PURPOSE, SCOPE, AND ACTIONS OF OVERSIGHT PANELS AND THEIR ROLE IN THE DECISION-MAKING PROCESS: THE U.S. ENVIRONMENTAL PROTECTION AGENCY'S SCIENCE ADVISORY BOARD

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ABSTRACT

The Science Advisory Board advises the Administrator of the Environmental Protection Agency on a variety of science and science policy issues. The Board is made up of scientists and engineers drawn as needed from the private sector, state and local government, public interest groups, and academia. The Board serves as one of several peer-review and public comment mechanisms of the Agency. As a Federal Advisory Committee, its meetings are open to the public, all documents sent to or prepared by the Board are available to the public, and public comment on the issues under review is encouraged. While some of the Board's work is required by legislation and some is initiated by the Board, about 90% of the Board's reviews respond to Agency requests. In the three year period Fiscal Years 87-89 the Board produced 117 reports, of which 14 were on radiation-related issues.

The Board has prepared two reports on radioactive waste disposal. In January 1984, the Ad Hoc High Level Radioactive Waste Disposal Subcommittee issued its report on the review of proposed environmental standards for the management and disposal of spent nuclear fuel, high-level and transuranic radioactive wastes (40 CFR 191). In 1986, the Radiation Advisory Committee issued a report on its review of the Background Information Document on Low-Level Radioactive Waste Disposal. Other SAB Committees have reviewed issues relating to waste management.

The Radiation Advisory Committee is currently developing a resolution encouraging EPA to develop guidance on residual radioactivity at waste disposal sites. As of this writing the SAB has no plans to review documents relating to the remanded High-Level Radioactive Waste Standard

INTRODUCTION

A little background on the Science Advisory Board will provide the context for a brief history of the Radiation Advisory Committee's activities in the radioactive waste management area, its plans for FY91, and the presentation of factors which associated with successful reviews. These remarks are based on seven years work on the Science Advisory Board staff; they were not prepared on behalf of the Environmental Protection Agency or its Science Advisory Board.

PURPOSE

According to its charter, the Science Advisory Board (SAB) exists "to provide advice to EPA's Administrator on the scientific and technical aspects of environmental problems and issues." The Board operates under the Federal Advisory Committee Act, announces its meetings in the Federal Register, holds public meetings, accepts public comment, and makes its final reports available to those who request them. (1)

OPERATIONS

The Executive Committee serves as a gate for the Board. It accepts requests for reviews on behalf of the Board and it approves final reports prepared by SAB committees. The EC sometimes coordinates reviews and identifies cross-cutting issues which might be worthy of separate study. In addition to the Executive Committee, the Board has eight standing committees:

1. Clean Air Scientific Advisory Committee
2. Drinking Water Committee
3. Ecological Processes and Effects Committee
4. Environmental Engineering Committee
5. Environmental Health Committee
6. Indoor Air Quality/Total Human Exposure Committee
7. Radiation Advisory Committee
8. Research Strategies Advisory Committee

Each committee can form subcommittees as needed. The Board is supported by a small staff of EPA employees and both Board and Staff are organizationally located in the Administrator's office.

The Board does not--cannot--review every important environmental issue facing EPA and is not the only source of scientific advice available to the Agency. Unlike some advisory committees, the SAB does not create a document for the Agency's use based on a review of original data, the SAB responds to documents prepared by Agency staff. Other options available to the Agency include the National Academy of Sciences; bodies of federal employees such as the Toxic Substances Control Act Interagency Testing Committee and the Federal Coordinating Council on Science, Engineering, and Technology; other FACA committees at EPA such as the Federal Insecticide, Fungicide, and Rodenticide Act's Science Advisory Panel and the National Advisory Council for Environmental Technology Transfer; the use of technical consensus developed by in-house experts through the Risk Assessment Forum; and through

various consulting agreements with various individuals and institutions.

How do issues come to the Board for review? Sometimes review requirements are written into the law as in the Clean Air Act and Safe Drinking Water Act. Some reviews are requested by the Administrator or are initiated by the Board itself, but 90% of the time, the Board responds to requests for review from the program offices. The Board, its committees, and subcommittees together hold about 60 meetings a year, producing about 40 individual reports.

