Manual

for

Independent Peer Reviews

and

Independent Scientific Assessments

Institute for Regulatory Science
Alexandria, Virginia
www.nars.org

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Preface

This manual was prepared initially prepared in 1996, revised in 2000, again in 2005 and most recently reevaluated in 2009. It is based on the experience of the authors going back to 1977 and most recently between 1996 and 2005. Much of this guide resulted from the cooperation between the staff of the Institute for Regulatory Science (RSI) and a large number of individuals and organizations notably the American Society of Mechanical Engineers (ASME also known as ASME International.

This manual has been applied to independent peer reviews, independent scientific assessments (also known as independent technical assessments), a series of other activities collectively referred to as technical reviews. In other words it is extensively field tested.

The number of individuals involved in the development of this manual too large to be mentions here. These include Clyde Frank, Gerald Boyd, Anibal Taboas, and Yvette Collazo of the U.S. Department of Energy. Other individuals included members of the ASME Peer Review Committee consisting of Charles O. Velzy, Ernest L. Daman, Nathan H. Hurt, Gary A. Benda, Erich W. Bretthauer, Irwin Feller, Robert A. Fjeld, William T. Gregory, III,Peter B. Lederman, Jeffrey A. Marqusee, Lawrence C. Mohr, Jr., Goetz K. Oertel, Glen W. Suter, II, and Cheryl A. Trottier

We were fortunate to have access to a large number of RSI staff who supported us. We are most grateful to all of them and numerous others who made the preparation of this guide possible

A. Alan Moghissi
B. Betty R. Love
C. Sorin R. Straja

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INTRODUCTION

The purpose of this manual is to describe the peer review and technical assessment processes developed by the Institute for Regulatory Science (RSI) in support of activities performed by government agencies at federal, state, regional, or local levels; various segments of the industry; and other organizations. It is based on a number of policies, statements, and traditions of various segments of the scientific community including the engineering community. Consistent with the historic tradition of science, the RSI peer review and scientific assessment processes are intended to provide an unbiased, independent, accurate, economical, and timely response to those organizations needing support on specific actions.

Although peer reviews and scientific assessments have a great deal in common, there are significant differences between them. Peer review provides a critical evaluation of a scientific or engineering product. The product may be a completed study; a paper; the outline of study; a research program; scientific foundation of a regulation or a standard; or any other activity that has a product that can be evaluated. In contrast to peer review, a scientific assessment provides a product to the sponsoring agency. Often the sponsoring agency needs advice on a specific subject. Consequently, during the scientific assessment process available existing information is gathered and critically assessed. Simply stated, whereas in a peer review a product is evaluated, an assessment consists of generation of new product.

ACTIVITIES BENEFITTING FROM PEER REVIEW AND SCIENTIFICASSESSMENT

For the purpose of this manual, any product or activity that is subjected to peer-review is referred to as a project. In contrast scientific assessment covers a subject. The traditional peer review of a project as performed routinely by many scientific and engineering organizations for their technical publications may have to be modified to accommodate the unique needs of each government agency, industrial operation, or research organization. Similarly, scientific assessments, as performed by certain technical organizations are also likely to require modifications. However, there are certain activities that would clearly benefit from peer review or scientific assessment as demonstrated by the following examples:

1. Many agencies have or must develop programs to accomplish a certain goal. Peer review or scientific assessment provides a reasonable method to ensure that the approach and implementation of the program are consistent with the desired goals. On occasion, the agency identifies the parameters of a program and asks for the review of existing approaches for the development of its desired program.

2. Government agencies and others routinely undertake the construction of large-scale projects. The objective of these projects may be to advance science and technology or to improve the quality of life. Peer review ensures that during the design and construction of the project, the underlying science is sound, the chosen technologies are appropriate, the road-map is reasonable, and correct economic principles are used.

3. Often agencies support competing technologies to ensure the availability of an option if one technology fails to meet its predicted performance. Depending upon the desire of the sponsoring

agency, the evaluation of competing technologies and the selection of the most promising technology can benefit from peer review or scientific assessment.

4. Many government agencies—including the U.S. Department of Energy and the U.S. Department of Defense—have facilities requiring environmental restoration. There are numerous other government agencies at the state or local level, as well as numerous industrial facilities, facing the same problems. Evaluation of technological needs; evaluation of available technologies and needed technology developments; and optimization of engineering processes are subject to peer review or scientific assessment.

5. A major function of certain government agencies at the federal, state, regional, and local levels is the promulgation of regulations. A number of these regulations are based on the evaluation of available scientific and engineering information. Peer review or scientific assessment provides the necessary tool to ensure that sound scientific and engineering principles constitute the foundation of the regulation.

