

United States
Environmental
Protection Agency

AN SAB REPORT: A RETROSPECTIVE REVIEW OF SAB/RAC ACTIVITIES

A RETROSPECTIVE REVIEW OF SAB/RAC ACTIVITIES: A SELF-INITIATED REVIEW AND ANALYSIS OF THE REVIEWS CONDUCTED DURING THE FIRST DECADE OF OPERATION OF THE RADIATION ADVISORY COMMITTEE (1985 - 1994) IN SERVICE TO THE ENVIRONMENTAL PROTECTION AGENCY

March 30, 1995

EPA-SAB-RAC-95-009

Honorable Carol M. Browner Administrator U.S. Environmental Protection Agency 401 M Street, S.W. Washington, D.C. 20460

Dear Ms. Browner:

In 1992, the Radiation Advisory Committee (RAC), on its own initiative, undertook a retrospective review of its activities from its unofficial inception and subsequently as a stand-alone committee from Fiscal Year (FY) 85 to the present.

While the compilation of this review was underway, the Science Advisory Board (SAB) under its Chair, Dr. Matanoski, encouraged each of the SAB Committees to review its activities over the past several years as a part of the Board's FY 1994 activity to "reinvent the SAB." The intent of the retrospective review is to refresh the SAB's collective memory, identify highlights and lowlights, and generally develop a list of lessons that can suggest quality improvements in the way that the Board carries out its mission of providing the Agency with advice on scientific and technical issues coming before the Agency.

The attached report from the RAC is more extensive than requested by the SAB's Executive Committee and represents a significant effort to collect, review and learn from the Committee's experience. The Committee has been particularly fortunate to have had Dr. Oddvar F. Nygaard, former Chair of the RAC, to provide information and perspective, as well as the major part of writing and editing to make this report a reality. Dr. Nygaard is the only member of the RAC who has served continuously throughout the period of this review, which covers FY 85 to the present.

While this report has been prepared primarily for the use of the RAC and the Board in its own self study, we felt that it was important to share the report with you as well. We believe that the Agency will benefit -- as have we -- from looking back upon where we have been so as to gain insight on where we are going. We look forward to working with you to make appropriate course adjustments that may improve the process.

This retrospective review examines forty-five SAB reports focusing specifically on radiation issues. The bulk of the reports are reviews that were made at the request of the Agency, but there are also a number of self-initiated communications, some of which may have had significant impact. The topics cover a multitude of scientific, technical and engineering aspects of radiation, including estimating risks from both ionizing and nonionizing radiation, National Emission Standards for Hazardous Air Pollutants (NESHAP), radionuclides in drinking water, radioactivity management and waste disposal issues, release of carbon-14 in gaseous form from high-level waste, numerous radon-related issues (including radon measurement and mitigation, radon research recommendations, the National Residential Radon and the National School Radon Surveys, the Citizen's Guide to Radon as well as the Homebuyer's and Seller's Guide to Radon), Naturally Occurring Radioactive Materials (NORM), drinking water wastes containing NORM, quantitative uncertainty analysis for radiological assessments, and harmonizing chemical and radiation risk-reduction strategies.

Some of our reviews have contained elements that certainly "nudge" the science and policy interface. The role of SAB is principally as an advisor on the scientific and technical aspects of EPA issues. At the same time, however, we recognize that the science and policy interface is, in reality, a continuum along which an inextricable linkage of science and policy can be found at many points. We believe that we serve you and the Agency best by being aware of our principal responsibilities in the scientific and technical realm which include, when appropriate, alerting you to the technical aspects of policy choices involved.

We call your attention particularly to the "lessons learned" portion of this report (see Section 10), where we have summarized some experiences and concerns that we wish to share. Some of the main conclusions and recommendations drawn from out ten-year experience are listed below.

- 1) Independent peer review of the Agency's documents is important to ensure that the development of the Agency's environmental policies are based on strong science. The RAC believes that it serves a useful function in this regard, and that it is as a whole, through the interaction among its members, that it achieves its greatest strength.
- 2) The RAC believes that in order to best serve the Agency, it should, when appropriate, alert the Agency to the scientific and technical ramifications of various policy choices, including through the preparation of self-initiated Commentaries or reports.
- 3) The average Committee member is relatively uninformed about the SAB's overall scope of operation and appears to have minimal or no input in matters such as nomination of new Committee members and the selection of documents to accept for review.

- 4) A practical problem in the relationship between the Committee and the SAB is the periodic shortage of staff support for the preparation of Committee reports.
- 5) The Agency should make a greater effort to ensure that the documents to be reviewed have been previewed internally for overall quality, especially when prepared by outside contractors. An additional way to facilitate the Committee's effort is to make the charge to the Committee as specific and clearly stated as possible.
- 6) The Agency's response to a Committee's review constitutes a very essential feedback and it is especially important that the Agency describe its reason(s) for not following the Committee's recommendations. A potential risk to be guarded against is the assumption, or perception, that a review by an SAB committee implies a complete endorsement of the document reviewed, which many times is not the case.
- 7) The Agency, through its program offices should give the Committees early warnings about issues in which the Agency plans to involve the Committee. Since a Committee cannot be expected to address every issue that relates to its expertise, it would be useful for the Committee to be informed about such issues that it will <u>not</u> be asked to review in order that it may be able to view its involvement in the context of the Agency's overall agenda. The Committee members would also benefit from a better understanding of the EPA's organizational structure and functions, through written material or briefings by staff.

These lessons certainly suggest avenues for further development and involvement in our future relationships with the Agency and the Science Advisory Board.

In addition to the items discussed above, there are continuing concerns regarding issues and recommendations that have come up in the RAC's reviews and commentaries. A number of these have been listed at the end of Section 10.

We deeply appreciate the cooperation that the RAC has received from the Agency over the past decade. We look forward to a future that will build on that past and will improve upon what we have done together.

In closing, we would certainly be interested in receiving any reaction you might have to this retrospective study. In particular, we invite you to meet with the SAB's Executive Committee and the RAC during FY 1995 to help us plot a course that may serve the Agency even better in the future.

We look forward particularly to your thoughts on our findings and recommendations resulting from this retrospective analysis.

Sincerely,

Dr. Genevieve M. Matanoski Chair, Executive Committee Science Advisory Board Dr. James E. Watson, Jr. Chair, Radiation Advisory Committee Science Advisory Board

Dr. Oddvar F. Nygaard Past Chair and Principal Writer Radiation Advisory Committee Science Advisory Board

NOTICE

This report has been written as a part of the activities of the Science Advisory Board, a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The Board is structured to provide a balanced, expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency; hence, the comments of this report do not necessarily represent the views and policies of the Environmental Protection Agency or of other Federal agencies. Any mention of trade names or commercial products does not constitute endorsement or recommendation for use.

The Radiation Advisory Committee (RAC) wishes to acknowledge with grateful appreciation that the bulk of this report was prepared by Dr. Oddvar F. Nygaard, former Chair of the SAB's RAC. This report was initiated during the last year of Dr. Nygaard's term and was largely completed during the term of the subsequent Chair, Dr. Genevieve M. Matanoski. Dr. James E. Watson, Jr., is currently Chair of the SAB's RAC.