In the 1970s and early 1980s much of the Board's "business" was with the Office of Research and Development. (4) Because the Clean Air Act Amendments in 1977 required that criteria documents for the national ambient air quality pollutants be given to the SAB's Clean Air Scientific Advisory Committee for review, the Office of Air Quality Planning and Standards also worked a lot with the Science Advisory Board.

Following the return of William Ruckelshaus to the EPA in 1983, the SAB found itself in increasing demand. The number of reviews conducted each year rose from 10-13 in 1980-1984 to 28-41 in 1985-1988 and has remained at the 35-45 reports a year level since. (1) Parts of the Agency which had never before sought advice of the Science Advisory Board, such as the Superfund Office, came to the Board and requirements for SAB review were written into additional laws, such as the Safe Drinking Water Act Amendments. As the number of requests rose, the Board was able to become somewhat selective in what it reviewed. While the Board retains the flexibility to address issues that arise during the year, having a good idea of workload and issues helps the organization set its priorities. A recent piece on the history of the SAB credited Ruckelshaus with reducing the tension between regulators and scientists.

> "Ruckelshaus had come back to the Agency with a formula designed to bridge the science-policy gap. In an important speech to the National Academy of Sciences in June 1983, less than two months after his reappointment. . . Ruckelshaus (said), 'Science and the law are thus partners at EPA . . . but uneasy partners. . . . The main reason for the uneasiness lies . . . in the conflict between the way science really works and the public's thirst for certitude that is written into EPA's laws. Science thrives on uncertainty . . . . But EPA's laws often assume, indeed demand, a certainty of protection greater than science can provide with the current state of knowledge.'" (4)

Earlier that year the National Academy of Science's Risk Assessment in the Federal Government: Managing the Process set out a framework for risk assessment. At EPA this is often called the risk assessment-risk management paradigm. The paradigm provided an intellectual framework for defining what was legitimately the role of the Science Advisory Board (risk assessment) and that of the Agency (picking regulatory numbers or strategies). Both the Agency and the Board seemed willing to abide by the distinction and Risk Assessment and Management: Framework for Decision Making (5) was routinely sent to new members. This "separation . . . achieved a breakthrough and created grounds for easing . . . tension" between scientists and regulators. (4)

Another improvement in EPA/SAB working relationships came with the June 25, 1985 memorandum from then Administrator Lee M. Thomas which required that the Agency respond in writing to the recommendations of the Board. In the 1980s the Board worked more with the Agency, the risk assessment-risk management paradigm appears to have made those interactions less tense, and the Agency (because of the Thomas memorandum) appeared more responsive.

Administrator Thomas also invited the Science Advisory Board to undertake a review of long-term research at EPA resulting in the 1988 report, Future Risk (6). This highly visible and well received report departed from the more risk assessment oriented SAB reviews of the past as described by historian, Perry Bush,

> In this report the SAB demonstrated the kind of impact it could have when given latitude to look ahead on its own and point to problems coming down the road. Indeed, in its conclusions and the ten specific recommendations it offered, the Committee furnished a road map for the EPA's environmental agenda for the next decade."(4)

The next EPA Administrator, William K. Reilly, invited the SAB to review the Unfinished Business report, a comparative risk study released by the Agency in 1987. In its review, the SAB "attempted to achieve four objectives:

1. Critically review Unfinished Business, reflecting any significant new information that bears on the evaluation of risks associated with specific environmental problems.
2. To the extent possible, merge the evaluations of 1) cancer and non-cancer risks and 2) ecological and welfare risks.
3. Provide optional strategies for reducing the major environmental risks.
4. Develop a long-term strategy for improving the methodology for assessing and ranking environmental risks and for assessing the alternative strategies that can reduce risks." (7)

The Board recognized, "that this . . . report . . . contain(s) policy-oriented findings and recommendations that are outside the normal scope of SAB purview. But in this case the EPA Administrator explicitly asked the SAB to

review, from a technical and scientific perspective, the optional strategies available for reducing risk. Thus this report includes recommendations on approaches to risk management and on the future direction of national environmental policy." (7)

Those interested specifically in radiation may be interested in the chart published in Science magazine which compared the top risks as the SAB saw them in 1990 with public concerns. Radiation from radioactive wastes, which was ninth on the list of public concerns, did not make it onto the list of "EPA's Top 11". (8) The SAB identified risks to human health which addressed major types of human exposure. Radon is specifically mentioned on this list as are pollutants in drinking water; radionuclides in drinking water were not separately addressed. Radionuclides were listed as a relatively low-risk problem in terms of risks to the natural ecology and human welfare. (Welfare in this context includes economics, but not health.) (7)