6. The regulated community is often faced with compliance to requirements that are subject to different scientific and engineering interpretation. Potentially-available options and their respective performance; cost-effectiveness; and numerous other topics are advantageously subjected to peer-review or scientific assessment. Because the needs of various organizations are not always foreseeable, the peer review and scientific assessment systems must be flexible enough to accommodate these needs as they arise.

7. Once a technology reaches a certain level of maturity, the supporting agency must make a decision on whether it should continue funding the work. The potential for success of that technology, based on specific parameters, is subject to peer review.

8. The results of research and development are often published in the form of internal reports. The scientific acceptability of information included in these reports can be peer-reviewed much like publications of professional societies.

9. A number of government agencies, industrial concerns, and foundations support research and development in specific areas of science and engineering. Often, the amount of funding requested by applicants is larger (in some cases, significantly larger) than available funds. Peer review provides a mechanism not only to evaluate the scientific acceptability of specific proposals but also to rank them in accordance with predetermined criteria.

10. A number of agencies routinely prepare requests for proposals (RFPs) and requests for applications (RFAs). Peer review provides a reasonable method for evaluation of the validity of the technical criteria of RFPs and RFAs; responses to them; and the prioritization of various responses based on specific technical criteria.

STRUCTURE OF THE PEER REVIEW AND SCIENTIFICASSESSMENT PROGRAMS

The RSI peer review and scientific assessment processes are based on a tiered system. For each specific area, the entire process is overseen by an Oversight Committee. If necessary, the Oversight Committee includes an Executive Panel (EP) that is responsible for the day-to-day operations of the Oversight Committee. The review

or assessment of a specific topic is performed by a Review Panel (RP) or an Assessment Panel (AP) that is formed to perform the specific task, and is disbanded once the task is completed.

Oversight Committee

Each Oversight Committee is formed to oversee peer review or assessment of a particular program in an agency or organization. Its members are chosen on the basis of their education, experience, contribution to their respective field, and peer recognition. An attempt is made to ensure that all needed competencies and diversity of scientific views are represented in the Oversight Committee. Specific functions of the Oversight Committee include the following:

1. As the overseer of the entire peer review or scientific assessment, the Oversight Committee enforces all relevant policies including compliance with professional and ethical requirements.
2. It approves the appointment of the members of RPs or APs based on criteria described under the section AReview and Assessment Panels@. However, it may authorize the EP to provide a provisional approval that must be reviewed for endorsement at its next meeting.
3. It reviews and approves peer review or assessment reports in various stages of their development.

If necessary, some of its approval functions can be performed by mail or electronic communication.

Executive Panel: In certain cases, it is impractical for the Oversight Committee to oversee the day-to-day operations of the peer review or scientific assessment program. For example, if the size of the Oversight Committee is large, an EP is formed to oversee the day-to-day operations of the program and act on behalf of the Oversight Committee between its meetings. It consists of three to five members and meets more frequently than the Oversight Committee, but most of its operations are performed by teleconference and correspondence (i.e., mail, fax, e-mail).

Peer Review and Scientific Assessment Panels

The scientific assessment of a subject or peer review of a project is performed by an Assessment Panel (AP) or Review Panel (RP). The number of individuals constituting a Panel depends upon the complexity of the subject to be reviewed or assessed. However, typically, a Panel consists of at least three individuals and, depending upon the nature of the subject, may be significantly larger. Members of a Panel must have appropriate qualifications in the area being reviewed or assessed and their selection is to be based on the competencies required for the review or assessment. Although every review or assessment is unique, it is desirable to establish a guide on the nature of the process. Accordingly, the following types of Panels are established:

Type I: Document Review (RP): Panels established for this Type perform the review of a document without the requirement of meeting at a location.

Type II: Single Project (AP or RP): Panels established for this Type will meet and perform a review or assessment of one project.

Type III: Complex or multi-projects (AP or RP): Panels established for this Type consist of at least five individuals who will meet and perform a review or assessment of a complex project or several similar projects.

Type IV: **Review of Competing Submissions; (RP):** Panels established for this Type review competing submissions such as grant proposals. The number of individuals constituting this Type depends upon the number and nature of submissions. However, each submission must be reviewed by at least three individuals who perform the review. Depending upon the desire of the sponsor, a part or the entire report resulting from the peer review will be designated as proprietary.

Type V: **Visiting Panels (AP or RP):** Panels are established for this Type to visit specific facilities and review or assess the planning, operation, and other aspects of specific projects at that facility.