ABSTRACT

The Radiation Advisory Committee (RAC) of the Science Advisory Board (SAB) carried out this self-initiated retrospective review of all its reports to the Agency generated over the first decade of the Committee's existence. In addition to reviews of issues and documents presented to it by the Agency, primarily the Office of Radiation and Indoor Air (ORIA), a number of reports and shorter communications were produced on issues that the RAC believed to be important to call to the Agency's attention. Besides serving as a "road map" to the Committee's past activities, the report also serves as a mirror for the issues that have required the EPA's attention in the radiation field as well as how some of these issues have developed over the ten-year period covered by the report. Finally, the report has served as a means for the RAC to evaluate its performance over this span of time and has formed the basis for certain conclusions and recommendations relating to the Committee's interaction with the Science Advisory Board and with the Agency at large.

<u>Key Words:</u> Ionizing Radiation, Nonionizing Radiation, Radioactive Waste Disposal, Radioactivity Management, Radiation Issues, Radiation Risk, Radon Related Issues, Radionuclides in Drinking Water, Risks from Radiation Exposures, Uncertainty Analysis

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1. EXECUTIVE SUMMARY

The Radiation Advisory Committee (RAC) of the U.S. Environmental Protection Agency's (EPA's) Science Advisory Board (SAB) was established in FY 1985 as a standing committee "to review and evaluate the scientific basis and quality of the Agency's risk assessments, research, and other scientific activities related to environmental radiation."

This retrospective review examines, in Sections 3 through 9, forty-five SAB reports focusing specifically on radiation issues. The bulk of the reports are reviews that were made at the request of the Agency, but there are also a number of self-initiated communications, some of which may have had significant impact. The topics cover a multitude of scientific, technical and engineering aspects of radiation, including estimating risks from both ionizing and nonionizing radiation, National Emission Standards for Hazardous Air Pollutants (NESHAP), radionuclides in drinking water, radioactivity management and waste disposal issues, release of carbon-14 in gaseous form from high-level waste, numerous radon-related issues (including radon measurement and mitigation, radon research recommendations, the National Residential and the National School Radon Surveys, the Citizen's Guide to Radon as well as the Homebuyer's and Seller's Guide to Radon), Naturally Occurring Radioactive materials (NORM), drinking water wastes containing NORM, quantitative uncertainty analysis for radiological assessments, and harmonizing chemical and radiation risk-reduction strategies.

The primary role of the Committee has been to serve as an independent reviewer of scientific analyses used to estimate the impact of radiation on the environment and human populations for EPA's rulemaking activities, provide advice to the Agency regarding technology developments, and identify priority research, monitoring, and other scientific needs to support regulatory activities. Notwithstanding the strong emphasis on dealing with evaluation of scientific and technical issues, the Committee believes that in order to best serve the Agency, it should, when appropriate, alert the Agency to the technical ramifications of various policy choices.

We call your attention particularly to the "lessons learned" portion of this report (see Section 10), where we have summarized some experiences and concerns that we wish to share. Some of the main conclusions and recommendations drawn from out ten-year experience are listed below as follows:

1) Independent peer review of the Agency's documents is important to ensure that the development of the Agency's environmental policies are based on strong science. The RAC believes that it serves a useful function in this regard, and that it is as a whole, through the interaction among its members, that it achieves its greatest strength.

- 2) The RAC believes that in order to best serve the Agency, it should, when appropriate, alert the Agency to the scientific and technical ramifications of various policy choices, including through the preparation of self-initiated Commentaries or reports.
- 3) The average Committee member is relatively uninformed about the SAB's overall scope of operation and appears to have minimal or no input in matters such as nomination of new Committee members and the selection of documents to accept for review.
- 4) A practical problem in the relationship between the Committee and the SAB is the periodic shortage of staff support for the preparation of Committee reports.
- 5) The Agency should make a greater effort to ensure that the documents to be reviewed have been previewed internally for overall quality, especially when prepared by outside contractors. An additional way to facilitate the Committee's effort is to make the charge to the Committee as specific and clearly stated as possible.
- 6) The Agency's response to a Committee's review constitutes a very essential feedback and it is especially important that the Agency describe its reason(s) for not following the Committee's recommendations. A potential risk to be guarded against is the assumption, or perception, that a review by an SAB committee implies a complete endorsement of the document reviewed, which many times is not the case.
- 7) The Agency, through its program offices should give the Committees early warnings about issues in which the Agency plans to involve the Committee. Since a Committee cannot be expected to address every issue that relates to its expertise, it would be useful for the Committee to be informed about such issues that it will <u>not</u> be asked to review in order that it may be able to view its involvement in the context of the Agency's overall agenda. The Committee members would also benefit from a better understanding of the EPA's organizational structure and functions, through written material or briefings by staff.

These lessons certainly suggest avenues for further development and involvement in our future relationships with the Agency and the Science Advisory Board.

In addition to the items discussed above, there are continuing concerns regarding issues and recommendations that have come up in the RAC's reviews and commentaries. A number of these have been listed at the end of Section 10.

2. INTRODUCTION

2.1 Preamble

In 1992, the Radiation Advisory Committee (RAC, or "the Committee") of the U.S. Environmental Protection Agency (EPA) Science Advisory Board (SAB) decided to undertake as a self-initiated project a review and analysis of the Committee's activities since its establishment in FY 85. This review has been carried out by a member and former Chairman of the RAC (Dr. Oddvar F. Nygaard) with input from some of the other Committee members (in particular, Dr. June Fabryka-Martin, who provided extensive and valuable editing). During the latter part of 1993, the Executive Committee of the SAB asked each of the standing Committees to prepare a self-evaluation report to cover its activities. Because the RAC retrospective review at that time was well underway, the RAC decided that the report of its ongoing effort, and in particular the last section, would satisfy the request of the Executive Committee.

2.2 Historical Notes on the Radiation Advisory Committee

The SAB was originally established administratively in January, 1974, by the EPA Administrator. It was recreated in 1978 by the United States Congress as a statutorily mandated Science Advisory Board. In the first ten years of its existence there was no committee dealing specifically with radiation within the SAB. During FY 1984 a number of radiation issues emerged which necessitated the establishment of several ad hoc subcommittees of the Science Advisory Board, viz., the "High Level Radioactive Waste Disposal Subcommittee," (Chaired by Dr. Herman E. Collier, Jr.), the "Biological Effects of Radiofrequency Radiation Subcommittee," (Chaired by Dr. Charles Süsskind), and the "Subcommittee on Risk Assessment for Radionuclides," (Chaired by Dr. Roger O. McClellan). These subcommittees all submitted reports of their reviews during that fiscal year. In anticipation of other radiation issues to be reviewed, and on the recommendation of the last of the above-listed subcommittees (see later), the SAB in the latter part of FY 84 decided to establish a standing "Radiation Advisory Committee." The Committee convened for the first time on February 4, 1985. The charter for the RAC is included as Appendix C.

