties discussed explicitly?	24	80
4a.	Are risks compared to other types of risks?	15	20
4b.	Are risks compared to benefits in terms of dollar values?	10	15
4c.	Are risks compared to benefits in other ways?	22	30
4d.	Are risks compared to risks or costs of possible control measures?	27	45
4e.	Are the comparisons made using formal methods (e.g., c/b analysis, decision analysis)?	10	35
4f.	Does the analysis show who bears the risks or receives the benefits?	22	60
4g.	Does the analysis place a value on human life or other intangibles?	5	5
5a.	Is there discussion of acceptability of risk to specified publics?	27	25
5b.	Is there discussion of perceptions of risk by concerned publics?	22	25
5c.	Are policy options for control measures of regulations discussed in terms of degree of risk or cost?	24	50
5d.	Are there policy recommendations?	54	85
6.	Is there a minority report or statement?	0	10
7.	Was there formal public input?	5	10

N/A = not applicable

QUESTIONS APPLIED TO 20 "MAJOR" RISK ASSESSMENTS

A. Charge
1a. Did the charge/study originate by Congressional mandate?
1b. Did the charge/study originate by external request?
1c. Was the charge/study internally generated?
1d. Does the approved Governing Board prospectus specifically mention risk estimation?
1e. Or does it specifically mention risk/benefit assessment?
2. Is the charge clearly stated at the outset of the report?
3. Does the report preface match the Governing Board prospectus?
4. Does the report match the Governing Board prospectus?
5. Does the report expand or narrow the Governing Board prospectus or contract charge?
6. Is this justified or mentioned in the preface?
7. If the charge was expanded or narrowed was this done in consultation with the sponsor?
8. Did a phone call to the committee staff officer reveal any constraints on the charge not immediately obvious from the report (e.g., SDWC should not consider costs)?

B. Elicitation of Judgment or Consensus
1a. Did an interview with the report editor reveal that committee dynamics affected the product substantially?
1b. Or affected the product somewhat?
1c. Or affected the product very little?
2. Were judgments elicited from committee members independently or in an interactive setting?
3a. Does the report generate its own quantitative estimate of risk or judge any particular one more accurate?
3b. Is this justified (in the text)?
4. Comments.

C. Institutional Memory
1a. Is there evidence of institutional memory (or lack of memory) of prior reports from the originating Assembly or Commission?
1b. Of reports from other Assemblies or Commissions?
1c. Does the report explain differences in judgments with prior reports?
1e. Comments.

D. Committee Composition
1a. Does the report generate or make judgments on risk to humans based on animal data?
  i. On qualitative risk estimations?
  ii. On quantitative risk estimations?
  iii. Rejects quantitative estimation based on animal data?
1b. Was any committee member appointed for expertise in toxicology?
1c. Was any committee member appointed for expertise in biomathematics/biostatistics?
2a. Does the report generate or make judgment on human health hazards?
2b. Was any committee member appointed for expertise in epidemiology?
3a. Does the report compare risks with other risks?
3b. Was any committee member appointed for expertise in comparative risk analysis?
4a. Does the report attempt to assess benefits?
4b. Was any committee member appointed for expertise related to benefits in economics?
4c. In psychology?
4d. In health care?
5a. Does the report make comment or make judgment (including assumptions) on the perception or acceptability of risk?
5b. Does the report attempt to compare risks with benefits?
5c. Does the report outline options for managing risks which are not quantified?
5d. Was any committee member appointed for expertise in risk perception?
5e. Was any committee member appointed for expertise in psychology?

E. Overall Comments