Type VI: Classified (AP or RP): Panels are established for this Type to review or assess classified information. Again here, although this Type may follow the Type II or Type III process, the meeting of the RP is closed to all but those with appropriate clearance. Furthermore, depending upon the desire of the sponsor, a part or the entire report resulting from the effort will be designated as classified.

Type VII: Rapid Response (AP or RP): Panels established for this Type provide a review or an assessment of a limited technical issue requiring a rapid response.

Peer Review Reports

Each member of the RP is expected to participate in the preparation of a report containing the outcome of the review. The comments of the members of the RP are subsequently combined into a *Report of the Review Panel*. The *Report of the Review Panel* contains some or all of the following parts:

1. The introduction or preface describing activities that led to the preparation of the *Report of the Review Panel*
2. An executive summary of the report
3. A description of the peer review process
4. A summary of the subject that was reviewed
5. Review Criteria and Findings of the RP consisting of shortcomings and meritorious aspects of the project
6. Recommendations of the RP
7. References to documents used during the review
8. Biographical summaries of members of the RP, the Oversight Committee, and others who participated in the review
9. Appendix containing the comments by each reviewer upon which no consensus could be reached; or were considered to be beneficial to the investigators and managers but were not important enough to be included in the main body of the *Report of the Review Panel*

On occasion, it may be more convenient to combine a set of *Reports of the Review Panel* into one report. For example, peer reviews performed for one agency during a given period can be combined. In these cases, the report is appropriately modified.

Scientific Assessment Reports

Each member of the AP is expected to participate in the preparation of a report containing the outcome of the assessment. The contributions of the members of the AP are subsequently combined, coordinated, and edited

into a *Report of the Assessment Panel*. This report contains some or all of the following parts:

1. The introduction or preface describing activities that led to the preparation of the *Report of the Assessment Panel*
2. An executive summary
3. A description of the scientific assessment process
4. Several sections describing relevant information on the topic that is being assessed
5. Assessment criteria and Findings of the AP responding to the assessment criteria
6. Recommendations of the AP
7. Specific recommended actions derived from Recommendations of the AP
8. References to documents used during the assessment
9. Biographical summaries of members of the AP, the Oversight Committee, and others who participated in the assessment
10. Appendix containing minority views, if any

Selection of Members of Oversight

As a general rule, RSI cooperates with a number of professional societies of scientists and engineers to appoint the Oversight Committee. In these cases, the EP is expected to be appointed among the members of the respective professional society with the necessary qualifications. However, other members of the Oversight Committee are selected entirely based on their competency, with no other requirement.

On occasion, it becomes necessary to establish an Oversight Committee that could not be formed by a professional society. In these cases, RSI establishes a Commission for Assessment and Reviews (CAR) to perform the necessary oversight. Members of CAR are chosen on the basis of their participation within various professional societies and other scholarly organizations in relevant activities.

Selection of Reviewers

The key to the success of every peer review is the selection of qualified reviewers. The selection of a reviewer must be based on the totality of qualification of that individual. However, there are several generally-recognized and fundamental criteria for evaluating qualifications of a member of an AP or RP as follows:

1. Education: A minimum of a B.S. degree in an engineering or scientific field would be required for any peer reviewer. In practice, the reviewers are likely to have advance degrees.

2. Professional Experience: Because of the rapid advancement of science and engineering, often relevant professional experience is as important as or more important than earned degrees. Consequently, significant experience in the area that is being reviewed is necessary.

3. Peer Recognition: Election to office of a professional society; serving on scientific committees of scholarly organizations; relevant awards; and similar activities are considered a demonstration of peer recognition.

4. Contribution to the Profession: The individual=s contribution to professional advancement may be demonstrated by publications, particularly those in peer-reviewed journals. In addition, patents and similar

activities are also considered.

RSI has an extensive database on potential members of APs and RPs which is updated continuously. Accordingly, RSI welcomes nominations of potential members of a specific RP or AP. The names of these individuals are subsequently added to the RSI database from which individuals are chosen for nomination as members of the RP or AP.

CRITERIA FOR PEER REVIEW

The Findings of the RP are responses to specific questions called review criteria, review questions, or lines of inquiry. Experience has shown that sponsoring agencies would benefit from the availability of general guidelines for selection of project-specific review criteria. The following general criteria provide guidance to the sponsoring agency for preparation of project-specific review criteria:

1. **Scientific and engineering validity:** By far the most important aspect of any project is its consistency with established scientific and engineering principles and industry standards.

2. **Relevancy:** All projects supported by a sponsoring organization must be relevant to its needs.