2.3 Overview of the Present Report

This review covers the period 1984-1994. There are several practical reasons for selecting this time frame: by the end of calendar year 1992 all but one of the original RAC members had rotated off the Committee and the original DFO was transferred to a different SAB committee. It was felt that this might be an opportune time for taking a backward look and a forward projection based on the experiences gained from the RAC's activities while some "corporate memory" still remained.

Appendix A lists the 3 forerunner reports and the 42 RAC reports that are covered in this review, listed in chronological order. The bulk of the reports relate to reviews of documents (such as Background Information Documents (BID's) for rulemaking) prepared by or for EPA,

but several (11) deal with Committee-initiated issues (commentaries and letters). Throughout the text of this retrospective review, the individual RAC reports are referred to by the sequential numbers they have been assigned in Appendix A. A list of cross-references between these reports and the Sections in which they are discussed appears at the end of Appendix A. Appendix B lists all other non-RAC generated reports that are considered relevant to this review, even though not all are cited within this report.

For the greater part (Sections 3-8), the reports are reviewed in groups of related subjects as this allows a perspective regarding the overall issues as well as the developments within an issue. A number of broader issues and generic opinions expressed by the RAC are outlined and discussed in Section 9. In Section 10, the Committee attempted to summarize some of its experiences and indicate steps that could facilitate its performance vis-à-vis the Agency.

In a number of places, reference is made to the Agency's reactions to the RAC's reports, but this is not done in a consistent manner. However, the Office of Radiation and Indoor Air (ORIA, formerly the Office of Radiation Programs, ORP), which is the EPA Program Office with which RAC has had the most frequent interaction, has recently updated its cumulative summary of its responses to the reports and recommendations submitted by RAC.

3. ESTIMATING RISKS FROM IONIZING RADIATION

3.1 Risks from Low-LET Radiation

The Radiation Advisory Committee (RAC) on a number of occasions has been asked to review EPA's risk estimates for ionizing radiations. One reason for the repeated requests is the continuous development and updating of the risk factors for radiation-induced cancers in humans resulting from the follow-up in the Life-Span Study of the Japanese populations in Hiroshima and Nagasaki who were exposed to the atomic bombs in 1945 and the periodic re-evaluations carried out by various national and international expert committees [e.g., Appendix B reports by the National Academy of Sciences/National Research Council's (NAS/NRC) committee on Biological Effects of Ionizing Radiation (BEIR), the International Commission on Radiological Protection (ICRP), and the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)]. An additional factor has been the revised dosimetry for the atomic bomb exposures, which significantly altered the calculated doses received by individuals in the two cities. Finally, as airborne radon became recognized as the greatest source of environmental radiation exposure, the estimation of risks attributable to radon became a major issue.

The RAC got its first opportunity to review EPA's radiation risk assessment in connection with the Agency's request for review of its March 13, 1985 Draft Background Information Document on Low-Level Radioactive Waste Disposal (Appendix A, Report #5). The following comments relate only to the risk assessment methodology used in this document; for further review of the document, see another section of this review. A major criticism by the Committee was that the Agency in many cases failed to draw on the most recent information available and instead relied too heavily on the National Research Council's 1980 report "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation: 1980" (Appendix B, BEIR III). For example, the (January 1985) report by the National Institutes of Health (NIH) Ad Hoc Working Group to Develop Radioepidemiological Tables (Appendix B, NIH Publ. No. 85-2748) contained updated estimates of human cancer risks as well as an approach to estimate overall uncertainty of such estimates. The Committee judged EPA's use of the averages of the values obtained from the relative and the absolute risk models, which might well produce "conservative" estimates of cancer risks, to be not preferable to what the Committee considered the "most probable risk estimate" which seemed to be the absolute risk for leukemia and bone cancer and the <u>relative</u> risk for the ten significant cancers evaluated by the NIH Working Group. The effect on the estimated risk coefficients of the ongoing re-evaluation of the Atomic-bomb (A-bomb) dosimetry had been anticipated by the Agency although there seemed to be some disagreement about the magnitude of the needed upward adjustments. The Committee further criticized EPA's treatment of genetic effects which largely depreciated the human evidence in favor of animal data and the Agency's over-interpretation of the data on teratogenic effects. Overall the document was judged useful as background for the proposed standards on low-level radioactive waste material; its heavy emphasis on the dosimetry of internal emitters relative to external radiation was found not unreasonable in the context of disposal of radioactive waste.

On reviewing various EPA documents dealing with radiation risk assessment, the RAC had several times recommended that the Agency adopt the concept of "effective dose equivalent." This entity, which had been introduced by the ICRP, is described as the sum over all tissues of the products of the dose equivalent of the tissue and a tissue-specific weighting factor which represents the fraction of stochastic risk (cancer and genetic) for that tissue relative to the total risk for the uniformly irradiated body. The Committee felt that the effective dose equivalents, rather than the dose equivalents of the specific organs, should be applied as the basis for regulations dealing with radiation exposure. In a letter to the EPA Administrator (Appendix A, Report #13), the Committee reiterated its belief and strongly encouraged the Agency to carefully examine its position on the effective dose equivalent concept, the use of which would also ensure consistency within the EPA as well as between the Agency and other government, national, and international committees. [In its response to the RAC the Agency pointed out that the concept "is most useful in implementation of regulations, but that it is limited and out-of-date and did not necessarily provide the best current assessment of risk."]

In the early part of 1988 the RAC responded to a request from EPA's Office of Radiation Programs (ORP) to advise the Agency on the reasonableness of using a range of 120 to 1200 annual fatal cancers (with a nominal central value of 400) per 10⁶ rad as an interim risk estimate for low-LET total-body irradiation. The Agency at that time was under a court-ordered deadline for rule-making under the Clean Air Act which would not allow it to wait for the publication of consensus reports from the National Academy of Sciences (BEIR-V) and the United Nations' Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), then under preparation. EPA's proposed risk estimate was based on the estimates provided by the 1980 BEIR-III report (Appendix B) and the RAC's earlier recommendation (*Appendix A, Report #5*) that the Agency adopt the relative risk model for all cancers other than leukemia and bone cancer. The partitioning of cancers among organs was based on the BEIR-III Tables V-14 and V-15 (Appendix B). The Agency expressed the hope that it would be able to incorporate any new information that might become available by the time of the final rulemaking.

In its letter report to the EPA Administrator (*Appendix A, Report #15*), the RAC's Dose and Risk Subcommittee found the Agency's proposed central estimate and range of risk acceptable "for the interim" until the anticipated consensus reports became available; in addition to the already mentioned BEIR-V and UNSCEAR documents, reports by the ICRP and the National Council on Radiation Protection and Measurement (NCRP) were known to be in preparation (Appendix B). The Subcommittee expressed the opinion that the effects of new information and new analyses, such as the recalculation of doses for individuals exposed to the atomic bomb in Japan, the increased follow-up (especially for individuals exposed as children), and the changes in the statistical model to the currently more widely accepted relative (or multiplicative) model, all would increase the estimated level of risk associated with exposure to low-LET radiation. In view of the additional information that would become available in the near future, the Subcommittee did not believe that an intensive effort to create an interim model at this time would be of lasting value to EPA. The Subcommittee also acknowledged that techniques to evaluate uncertainty inherent in the risk projection lagged behind understanding of its importance and pointed out that "these uncertainty estimates address only the uncertainties in the existing

human data and models and not those in estimating environmental sources, transport and human exposures."

