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Presented at the hearings on H.R. 2138 - Elevating the Environmental Protection Agency to Department of Environmental Protection.

Mr. Chairman, Members of the Subcommittee:

Thank you for the opportunity to provide testimony on elevation of the U. S. Environmental Protection Agency (EPA) to the Department of Environmental Protection. My testimony is based on my perspective as a charter member of the EPA; a research scientist; a science administrator; an editor; and a manager who had to comply with environmental regulations. In addition, for the last two decades I have been actively involved with promotion of the concept of Best Available Science (BAS) because of my concern over the quality of science used in many of our societal decisions notably on matters related to environmental protection.

When EPA was formed, we were most enthusiastic about the prospect of having one agency handling all environmental issues. Although I am proud of our achievements, I am not so proud that opportunities were lost to enhance the quality of the environment. I am even less proud that significant funds were spent on activities that had a relatively small impact on the quality of the environment, while true environmental issues were either insufficiently addressed, addressed late, or not at all. It is true that the EPA was asked to perform a nearly impossible task of promulgating regulations when the necessary data were insufficient or lacking. However, EPA has made numerous decisions that are based on less than Best Available Science regardless of the availability of scientific information. This accusation is made not only by those who had to live with the often stringent regulations, but also by a rather large number of independent reviews and studies performed by various scholarly organizations.

We at the Institute for Regulatory Science are in the initial phases of performing two studies that would have an immediate impact on the proposed formation of the Department of Environmental Protection. Currently, we are seeking funding to continue these two studies and hope that we can complete them reasonably soon. The basic thrust of these studies is as follows:

1. The first study deals with the criticism of the quality of science used at the EPA. We are evaluating studies performed by scholarly organizations such as the National Research Council (the research arm of the National Academy of Sciences, National Academy of Engineers, and the Institute of Medicine); the General Accounting Office; and various professional societies. We are also evaluating relevant decisions by the courts, and information published in peer-reviewed journals. Although this study is in its initial phases, the evidence is overwhelming that the mainstream scientific community has significant reservations regarding EPA's science. The key reason for the science problems at the EPA is the lack of recognition that the foundations of acceptability of scientific information is independent peer review. Precisely because EPA's decisions are often highly contested, one would have expected that the EPA would attempt to err on the side of caution and rely upon independent peer review. Instead, the evidence is overwhelming that most relevant scientific documents used in regulations are not independently peer reviewed. The situation is even less favorable for guides.

2. The second study covers environmental laws. In this study we are trying to evaluate Congressional Findings in various environmental laws. We are particularly interested to determine the emphasis of Congress relative to the protection of humans versus the protection of other living things, including the ecosystem. Again here initial results clearly indicate that Congress has given high priority to protecting humans.

A closer look at the reason for the relatively poor scientific performance of the EPA indicates that the management notably the political leadership of the EPA has traditionally accepted and sometimes favored the intrusion of ideology, societal objectives, and numerous other non-scientific issues into the science underlying regulatory decisions. This tradition has resulted in a culture at the EPA which is responsible for the negative view of the scientific community notably those in the regulated community on the science of EPA. By far the most serious accusation is that EPA has been selective in using scientific information by choosing the information that supported its preconceived views and disregarded the information that did not. There are significant potential dangers in the continuation of such a culture. The impact of such a culture is not only economical, but at a minimum it includes the development of a potentially deep-seated mistrust in all decisions related to environmental protection. Please note that the history is littered with remnants of those societies that tried to infuse ideology, societal objectives, and other non-scientific desires into science.

I want to be sure that my criticism of science at the EPA is not construed as questioning the competency or dedication of scientists and engineers at the EPA. Based on my personal experience, I am convinced that the competency and dedication of EPA's scientists and engineers compare favorably with those in other federal agencies and elsewhere.

Precisely for reasons described above, I believe that the structure of the Department of Environmental Protection as included in H.R. 2138 is reasonable. I hope that the Congress can impress upon the science part of the Department of Environmental Protection the significance of reliance upon Best Available Science. This includes the following core requirements:

1. The science must be entirely separated from societal objectives. Scientific facts should be provided to the regulators; and the regulators are the ones to introduce societal objectives in applying science.

2. All scientific information that is used in promulgating regulations or in preparing guides must be subjected to independent peer review. Obviously, there are minor decisions that can be exempted from such a requirement. In contrast to scientific information, societal decisions cannot be judged by scientists. Scientists are no more qualified to decide societal issues than members of any other profession or trade.