SCOPE

The Science Advisory Board's scope ranges from review of the design of research plans (such as the review of the Radon Mitigation Test matrix) to consideration of the scientific basis for a regulation and (such as criteria documents for the National Ambient Air Quality Standard pollutants), on occasion, policy recommendations (as in Future Risk and Reducing Risk). Relatively little of its work is on radiation issues; in the three year period FY87-89 the Board produced 117 reports, of which 14 were on radiation-related issues. (1)

ACTIVITIES AND HISTORY OF THE RADIATION ADVISORY COMMITTEE

In the early 1980s there were three ad hoc committees of the Science Advisory Board which reviewed radiation issues. These issues were biological effects of radiofrequency radiation, a hazardous air pollutant regulation for radionuclides, and high -level radioactive waste disposal. The SAB's report on the radionuclides NESHAP included two far reaching recommendations. (9)

1. The Agency should assemble and integrate the available information into a risk assessment that provides a scientifically sound basis for regulatory decisions.
2. The SAB should form a standing committee to provide continuing advice to the Agency on radiation matters.

Each of these ad hoc committees worked hard and long to conduct their reviews. The SAB's High-Level Radioactive Waste Disposal Subcommittee's thirteen members met publicly nine times between its first meeting in January 1983 and its final report in January 1984--and its seven subgroups had many other informal meetings. Their report addressed many issues, including:

1. a ten-fold increase in the release limit specified in the proposal,
2. modifications to the probabalistic release criteria,
3. retention of the 10,000 year time frame for determining the adequacy of repository performance,
4. retention of a population risk criterion as a performance measure,
5. establishment of an interagency council to coordinate the development of high-level radwaste policy, standards, etc.
6. various research needs,
7. the use of conservative assumptions in risk assessment,
8. the use of radioactivity in natural waters and ambient radiation for comparison with risk from radwaste disposal,
9. shortcomings in the economic analysis, and
10. improvements to EPA's analytical methodology and modeling. (10)

The eight member Radiation Advisory Committee, which was formed as a result of the radionuclides NESHAP subcommittee's recommendation met for the first time in February 1985. Dr. William J. Schull from the University of Texas chaired the Committee and Drs. Terry Lash and James Neel who had been on the High-Level Radioactive Waste Disposal Subcommittee were members. Members of the other two ad hoc subcommittees were also included.

This was before radon was recognized as a problem by EPA and the first issue brought to the Committee by the Office of Radiation Programs was the review of a background information document for low-level radioactive waste disposal. This request demonstrated that the Agency had accepted at least some of the recommendations of the earlier subcommittees--a separate document presenting the scientific analyses had been prepared for public review (not just the rule) and the advice of the Board was being sought on a radiation matter. The Agency formally responded to the Committees recommendations by letter after the report was transmitted to the Administrator.

In 1988 and 1989, the Committee looked at the Agency's plans to revise the Radionuclides National Emissions Standard for Hazardous Air Pollutants (NESHAP) and the proposed revisions. While this review was not directed at the disposal of radioactive wastes, EPA included phosphogypsum piles, DOE facilities, Nuclear Regulatory Commission licensed facilities, underground uranium mines, uranium mill tailings, and high-level waste management among the sources and releases it addressed. (11)

The Radiation Advisory Committee is now considering a commentary on residual radioactivity. A commentary is an SAB term for, "advice you didn't ask for and are going to get anyway." The current draft suggests that the Agency

consider the following technical issues in developing guidance on residual radioactivity:

1. types and forms of radioactive substances at waste disposal sites,
2. protocols for exposure assessment and risk estimation that recognize both spatial and time dimensions associated with radiological contaminants,
3. the degree to which other contaminants may enhance or inhibit migration of radionuclides, and
4. feasible technical approaches for stabilization, fixation or removal of radionuclides.

The Committee is also reviewing the Office of Radiation Programs' Idaho Radionuclide Exposure Study which considers radiation exposure to (and resulting risk from) wastes from the mining and milling of phosphate ore in southeast Idaho,particularly from the use of phosphate slag in construction. Otherwise, the Committee has been largely occupied with radon-related reviews since its formation in 1985 and with occasional activities relating to nonionizing electric and magnetic fields.