In January, 1992 the issue of cancer risk from ionizing radiation was again put before the RAC, which was asked to evaluate EPA's revised methodology for estimating radiogenic cancer risks. The proposed methodology was essentially the Agency's attempt to select the best features of the different risk estimates that had been prepared by a number of national and international committees, incorporating the new data that had become available, and in particular the revised dosimetry and further epidemiological follow-up on the Japanese atomic bomb survivors. The material presented to the Committee by ORP primarily addressed the risk from low-LET radiation with only minor reference to the effects of alpha radiation.

At an initial meeting, the Committee orally informed the ORP that its preliminary analysis was sufficient to guide further work and tentatively accepted ORP's proposal to limit further consideration to the cancer risk models developed for the Nuclear Regulatory Commission (NRC) by Ethel Gilbert and for the ICRP by Charles Land and Warren Sinclair (Appendix B). At the second meeting, ORP described the procedures and risk coefficients it proposed to adopt. These were primarily derived from the risk coefficients contained in ICRP Publication 60 (released in 1991) which presented two sets of coefficients differing in the model that was used to "transport" Japanese Atomic-bomb (A-bomb) survivor data to the U.S. population: one was based on the assumption that excess relative risk would be the same in the two populations regardless of differences in baseline cancer rates, and the other that the excess absolute risk would be the same and then extrapolate a constant relative risk forward in time for the US population (this latter approach was the one used by NIH in its 1985 report on Radioepidemiological Tables). EPA proposed to adopt the geometric mean of these two sets of estimates for its tissue specific risk coefficients, with the exception of breast cancer for which it chose the risk coefficient derived by NRC from the available North American data, thus bypassing the problem of transporting breast cancer risk estimates across populations. A minimum latent period of ten years was assumed to apply for all solid tumors. In the case of individuals exposed under the age of 10, EPA proposed to use the risks for the age group 10 to 19 years at exposure for which the data were more numerous and consistent.

In the opinion of the Radiation Advisory Committee (*Appendix A, Report #36*), the Agency had considered all major analyses of the Japanese epidemiology as well as other studies of radiogenic cancer risk, and had presented a thorough and unbiased description of the strengths and limitations of the various data sets and analyses. Whereas the BEIR-V report (Appendix B) contained results that might have been given greater consideration, the risk estimates for overall cancers (upon which most regulations most likely will be based) were relatively constant among all analyses of the Japanese experience. The Committee recognized the necessity of making organ-specific risk estimates for situations involving internally deposited radionuclides that are not distributed uniformly in the body; however, it believed the Agency's documentation should make it clear that relatively larger uncertainties apply to organ-specific risk estimates than to the estimated total cancer risk. With regard to the question of assigning a dose rate effectiveness factor (DREF), epidemiological studies had not produced data in support of a dose rate effect for

cancers in humans; nevertheless, the Committee agreed that EPA's choice of a DREF of 2 for low-LET radiation was reasonable as it was consistent with current scientific judgment (cf. Appendix B, ICRP-60 and BEIR-V) and was further supported by the reduced effectiveness of low-LET radiation at low dose rates in many experimental systems.

As to risk estimation for high-LET radiation, the Committee agreed with EPA's suggested quality factor for alpha radiation for use with low-LET risk coefficients in situations where epidemiological data were not available to provide direct risk estimation for alpha radiation exposure.

The Committee commended the Agency for its intent to calculate cumulative uncertainties in its estimated risk coefficients because this undertaking was considered crucial to informed use of the risk estimates. Overall, the Committee judged the recommended methods for estimating radiogenic cancer risk to be appropriate and supportable in light of current scientific evidence.

3.2 Radon Risk Estimates

In September, 1985, the RAC was asked to review the relative risk coefficient (1.2 to 2.8%) that EPA intended to use for the interim (emergency) assessment of risk for individuals residing in the Reading Prong (PA) area where high levels of indoor radon concentrations had been detected. In its letter to the EPA Administrator, the Committee recommended a slightly wider range for a credible risk estimate than had been suggested by EPA. In response to a follow-up question, the Committee stated that it was not aware of any evidence that the risks per unit of exposure for long-term and short-term exposures would be different (*Appendix A, Report #6*).

Subsequently, the RAC was asked to review the Office of Radiation Program's (ORP's) proposed radon risk estimates, to be considered for use on part of the revised radionuclides NESHAP (see later in this report). The Dose and Risk Subcommittee this time took the position that none of the available models for lifetime cancer risk from radon exposure (Appendix B, BEIR-IV, ICRP 50, and NCRP report 78) was clearly pre-eminent, and suggested that the Agency average the results obtained with the BEIR-IV and ICRP 50 models. This averaging would have the effect of assigning a higher risk to individuals exposed as children and young adults than would be the case if the BEIR-IV model alone were used (*Appendix A, Report #16*).

In February, 1990, the Committee was again asked to review the ORP's radon risk assessment. Because the Agency proposed to use the RAC's suggested approach (involving the averaging of two models) with some minor modifications, the Committee saw no reason to alter its prior recommendation other than to suggest that the Agency emphasize the significantly greater risk to smokers than to non-smokers "to allow smokers to recognize that their overall risk may be greatly reduced by the combination of cessation of smoking and radon reduction" (*Appendix A, Report #21*). In an addendum to the report, the RAC alerted the Agency to the general lack of data supporting the assignment of a greater risk from radon to individuals exposed at an early age and recommended that high priority be given to the possible reassessment of that issue as more information became available.

During the next year, as the Agency was preparing its "Revised Citizens' Guide to Radon" (see later), such additional information had appeared when the RAC was asked, in April 1991, to review ORP's "Revised Radon Risk Estimated and Associated Uncertainties." By this time the preliminary results from EPA's "National Residential Radon Survey" (Appendix A, Report #11. See also Section 7.4) were available and the NAS/NRC had published its EPAsponsored report on "Comparative Dosimetry of Radon in Mines and Homes." On this occasion the RAC endorsed the sole use of the BEIR-IV (Appendix B) model for estimating overall lung cancer risk from exposure to radon and recommended that no adjustment be made for individuals exposed as children and young adults. While this latter point may be considered controversial, the Committee found no direct support for increased sensitivity to lung cancer from early exposures to radon; however, it suggested that the possible variation of risk with age might be addressed as part of EPA's analysis of the uncertainty range around the central estimate of radon-related lung cancer deaths in the U.S. population. In addition, because the dose-estimate for radon-related lung cancer is based on a relative risk model, the Committee recommended that EPA review the changes over time in the underlying lung cancer incidence rate, as well as changes in smoking habits (Appendix A, Report #25).

4. NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS (NESHAP)

In December, 1983, the SAB received a request to review the methodology used by the Office of Radiation Programs (ORP) in assessing human health risks from airborne releases of radionuclides. The SAB formed a "Subcommittee on Risk Assessment of Radionuclides" to carry out the review. The charge to the Subcommittee, as stated by the EPA Administrator, was (1) "to review the scientific basis of the risk assessments used to develop standards for protection from radionuclides in the environment," and (2) "to critically review the process by which the Agency estimates human cancer and genetic risk due to radionuclides in the environment.... [including] examination of the methods used to estimate the transport of radionuclides in the environment due to emissions into air, the organ doses received by persons inhaling or ingesting this radioactivity and, finally, the cancer and genetic risks due to these organ doses." A list of ten questions prepared by the ORP accompanied the Administrator's request.

The Subcommittee's report (*Appendix A, Report #3*) was in many ways a seminal one which went into great detail as to how, in the Subcommittee's opinion, ORP should develop and present a radiation risk assessment and deal with a number of other issues relating to the development of environmental radiation protection standards. In addition, the Subcommittee strongly recommended that a standing committee of the SAB be created to "provide advice on the full range of scientific activities of ORP's programs," and it even provided the charge for such a committee, thus becoming the major driving force in the establishment, in 1984, of the Radiation Advisory Committee (RAC). For these reasons, the Subcommittee's report is given relatively extensive coverage in this retrospective review.

The Subcommittee's activities can be viewed as addressing two interrelated major questions. First, did the Agency staff collect the scientifically relevant data and use scientifically defensible approaches in modeling the transport of radionuclides through the environment from airborne releases, in calculating the doses received by persons inhaling or ingesting this radioactivity, and in estimating the potential cancer and genetic risks of the calculated doses? Second, were the individual facts, calculational operations, scientific judgments and estimates of uncertainty documented and integrated in a clear and logical manner to provide risk assessment that could be used as a scientific basis for risk management purposes, i.e., standards setting?

With regard to the first question, the Subcommittee concluded that ORP had generally gathered the appropriate scientific information in a technically proficient manner for individual elements of a risk assessment. With regard to the second question, the Subcommittee concluded that ORP had not assembled and integrated this information in the format of a risk assessment that provided a scientifically adequate basis for regulatory decisions on airborne radionuclides.

The document that most nearly represented such a risk assessment, but still stopped far short, was the proposed rule for "National Emissions Standards for Hazardous Air Pollutants: Standards for Radionuclides," published in the <u>Federal Register</u> [Appendix B, Vol. 48, pp. 15076-15091, Apr 6, 1983]. By its very nature as a proposed standard, this document included an

interweaving of scientific facts and interpretation, economic considerations, and social and political value judgments. A second document, the "Background Information Document: Proposed Standards for Radionuclides," was a useful supplement to the <u>Federal Register</u> notice. However, even when the proposed standard and the background document were considered together, they were neither sufficiently complete nor organized to serve as a scientifically adequate statement of the health risks from emissions of radionuclides.

For comparison with other scientific activities of the Agency, the Subcommittee referred to the process used by the EPA in its development of the National Ambient Air Quality Standards (NAAQS). In that process the Agency had found it appropriate to prepare both a criteria document and a staff position paper and to obtain reviews by the SAB (specifically the Clean Air Scientific Advisory Committee, CASAC) of both documents. The staff position paper served as an intermediary step between the criteria document and the risk management functions of setting NAAQS.

The Subcommittee believed that the concept of a staff position paper could be readily applied to assessing radiation risk and to defining the use of scientific concepts and data in developing emission standards for radionuclides. Such a staff position paper should include the conceptual framework for assessing radiation risk, starting with identifying sources of radionuclide emissions, analyzing the movement of radionuclides from a source through environmental pathways, calculating doses received by individuals or populations, estimating genetic and somatic health effects, and presenting a statement of uncertainty in the risk estimates. This uncertainty should be expressed as central estimates with lower and upper bounds for cancer and genetic endpoints. These estimates should then be compared to available information on incidence of cancer and genetic risks in the relevant population. It might also be appropriate for the position paper or a complementary document to identify various potential levels of a standard, noting for each level if compliance could be established by direct measurements or only indirectly by modeling.

In the case of the proposed emissions standards for airborne radionuclides, a staff position paper was not prepared and the Subcommittee was uncertain as to how and to what extent the scientific data base was used to set the standard. Also, neither the scientific community in general nor the SAB was asked to review thoroughly ORP's use of scientific data in early stages of the radionuclide standards development process.

To improve the scientific basis for regulatory decisions on radiation issues, the Subcommittee recommended a number of actions, among which were:

- (1) "that procedures be established to delineate more clearly the risk assessment and risk management aspects of the total radiation standards development process,"
- (2) "that for each regulatory action considered, the risk assessment process include development of a risk assessment document that makes reference, as appropriate, to more detailed analyses found in the scientific literature,"

- (3) "that such a risk assessment document be prepared for airborne radioactivity as a basis for making any further risk management decisions on the airborne radionuclides emission standards, including promulgation of final standard(s),"
- (4) "that a standing committee be created as a part of the Science Advisory Board to review risk assessments for radiation standards and to provide advice on the full range of scientific activities of the Office of Radiation Programs" (emphasis ours),
- (5) "that procedures be developed for soliciting and receiving public comments <u>and SAB review</u> (emphasis ours) of radiation risk assessments <u>before</u> proposed standards are developed," and
- (6) "that steps be taken to enhance communication between the Office of Radiation Programs and other staff offices of the Agency and the scientific community on issues relating to risk assessment."

Responses to ORP's list of 10 specific questions were also provided.

The Subcommittee's overall conclusions and recommendations were summarized under the following four headings:

- 1) "Need for a Scientific Issues Staff Paper to Identify and Evaluate the Scientific Basis for Radiation Risk Management Decisions."
- 2) "Establishment of a Continuous Scientific Oversight Mechanism to Review Assessments for Radiation Standards and other ORP Activities."
- 3) "Integration of Risk Assessment Between the Office of Radiation Programs and Other Staff Offices Within EPA."
- 4) "Research Needs" under which were identified: development of air transport radioactivity models; continuing assessment of the Japanese A-bomb data; determination of dose-response relationships at low dose rates; validation of radiation doses estimated with models and subsequent computer codes; the ultimate development of dynamic models having applicability to specific geographic regions; and development of more sensitive methods to determine genetic damage.