3. The Management of the Department of Environmental Protection must formally respond to the findings and recommendations of peer review panels, and must make the response available to the public. The publication of such a response does not need to violate requirements to protect proprietary information and protection of human subjects. There is a well-established process to do so.

4. The scientists and engineers at the science side of the Department of Environmental Protection should be encouraged to publish the results of their activities in peer-reviewed journals, and should actively participate in the professional societies of their respective disciplines.

5. The program offices of the Department of Environmental Protection should be discouraged from intruding in the scientific deliberations of the science side. This requirement should not be interpreted as discouraging interaction between the two groups. Instead, this requirement should prohibit the program offices from dictating or asking the science side to provide evidence for a preconceived outcome.

6. The Department of Environmental Protection should be encouraged to revisit its decisions and correct decisions based on poor science or new information. Although many laws require such a revision, in practice, EPA has been reluctant to do so.

I have no illusion that it will take some time to restructure the tradition and the culture of an agency that is accustomed to ideologically-processed science. However, H.R. 2138 provides a mechanism to reduce the problem and hopefully initiate a new tradition.

I do have some comments for consideration by the Subcommittee. For the sake of simplicity, I am dividing my comments into two groups. The first group consists of those comments that I strongly urge the Subcommittee to consider, as they are critical to the success of the Department of Environmental Protection. The second group consists of those comments that are desirable.

Let me address the first group which I **strongly urge**:

1. As stated above, it appears that the primary focus of the majority of environmental laws is the protection of humans. The protection of other living things is based not only on ethical concerns but also on the recognition that medicine has benefited from the availability of a vast pool of biologic materials. Obviously, there are numerous other reasons for protecting other living things. Consequently, it is imperative that the word environment is defined in the bill. I am suggesting that under section 3 definitions after item (2) the word environment is defined and the remainder of that section is renumbered accordingly as follows:

(3) Environment means humans, other living things, and environmental media

2. In several instances the bill included wordings such as humans and the environment. Consistent with the definition described above, it should be changed to **environment and particularly humans**. The affected sections include 4 (b) (3); 4 (b) (4); 7 (d); and 7 (g) (1).

The **desirable** modifications are as follows:

1. Section 8 (j) establishes a Bureau of Environmental Statistics. The formation of this Bureau and its functions is appropriate and long overdue. Section (8) (j) (2) establishes a Peer Review Team. I am suggesting that the title of the Team be changed to **Peer Review Oversight Team** and its function be changed to oversee the peer review of a variety of information managed by the Bureau. This recommendation is based on many years of my experience with independent peer review of various projects many of them related to environmental protection. The **Peer Review Oversight Team** would have the ability to appoint independent peer review panels to review various aspects of the highly-complex topics covered in the responsibilities of the Bureau. At a minimum, the text must include provisions that the **Peer Review Oversight Team** can appoint panels for specific reviews in support of the Team's efforts.

Mr. Chairman and members of the Subcommittee, you have undertaken an important task of converting a cabinet agency to a department. During this process, you have attempted to correct the most important shortcoming of that agency. I believe that the chosen approach is sound. I hope that my comments will help to improve the bill. Those of us who have dedicated our professional lives to protection of the environment hope that you will be successful in your efforts.

Attached to this testimony are three documents:

1. A description of Best Available Science which constitutes the foundation of the Institute for Regulatory Science.

2. Fundamentals of Independent Peer Review as practiced by the Institute for Regulatory Science and many other scholarly organizations.

3. A biographical summary describing my professional qualifications.

Attachment 1: What is Best Available Science?

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WHAT IS 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, 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:

Status of science
Selection process
Science vs non-scientific objectives

Status of Science

The status of scientific knowledge can be categorized into three classes, each having two subgroups as follows:

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

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

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

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

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

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

Selection Process

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

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

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

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

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

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

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

disregard these interests during the consensus process.

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

Science vs Non-Scientific Objectives

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

Attachment 2: Fundamentals of Independent Peer Review

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Fundamentals of Independent Peer Review

INTRODUCTION

The need to provide scientific advice to the nation was recognized as early as the administration of Abraham Lincoln who established the National Academy of Sciences which resulted in the formation of the National Academy of Engineering and the Institute of Medicine. Recognizing the need for a joint research organization, the academies formed the National Research Council (NRC). More recently, Congress has found it necessary to establish the National Council on Radiation Protection and Measurements and the National Academy of Public Administration to supplement the activities of the NRC. The development of science, engineering, and technology has reached a level whereby it is not only desirable but mandatory to ensure that societal decisions rely upon the Best Available Science (BAS). Inherent in the BAS concept is independent peer review. For a number of reasons, including the passage of several laws by the Congress, it has become fashionable among federal agencies to claim that they perform peer review of many of their activities. Numerous reports of the NRC, along with those from the General Accounting Office (GAO) and many other organizations, indicate the deficiency of these claims. The fact is that several federal agencies notably the U.S. Environmental Protection Agency (EPA) have a long way to go to embrace the concept of BAS, including the independent peer review.