As requests for Science Advisory Board reviews have increased, the Board has invited the Agency to identify the issues it would like reviewed early in the planning process so that the SAB can consider what its priorities are for the next fiscal year. While the June 29, 1990 memorandum Office of Radiation Program Director Richard J. Guimond sent to Science Advisory Board Director Donald G. Barnes identifying possible FY91 requests did not mention the high level radioactive waste standard, the topic was briefly raised at the October 1990 and February 1991 Radiation Advisory Committee meetings, and the Office of Radiation Programs will brief the Committee on its plans at the May 20-22, 1991 meeting in Montgomery, Alabama. (12)

If a review were to be requested by the Agency or initiated by the Board, the development of a charge for the review would be an early important step in framing the review. While the SAB is not limited by the charge--it may, and usually does, address additional issues--and it does not have to answer each question, a well-articulated charge helps focus the review on the important scientific issues. A charge for a high-level radioactive waste management review would probably consider the recommendations found in the SAB's earlier report (10) and the recent National Research Council Report, which recommended:

> The Environmental Protection Agency, during its revisions of the remanded 40 CFR Part 191, should reconsider the detailed performance standards to be met by the repository, to determine how they affect the level of health risks that will be considered acceptable. In addition, EPA should reexamine the use of quantitative probabalistic release criteria in the standard and examine what will constitute a reasonable level of assurance (i.e., by what combination of methods and strategies can DOE demonstrate that those standards will be met?).
>
> All other countries use only a dose requirement. In setting regulatory standards and licensing requirements, the EPA should consider using only dose requirements. (13)

In summary fashion, those are the activities of the Science Advisory Board which relate to radioactive waste management.

FACTORS ASSOCIATED WITH SUCCESSFUL REVIEWS

There is tension in the relation of scientists and regulators, of the Environmental Protection Agency and the Science Advisory Board. (4, 5, 6, 7) How can that tension be handled in ways that make a good review possible and make it possible for a review to do some good? Certainly the risk assessment/risk management paradigm has helped that EPA and SAB work constructively with one another. (4) While the practical difficulties of organizing and conducting a review on a complex and controversial topic can sometimes seem overwhelming, some comfort can be taken from Dr. Sheila Jasanoff's statement, "... that in our society there are certain shared norms of good decision-making that apply to all intellectual activity, whether it is law, policy or science." She went on to describe those norms as, "The qualities that characterize good science--integrity, critical thinking, a willingness to disclose the weaknesses in one's argument". (14)

Dr. Jasanoff, Mr. Thomas S. Burack, and the American Chemical Society together with The Conservation Foundation have identified factors which contribute to successful reviews of science in the regulatory context. (15, 16, 17) Some of these are procedural and include questions of committee formation, balance, conflict of interest, open or closed process, opportunity for fact-finding or public comment, preparation of a written report and the requirement for a written Agency response.

Timing remains an important factor in the success of a review because earlier involvement means more time for a thoughtful review and more opportunity for the Agency to implement the advice given. Furthermore, late involvement is often associated with the committee's impression that the Agency doesn't really want its advice and a tendency for risk assessment and risk management issues to be intermixed.

The ACS/TCF report addressed seven types of Agency actions and recommended peer review in certain cases, such as standard setting. The report recommended against peer review in other cases such as the granting of licenses and permits.(17) So it appears that how the Agency is going to

use the science is one important factor in whether the peer review will be successful.

The current state of science is another important factor. The amount and quality of the available scientific information, whether important new data are expected shortly, the variety of interpretations of the data held by different parts of the scientific community may influence whether consensus is possible or whether a public peer-review may actually increase the polarization of views held by scientists. (15)

CONCLUSION

No Science Advisory Board review of high-level radioactive waste management issues is planned. Should the Agency request a review of a radioactive waste disposal issue or should the Radiation Advisory Committee propose such an initiative, the Science Advisory Board's Executive Committee would consider a variety of factors in determining whether or not to undertake such a review. Criteria articulated by the Board which are used to guide the selection of SAB activities are:

1. impact overall environmental protection
2. address novel scientific problems or principles
3. integrate science into Agency actions in new ways
4. influence long-term technological development
5. respond to emergencies
6. deal with problems that transcend federal-agency or other organizational boundaries
7. strengthen the Agency's basic capabilities
8. serve Congressional and other leadership interests. (1)

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