In 1988, ORP presented to the RAC its plans for revising the technical basis for the revision of "National Emission Standard for Hazardous Air Pollutants; Standards for Radionuclides" (Radionuclides NESHAP). This revision was considered an important activity that could benefit from the use of new data and improved scientific techniques developed in the previous five to ten years. The RAC formed the "Sources and Transport Subcommittee" to conduct the review of the NESHAP for Radionuclides Assessment Methodologies. [The Dose

and Risk Subcommittee of the RAC had earlier in the year prepared reviews of ORP's Low-LET Risk Estimate for Regulatory Purposes (*Appendix A, Report #15*) and ORP's Radon Risk Estimate (*Appendix A, Report #16*).] The objective of the present review was to examine the scientific basis for the evaluation of source terms and radiological assessment models that were to be used in the revisions to the Radionuclides NESHAP Background Information Documents scheduled for completion in early 1989. Since no formal issues were raised by the Agency in preparation for the review, the Subcommittee, on its own, identified several topics for discussion.

Of the numerous findings by the Subcommittee (*Appendix A, Report #17*), three were highlighted to warrant the most serious attention by the Agency:

- 1) "Portions of the AIRDOS-EPA methodology are no longer state-of-the-art and must be updated to incorporate important recent advances in modeling radionuclide transport through environmental pathways."
- 2) "To date, EPA's treatment of modeling uncertainties has been qualitative rather than quantitative although state-of-the-art methods for estimating uncertainty are available."
- 3) "Best estimates with appropriate uncertainty statements should be used in all risk assessments. The best estimate should be statistically defined, according to the target population or individual, and the shape of the uncertainty distribution."

To correct these deficiencies, the Subcommittee urged the Agency to make use of qualified groups of individuals to help implement immediate and long-term improvements in model structures, uncertainty and sensitivity analyses, and model validation. Results from evaluation of similar radiological assessments were at that time available which the Agency could use to guide its immediate activities. The Subcommittee recommended longer-term efforts to substantively upgrade and maintain the Agency's radionuclide transport codes to a state-of-the-art status.

These concerns aside, the Subcommittee commended the Agency for its intentions to present radiation consequences as a function of risk level; for the initial steps taken to validate the atmospheric dispersion code within AIRDOS-EPA; and for the use of simplified models for initial screening in the case of compliance procedures. With reference to the present review, the Subcommittee reminded the Agency that very similar findings and recommendations had been presented to it in SAB's 1984 review (*Appendix A, Report #3*). The apparent lack of responsiveness on this matter by the ORP during the 4-year interval was of grave concern to the SAB. It was the opinion of the Board that some action was required to assure that future reviews would yield evidence of a more defensible scientific basis for regulatory decisions on radionuclide emissions.

The Subcommittee expressed the hope that ORP would incorporate the recommendations of the present review into the Background Information Document (BID) for the Radionuclides

NESHAP. It also reminded the Agency that the Radiation Advisory Committee had asked for the opportunity to review Volumes I and II of the new BID when they became available.

On April 26-28, 1989, the RAC met at the request of the ORP to consider the scientific merits of ORP's BID on the proposed regulatory action on radionuclides in the NESHAP that had been published in the <u>Federal Register</u> on March 7, 1989 (Appendix B). The Committee recognized that the document it had seen was not the final version and that, as a result of the court-mandated constraints under which the rulemaking had to be formulated, the Agency in its published BID may have anticipated and addressed some of the recommendations offered in the RAC's report (*Appendix A, Report #19*).

Overall, the Committee found the estimates of the health risk factors described in the BID acceptable; however, it expressed reservations about the data and arguments used to derive the risks and offered several recommendations for the improvement of the document. A series of 17 recommendations were included in the report; special attention was called to three issues that permeated most of them. These were:

- 1) the need to use the most current, relevant data available as estimates of the parameters used in the modeling process,
- 2) the establishment of a clear demonstration of the objectives of the risk assessment and the relationship of the BID to the model used to derive the overall risk, the ultimate basis for the rule-making, and
- 3) the choice of the estimates of risk used to establish standards and compliance to those standards.

The following paragraphs enlarge on these items:

The RAC had urged ORP on previous occasions to be certain that the data used to derive its estimates of risk were the most current available and, wherever practicable, to base its assessments on consensus documents such as those of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the National Academy of Science's Committee on the Biological Effects of Ionizing Radiation (BEIR), the International Commission on Radiological Protection (ICRP), and the National Council on Radiation Protection and Measurements (NCRP) (Appendix B). Customarily, the Office had followed this advice; however, in the present instance, the consensus document that had been used, BEIR-III, was under revision to acknowledge the dosimetric changes and the further follow-up that had occurred in the studies of the Abomb survivors and of the patients treated with ionizing radiation for ankylosing spondylitis. This revision would have been available soon; however, a similar reassessment by the UNSCEAR already existed. The Committee believed strongly that the credibility of the BID was compromised by its failure to reflect these recent

developments and that the BID should be revised to incorporate the newer data and their assessments.

- 2) It was difficult for the Committee to determine what the actual objectives of the risk assessment were, and it assumed that if the Committee itself experienced this, the public and the regulated community would have similar problems. For example, it was not clear whether the purpose of the risk assessment was to calculate doses and their health impact on a hypothetical, maximally exposed individual in order to establish a conservative decision, or to obtain a best estimate of the dose and health implications for a real person or population. Accordingly, it was recommended that the first chapter of the final BID state clearly and in detail the overall objectives to be accomplished by the risk assessment, and that each succeeding chapter culminate in a summary statement on how it related to the stated objectives of the risk assessment.
- 3) The Committee recognized that risk assessment is at best a tenuous art, and that estimates of hazards are commonly dependent on a variety of assumptions, many of which are of uncertain reality. The RAC and the SAB had repeatedly urged the use of best estimates and ranges in the specification of risk, and the need to provide a detailed explanation of the uncertainties in the estimates themselves. It did not appear to the Committee that this advice had been consistently applied in the BID. Therefore, the Committee reiterated its recommendation that the Agency develop its overall risk assessment on the basis of best estimates of all of the parameters involved in the modeling process, and not merely some, and that it clearly describe the uncertainties and possible biases inherent in each estimate.

This third recommendation was offered in the context of the risk assessments used to support the establishment of standards where, in the Committee's view, best estimates should always be used for all variables in the modeling process. In contrast, determination of compliance was considered to be a separate matter in which, for the purpose of demonstrating compliance well below the standard, the use of conservative values in a model would be acceptable.

5. RADIONUCLIDES IN DRINKING WATER

5.1. Drinking Water Criteria Documents

In January, 1986, EPA's Office of Drinking Water (ODW) requested that the SAB review a number of scientific issues related to its evaluation of radionuclides in drinking water. The review was referred to the RAC which formed a "Drinking Water Subcommittee" to fulfill the charge. Subsequently the SAB received a document entitled "Radionuclides in Drinking Water" (for publication in the Federal Register) and four "Criteria Documents" on manmade radionuclides, uranium, radium and radon, in addition to a memorandum that included four issues for review.

The Subcommittee offered the following comments in response to the four issues raised by the ODW (*Appendix A, Report #9*):

It recommended that the ICRP weighting factors (rather than those developed by EPA based on the BEIR-III report) should be used in calculating the effective dose equivalent because they were well established, and widely published and used. The ICRP factors had not been invalidated in any way; furthermore, they included a component for genetic risk.