PRINCIPLES OF INDEPENDENT PEER REVIEW

The formation of the Institute for Regulatory Science (RSI) was a direct consequence of the recognition that a large number of our regulations are based on poor science. The expressed mission of RSI is the promotion of BAS. The concept of BAS separates scientific from societal aspects of a decision that include value judgements. In recent years, RSI has teamed up with the American Society of Mechanical Engineers (ASME)Cone of the largest and oldest professional societies in the world to formulate clear and unambiguous criteria guiding the performance of independent peer review. Based on the experience of ASME/RSI, the following principles were identified as the most important requirements for an independent peer review program:

Principle 1: *The selection of reviewers and the outcome of the peer review are the result of the consensus of a group rather than the decision of an individual.*

This principle implies that all decisions dealing with selection of reviewers and the review must be made collectively by a group of qualified individuals rather than a single individual. Consequently, the ASME/RSI process uses a committee appointed by a duly organized entity of ASME. This committee appoints Review Panels (RPs) who in turn perform the review.

Principle 2: *Clear and unambiguous policies ensure that conflict of interest is avoided or at least minimized.*

The issue of conflict of interest is normally addressed by having each reviewer sign a conflict of interest form implying that the individual has no conflict of interest. However, such an approach leaves the judgement entirely to the reviewer. An independent peer review process requires clear policies indicating what constitutes a conflict of interest. The policy guiding the conflict of interest should be: *Those who have a stake in the outcome of the review may not act as reviewer or participate in the selection of reviewers.*

Principle 3: *The findings and recommendations of the review panel address unambiguous and clear questions (sometimes called review criteria or lines of inquiry) identified by the sponsoring organization.*

The past experience of many federal agencies has resulted in skepticism indicating that reviewers appeared to have had a free reign in addressing any issue. A properly-managed independent peer review must be based on clearly identified questions (review criteria or lines of inquiry). To be sure, questions (review criteria in lines of inquiry) must be technically reasonable. However, they must be based on the needs of the manager and must be responsive to those needs.

Principle 4: *The findings and recommendations responding to the review criteria are constructive and helpful rather than being adversarial.*

This important and hereto under-emphasized principle is an integral part of independent peer review. As the review is intended to assist the managers in their decision process, it should be helpful to the decision makers rather than being confrontational.

Principle 5: *The participation of appropriately selected stakeholders significantly enhances the credibility and acceptability of the results of peer review.*

The participation of stakeholders in an independent peer review is an asset. In the context of this principle, stakeholders are those who are personally impacted by a decision; those who must deal with it during the course of their occupation; and all others who have an interest in the outcome of the peer review or the peer review process. Experience indicates that a properly-managed program of stakeholder participation can avoid the sometimes disorderly and chaotic conditions that can result from such participation. Also, the experience indicates that a properly-designed and properly-conducted peer review will enhance the acceptance of the decision that is based on the results of the peer review.

DEFINITION OF INDEPENDENT PEER REVIEW AND RELATED ACTIVITIES

Independent peer review is often confused with other processes notably internal reviews, technical advice, and many other forms of reviews. It is also confused with an important process called independent technical assessment. Although there are similarities among these processes, they are not identical.

Independent Peer Review

Independent peer review consists of a critical evaluation of a project. The project may consist of a study; the scientific foundation of a regulation; a program; competing submissions such as grants; scientific claims; or any other technical document. It is performed by an RP consisting of individuals who by virtue of their education, experience, and acquired knowledge are qualified to be peers of the investigators who participated in the performance of the project. A peer is an individual who is able to perform the project, or the segment of the project that is being reviewed, with little or no additional training or learning.

As indicated in the ASME/RSI principles described above, there are several critical criteria defining requirements for the appointment of members of an RP and the peer review process as follows:

1. Qualifications of the reviewers.
2. Independency of the reviewers from individuals, agencies, or organizations who may be impacted by the outcome of the review.