3. **Competency:** Those who propose to perform a project must have sufficient competency to be able to accomplish the proposed tasks.

4. **Facilities:** Those who propose to perform a study must have demonstrated access to facilities commensurate with the requirements of the study.

In addition to these criteria, other criteria may be considered as follows:

5. **Regulatory acceptability:** If a study includes a subject which requires regulatory compliance, this criterion must be considered during the peer review.

6. **Reducing human health and ecological risks:** If a project is associated with a potential exposure to materials that pose a human health risk, reduction of risk to the general public or the workers is an important parameter in peer review. Similarly, a reduction of risk to the ecological system can be a parameter in peer review.

7. **Cost-effectiveness:** Cost assessment of a decision is an exceedingly important and often neglected parameter. The cost of a decision for a given level of risk is subject to peer review. Similarly, the life

cycle cost of a technology is an important criterion for its desirability.

CRITERIA FOR SCIENTIFICASSESSMENTS

Much like peer review, the Findings of the AP are responses to specific questions called assessment criteria, assessment questions, or lines of inquiry. In contrast to review criteria, it is difficult to provide guidance to the sponsoring agency for preparation of specific assessment criteria. However, as a general rule, scientific assessments deal entirely with scientific and engineering questions and exclude societal decisions.

CONFLICT OF INTEREST

One of the most complex and contested issues in peer review and scientific assessment is a set of subjects collectively called Aconflict of interest@. The ideal member of the RP or AP is an individual who is intimately familiar with the subject and yet has no monetary interest in it. Despite this apparent difficulty, the scientificCincluding the engineeringCcommunity has successfully performed peer reviews and scientific assessments without having a real or an apparent conflict of interest. The guiding principle for conflict of interest in peer reviews is as follows:

Those who have a stake in the outcome of the review may not act as a reviewer or participant in the selection of the reviewers.

This principle applies not only to peer-reviews but also to scientific assessments. The RSI has a well-established process to implement the guiding principle of conflict of interest. Everyone who participates in the RSI peer review or scientific assessment program must sign a statement indicating a lack of personal or financial interest in the outcome of the review or assessment. The statement appears as an Appendix to this manual.

For obvious reasons, conflict of interest is most severe for members of the Oversight Committee particularly for members of its Executive Panel. Because of the large number of projects that may be reviewed by the Oversight Committee, it is not always predictable if a member may have a conflict of interest in participating in the review of a future project. Accordingly, the RSI peer review program has provisions for a member of the Oversight Committee to be recused from participation in a specific project.

The management of conflict of interest is significantly simpler for members of the RPs or APs because the projects are reasonably well-known and narrowly defined in advance of formation of the RP or AP. However, the process of recusing members of the RP or AP is identical to that for members of the Oversight Committee.

This does not preclude their attendance and participation at any meeting of a committee or other body on the same basis as any nonmember of the committee or other body.

COOPERATION WITH PROFESSIONAL SOCIETIES

The RSI staff has a long-standing association with a number of professional societies. As a general rule, RSI

attempts to rely upon professional societies to establish an Oversight Committee. Alternatively, RSI relies upon professional societies to identify qualified individuals to participate in the CAR.

STAKEHOLDER PARTICIPATION

There is ample evidence suggesting that participation of stakeholders enhances the appreciation of the decision process. In particular, the participation of stakeholders in peer review increases the probability of their acceptance of solutions resulting from the peer review. The review criteria are the scientific issues of concern to the stakeholders. Consequently, these criteria should consider stakeholder concerns. Experience shows that comments by the stakeholders are taken seriously by the Review Panels and thus provide a powerful incentive for stakeholder participation. The impact of comments by the stakeholders is the major reason for their acceptance of the results of peer review.

RSI has developed a stakeholder participation process and has implemented it in a number of peer reviews. This process is based on the notion that stakeholder participation must be based on a reasonably clear identification of stakeholders and how they can be reached. Briefly, the RSI process categorizes stakeholders into four groups: 1) personally impacted, 2) administratively impacted, 3) generally concerned, and 4) process concerned stakeholders. In addition, the RSI process provides approaches on how to reach each group, and provides appropriate rules for their participation.

IMPLEMENTING PROCEDURES

In addition to this guide, RSI has developed procedures of the day-to-day operation of peer reviews and scientific assessments. The RSI procedures supplement this guide and include certain details of various aspects of the program. The RSI procedures are divided into five distinct categories as follows:

1. Oversight of the Program
2. Preparation for Peer Review
3. Operation of the Panels
4. Preparation of the Reports
5. Other aspects of the Program.

The procedures include numerous forms that are used in conjunction with the program.