In reference to uranium, the Subcommittee considered that the radiotoxic health effects (renal effects) were not sufficiently well substantiated to provide a scientifically credible basis for regulation; however, uranium should be in category A on a presumed (but not demonstrated) likelihood of carcinogenicity. The Subcommittee agreed with the non-radiotoxicity health assessment and concluded that chemical toxicity should constitute the scientific basis used for regulation. The Subcommittee agreed with the Agency that the dose-response relationship for naturally occurring alpha particle-emitting radionuclides should be considered to be linear in the dose range of interest.

Finally, although (at the time) there were no data enabling a clear scientific choice between relative and absolute risk models for most cancers, the Subcommittee believed that the Agency should use the absolute risk model for leukemia and bone cancer and the relative risk model for other sites identified as associated with radiation induction, as recommended earlier in the RAC's review of low-level radioactive waste disposal (*Appendix A, Report #5*) in 1985.

The Subcommittee also expressed the opinion that the justifications for the risk estimates in the documents were not sufficiently documented and that theses values were not consistently applied. Among technical issues, it proposed that the EPA should consider using performance specification rather than prescription of specific methods since many available procedures were equal to, or better than, those presented in the documents. The rationales for the Agency's choice of certain risk parameters, such as latency periods for some of the tumors of soft tissues and the quality factor (Q) used with different tissues, were questioned.

In regard to the risk for radium, the Subcommittee noted that the high risk estimates for leukemia and soft-tissue cancers relative to bone cancer were contradicted by epidemiological studies of radium dial painters, among whom only bone cancers and head carcinomas were found in excess over normal rates.

Finally, the RAC pointed out that radon exposure from water derives from its domestic uses, not from drinking water. It was felt that this could be emphasized further, possibly by using the term "drinking and domestic water supplies."

At the meeting of the RAC in January, 1990, the ODW presented its plans to propose regulations for radionuclides in drinking water, as directed by the Safe Drinking Water Act (SDWA). Although ODW was the lead office in this effort, it was assisted by the ORP. The RAC accepted the request to review the criteria documents and related materials as they became available, to assess their credibility and correctness, and formed a "Radionuclides in Drinking Water Subcommittee" to conduct the review. During the course of the review the following documents were received:

Drinking Water Criteria Document for Uranium, draft dated November, 1989;

External Review Draft for the Quantification of Toxicological Effects Document on Radium, draft dated July 10, 1990;

Quantitative Risk Assessment for Radon in Drinking Water, draft dated May, 1990;

Quantitative Risk Assessment for Beta Particle and Gamma Emitters in Drinking Water, draft dated May, 1990; and

several papers relating to ingestion of radon-222 and transfer of radon from drinking water to indoor air.

The ODW posed five specific questions to the Committee on uranium metabolism, risk from ingested radon, the basis for estimating the risks from radon in water, the use of epidemiological data and modeled risk estimates in evaluating radium risks, and methodology for risks from man-made radionuclides.

The Subcommittee returned a very critical review of the drinking water document (*Appendix A, Report # 26*), as reflected in the following extensive excerpts of the report:

"The overall quality of the four draft criteria documents was not good. Taken as a set, the documents are inconsistent in approach and with Agency practice in the derivation of drinking water criteria such as those for volatile organic contaminants. The Subcommittee found that recommendations from a 1987 Science Advisory Board report on its review on the basis for standards for radionuclides in drinking water (*Appendix A*, *Report # 9*) had not been addressed. Nor did the new criteria documents address

recommendations from other available SAB reports that are directly relevant (such as *Appendix A, Report #13* and the resolution on use of mathematical models (Appendix B, EPA-SAB-EEC-89-012). Technical decisions contrary to those recommended by the SAB were presented without justification and with acknowledgment of the existence of the SAB recommended alternatives. Relevant recommendations of the National Research Council's Committee on the Biological Effects of Ionizing Radiation [Appendix B, BEIR-III] were ignored or selectively adopted without explanation or rationale. Uncertainties associated with the selection of particular models, specific parameters used in the models, and the final risk estimates are not adequately addressed in any of the documents."

The following quotes from the cover letter to the EPA Administrator represent the Subcommittee's responses to the ODW's specific questions.

- a) "The estimates of the absorption, distribution, and excretion of uranium when ingested are not appropriate or supported by the data. The basis for the metabolic model chosen and the value of the gut-to-blood absorption factor (f_1) have not been adequately discussed. Furthermore, the chosen value of f_1 appears to have been arbitrarily selected from among the highest of all reported values. The uncertainties associated with parameter and model selections are not discussed."
- b) "The methods employed in the radon document do not form an appropriate basis for assessing the risks of directly ingesting water containing radon. The assumption of a tap water consumption rate of 0.66 liters per day conflicts with other Agency practice as does the assumption of a 20% volatilization loss between the tap and container. The basis for and uncertainty associated with the assumed values are not adequately addressed."
- c) "The appropriate basis for estimating risks from radon in water requires that both the direct (ingestion) and indirect (inhalation) exposure routes be carefully assessed. The EPA draft document treats both pathways; however, possible inhalation exposures to high concentrations at the point of use have not been addressed. Assessment of uncertainties is an essential component of the evaluation of both pathways. The risk estimate for exposure to airborne radon presented in the document disagrees with an Agency position paper previously submitted to the SAB for review (SAB-RAC-LTR-91-001)" [Appendix A, Report #21].
- d) "For radium, the available human epidemiologic data should most definitely be used to determine risk, rather than a mathematical model. This recommendation reaffirms the previous response (SAB-RAC-87-035)" [Appendix A, Report #9].
- e) "The methodology for assessing risk from man-made radionuclides (both individually and collectively) is incomplete, because there is not a criteria document for man-made alpha emitters. The draft document employs a set of *ad hoc* risk factors that have not been reviewed. Instead of providing the basis for selection of a guide value, the level of 4 millirem per year was assumed. The document does not employ the effective

dose equivalent concept and does not adequately address uncertainty in the input parameters and risk estimates."

The Subcommittee was troubled by the Agency's failure to address the SAB's earlier comments and recommendations, as well as relevant recommendations contained in the BEIR-IV and BEIR-V reports (Appendix B). The EPA 1990 documents reflected technical decisions contrary to those specifically recommended by the SAB, selectively adopted material from other technical consensus reports, and presented decisions concerning the risks of radionuclides in drinking water without justification or acknowledgment. Given this pattern, particularly the inattention to uncertainties and previous BEIR Committee and SAB recommendations, the Subcommittee found it difficult to understand the scientific basis for the selection of maximum contaminant levels.

In January, 1992, the RAC submitted a self-initiated Commentary to the EPA Administrator (*Appendix A, Report #30*) dealing with two issues that had come up as the result of the earlier reviews of ODW's drinking water documents (*Appendix A, Reports #9 and #26*), already discussed above. The purpose of the Commentary was two-fold: (1) to address the fragmented and inconsistent approach regarding reduction of radon risk, and (2) to provide closing comments on the revised drinking water criteria documents supporting the proposed regulations.