3. Evaluation of criteria on qualifications and independency of each proposed reviewer by a group with the functional title Peer Review Oversight Committee (PROC) whose members, in the judgement of an uninvolved technical organization, meet both the requirements on qualifications and independency.
4. Transparency of the peer review and its process.

Independent peer review constitutes the core of acceptability of scientific and engineering information; thus it is performed virtually by all professional societies of scientists and engineers in their publications and other activities. They are uniquely qualified to establish PROCs for peer review of specific subject areas.

Independent Technical Assessment

Independent technical assessment consists of a critical evaluation of a topic. There are significant differences between an independent peer review and an independent technical assessment. The independent peer review consists of rendering judgement on existing information. In contrast, the results of an assessment consist of information gathered, developed, or synthesized by the Assessment Panel (AP). The requirements for appointment of members of an AP are identical to those for independent peer review. Accordingly, the three criteria described under independent peer review apply equally to APs. In this case, the PROC is referred to as Technical Assessment Oversight Committee (TAOC).

Other Forms of Review

There are numerous other forms of reviews that do not qualify as either independent peer review or independent technical assessment. A large number of peer reviews performed by federal agencies fall into this category. In many cases, an individual within the federal agency evaluates the qualifications of the reviewer and assesses the reviewer's independence. Clearly, such an approach does not meet the three criteria identified above.

Examples

There are numerous examples of the three categories of reviews. The following examples are intended as illustrations of each category of reviews.

1. **Independent Peer Review:** The U.S. Department of Energy (DOE) and its predecessor organizations had used the Nevada Test Site for testing nuclear weapons. Approximately 900 explosions took place above ground, above groundwater, at groundwater, and below groundwater. A strategy had been developed by the DOE for remediation of groundwater contamination at that site. The DOE asked the team of ASME/RSI to establish an RP to independently review its strategy. The DOE in cooperation with certain stakeholders identified 11 questions dealing with the validity of the approach, and several other specific questions on how DOE intended to address the problem. The RP was asked to respond to each question with yes or no with appropriate qualifications, and describe its response in its Findings. Subsequently, the RP provided 11 Findings responding to the 11 review criteria. The RP also provided eight recommendations that were directly derived from these Findings. Note that the sole responsibility of the RP was to review DOE's strategy.

2. **Independent Technical Assessment:** The EPA was instructed by the U.S. Congress to initiate an independent study to be performed by the NRC to identify the most important research relevant to setting particulate matter standards, to develop a conceptual plan for particulate matter research, and over five

years, to monitor research progress toward improved understanding of the relationship between particulate matter and public health@. In 1998, the NRC prepared its first response to the Congressional mandate. The structure of the report, its content, and the distribution of information among its various chapters were entirely decided by the committee established by the NRC.

3. **Other Forms of Review:** There are too many examples of other forms of review. For example, on numerous occasions managers of a laboratory or an office seek technical advice from a group of individuals whom they appoint to review a specific project. Such an activity is appropriately referred to as technical advice.

STRUCTURE OF INDEPENDENT PEER REVIEWS

A properly-designed independent peer review process is based on a tiered system. A peer review oversight committee (PROC) establishes policies and ensures that they are followed. The peer review of each project is performed by an RP established by the PROC. The elements of the program include the following:

1. Oversight of Peer Review
2. Review Panels
3. Review Criteria
4. Technical Peer Review Reports
5. Requirements for Transparency of the Process

Peer Review Oversight Committee

The oversight of the peer review is the responsibility of a PROC to be established preferably by a relevant professional society of scientists and engineers. There is a tradition of cooperation among the professional societies to ensure coverage of the necessary disciplines among member of the PROC for the review of multi-disciplinary projects. The functions of the PROC include the following:

1. As the overseer of the entire peer review process, the PROC should enforce all professional and ethical requirements.
2. The PROC evaluates the qualifications and independency of members of each RP and approves those that it deems acceptable.
3. It reviews and approves reports resulting from peer review for compliance with professional and ethical requirements.
4. On occasion the sponsoring organization responds to the recommendations of the RP. In these cases, the PROC renders a judgment on the responsiveness of the sponsoring organization to the recommendations of the RP.

Review Panels

Criteria for acceptability of members of an RP are as follows:

Education: A minimum of a B.S. degree, preferably an advanced degree in a relevant discipline is required. In rare cases, this criterion may be waived if the candidate is so outstanding, as demonstrated by the other three technical criteria.

Experience: In addition to education, the reviewer must have significant experience in the area that is being reviewed.

Peer recognition: Election to an office of a professional society; serving on technical committees of scholarly organizations; and awards by recognized technical groups similar activities are considered to be a demonstration of peer recognition.

Contributions to the profession: Contributions to the profession may be demonstrated by publication, primarily in peer-reviewed journals. In addition, patents; presentations at meetings where the papers were peer-reviewed; and similar activities are considered to be contributions to the profession.

5. **Independence:** One of the most complex and contested issues in peer review is a set of subjects collectively called conflict of interest. The ideal reviewer is an individual who is intimately familiar with the subject and yet has no monetary interest in it. The guiding principle for conflict of interest is as follows: *Those who have a personal stake in the outcome of the review may not act as a reviewer or participate in the selection of reviewers.*

Peer Review Criteria

Sometimes referred to as lines of inquiry, peer review criteria are questions provided to the RP to be answered. In a properly-performed independent peer review, the RP responds to review criteria affirmatively or negatively and explains the rationale for the response. In addition, the RP may decide to respond to more than one criterion or the totality of criteria. Responses to questions that were not asked or descriptions outside the scope of peer review are seldom if ever helpful.

Review reports

The *Technical Peer Review Report* with the subtitle *Report of the Review Panel* contains the results of the peer review. Typically the report should consist of the following items:

5. Introduction describing activities that led to the preparation of the report, including a listing of submitted documents.
6. Executive Summary.
7. Summary of the subject that was reviewed.
8. Peer Review Criteria.
9. Findings of the Panel consisting of shortcomings and meritorious aspects of the project. Note that often Review Criteria and Findings are combined.
10. Recommendations of the Panel.
11. References.
12. Appendix containing significant comments of one reviewer which were not shared by others, or those that were considered to be beneficial to the Project Team, but were not important enough to be included in the main body of the report.
13. Biographical Summary of the members of the RP and the PROC and others who had significant technical impact in preparing the report.

Note that for competing submissions or other reviews containing proprietary information, provisions must be made to modify the process. Such a process is in place in the ASME/RSI independent peer review process.

Ideally the *Technical Peer Review Report* is not completed with the *Report of the Review Panel.* It should be incumbent upon the sponsoring organization to respond to the recommendations of the RP. If such a procedure is followed, the addition of the response of the sponsoring organization converts the subtitle to *Interim Report.*

The *Interim Report* is converted to *Final Report* after the PROC reviews and approves the *Report of the Review Panel* and accepts the response by the sponsoring organization.

Transparency of Peer Review

One of the major reasons for mistrust of the scientific foundation of many regulations is the lack of transparency of the peer review process. Transparency of peer review implies that members of the public notably the stakeholders are as informed about the entire peer review proceedings as is the sponsoring organization. This requirement implies that information which is provided to the RP is made public at the same time that it is provided to the RP. It also implies that meetings of the RP, except its executive sessions when the RP writes its report, are open to the public. It also implies that any information about the review process, members of the RP, and any other information which is provided to the sponsoring organization is also provided to the public. The only exception to the transparency requirement is the distribution of proprietary and classified information to the public.

Public participation is a legally-mandated process and often requires a public hearing where every entity individual or corporate can participate. In contrast to public participation, stakeholder participation if properly managed is significantly more structured by identifying and addressing stakeholders′ concerns about the issue at hand. On more than one occasion, arguments have been heard by stakeholders who consider their participation as window dressing. Conversely, many decision makers are often concerned by some stakeholders who believe that their recommendations *must* be adopted by the decision makers.

Stakeholder participation is particularly important in issues involving scientific decisions. Most stakeholders are highly critical of those organizations responsible for making scientific decisions, particularly U.S. agencies and industry. Consequently, stakeholder participation in independent peer reviews is a key to the acceptability of the final decision.

OTHER RELEVANT SUBJECTS

Management of an independent peer review requires attention to many more details than is described in this document. For example, in a large-scale project, no reviewer should be used more than two to three times during the life of that project. If so, the Project Team tends to pander to idiosyncrasies of individual reviewers. Similarly, members of the RP should include senior individuals who may have broad knowledge, as well as junior investigators who have detailed knowledge of a specific subject, but may not have the experience and wisdom of more senior investigators. Finally, maintenance of the integrity of the review requires that members of the RP avoid private interactions with members of the Project Team.

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The following list covers references used in preparation of this document. It is intended as a general list covering the entire subject rather than a specific topic in the text. However, it covers all subjects discussed in the text.

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