5.2. Proposed Drinking Water Regulation in Relation to "Reducing Risk" Report

In this part of its Commentary, the Committee acknowledged that technical aspects are only one (*Appendix A, Report #30*) of many factors that must be considered in making policy determinations. However, the Committee decided to express its view on the relative risks addressed by the proposed regulations *vis-à-vis* other radon risks reviewed by the Committee and to offer its views on the implications of its technical observations for matters of policy.

The ODW, after considerable deliberation, had proposed to regulate radon in drinking water in the manner adopted for other contaminants under the SDWA, that is, at an approximate lifetime risk level of 10⁴. The chief risk from radon in water is its release into the air and subsequent inhalation, as opposed to ingestion of waterborne radon. Thus a 10⁴ risk level (averaged over smokers and non-smokers) translates into about 0.03 pCi/L in air, or approximately 300 pCi/L in water. That air concentration is more than 100 times smaller than the Agency's voluntary guideline of 4 pCi/L for radon concentration in indoor air. It is also well within the natural year-to-year variation in indoor radon concentrations in average houses. Congress, as part of the *Indoor Radon Abatement Act*, defined the goal of achieving an indoor radon level equal to the natural outdoor level, which is 0.1-0.5 pCi/L, depending on the area of the country. This goal is a factor of 8-40 below the indoor action level, but a factor of 10 higher than the indoor radon level corresponding to the proposed regulation for radon in drinking water.

The Agency estimated that about 5% of the total indoor radon in homes served by ground water would be due to radon released from household water use. Data in the radon criteria

document indicated that approximately 10-30% of the population relying on ground water sources was exposed to water with radon concentrations above the proposed maximum contaminant level of 300 pCi/L. Overall, about 1% of the total indoor radon in areas dependent upon ground water supplies would be addressed by adopting the proposed regulation.

The Committee concluded that the radon exposure situation reflected the fragmentation of environmental policy as identified in the SAB's "Reducing Risk" report (Appendix B, EPA-SAB-EC-90-021). The tactics and goals of different laws designed to address radon exposures have clearly not been consistent, and efforts within the Agency to reduce radon risk, while not uncoordinated, were rooted in programmatic areas that responded to different laws.

In harmony with Recommendation 4 of "Reducing Risk,"

a) "EPA should reflect risk-based priorities in its strategic planning processes. The Agency's long-range plans should be driven not so much by past risk reduction efforts or by existing programmatic structures, but by ongoing assessments of remaining environmental risks, the explicit comparison of those risks, and the analysis of opportunities available for reducing risks."

Analyses have shown radon in drinking water to be a very small contributor to radon risk except in rare cases, and the Committee therefore suggested that the Agency focus its efforts on primary rather than secondary sources of risk. The RAC recommended that the Agency conduct a full media-based risk assessment of the various options for regulating radon in drinking water. Such an evaluation should also include the risk posed by the treatment or disposal of any wastes produced by water treatment.

5.3. Closing Comments on Revised Drinking Water Criteria Documents

Following the Committee's review of the second set of draft documents in the summer of 1990, the ODW, with the assistance of the ORP, revised the criteria documents supporting the proposed regulation. The Committee decided not to undertake a formal review of the third set of criteria documents, however, since the fundamental scientific questions had been discussed in its previous reviews, cited above. The Committee chose to stand by its original positions and believed that the Agency could further improve the scientific credibility of the criteria documents by adopting its recommendations (*Appendix A, Report #30*). The new set of documents were found to be more complete and individual reports now included more explanations of the options considered, selection criteria, and possible alternative choices. The Agency had been less successful in implementing the Committee's advice on uncertainty analysis; although each revised criteria document included a chapter discussing uncertainty, the contents of those chapters were found to be very qualitative and not the rigorous technical analysis envisioned by the Committee. Overall document quality and clarity were still judged inadequate for reports that were intended to be the technical bulwark for Agency decisions.

The Committee proposed that broad scope assessments, of the type recommended above for radon, were also needed for other of the proposed regulations. It further believed that the Agency's analyses should also include the risks resulting from the concentration of radium, uranium, and other radionuclides in wastes resulting from water treatment. These risks included those to workers involved in disposal activities as well as those of disposal itself.

5.4. Drinking Water Treatment Wastes Containing NORM

In the wake of reviewing the ODW's drinking water criteria documents, the RAC reviewed the Agency's "Suggested Guidelines for the Disposal of Drinking Water Treatment Wastes Containing Naturally-Occurring Radionuclides," a document dated July, 1990. Staff from both the Office of Drinking Water and the Office of Radiation Programs briefed the Committee at its public meeting in May, 1992: the Committee's report (Appendix A, Report #35) was submitted in September of the same year.

In developing these guidelines, the ODW had clearly recognized the potential magnitude of this source of exposure. The Committee applauded the ODW's initiative but found that the guidelines document lacked information needed to fully assess the magnitude of risk from exposure to radioactivity in drinking water treatment wastes. (Such a risk assessment was also missing from the regulations proposed in 1991: the need for such an assessment was cited by the Committee in its drinking water Commentary (Appendix A, Report #30). Another important shortcoming was the failure to specify whether the radiation exposure to water treatment plant workers should be considered as occupational exposures or be viewed against the dose limits for the general public. This decision would have considerable bearing on any final guidelines. However, the Committee commended ODW staff for recognizing that public water supply operators would need guidance both about the management and disposal of the drinking water waste residues and about the protection of treatment plant workers. It appeared to the Committee that the staff had recognized the very important issue of "risk-risk analysis" (i.e., considering the net effect of eliminating or reducing a risk by introducing an action that by itself carries a risk) before this concept was prominently discussed by various committees of the SAB.

The Committee recommended that the Agency revise and strengthen the "Guidelines" by obtaining additional data and by clarifying both the scientific rationale and the policy decisions underlying many of the recommendations. The 1990 "Guidelines" document was found to include all the relevant treatment technologies but, because the discussion of these and of the waste disposal practices was highly qualitative, the document was not sufficient by itself for making scientific, engineering or economic choices. As for the recommended radiation exposure guidance for workers, it was unclear to the Committee whether the suggested external gammaradiation exposure guide was based on a policy of As Low As Reasonably Achievable (ALARA) or on an apportionment of the widely accepted guidance of a maximal acceptable dose of 100 millirem per year for the general population. The Guidelines conclusion that "an occupational exposure level of 25 mrem/year for external and committed effective dose equivalent at water treatment plants" was not supported; furthermore, the Agency should evaluate the feasibility of measuring exposure rates that would produce 25 millirem per year. While there are both public

and work-related exposure issues associated with water treatment plant operation and waste handling and disposal, the Agency had not estimated the risk to either group, nor compared them with the risk reduction estimated to accrue from radionuclide removal from water. Although this comparison would not be an entirely straightforward process, an overall risk/benefit perspective would have been useful.

5.5. Chafee-Lautenberg Amendments

In November and December, 1992, the RAC, together with SAB's Drinking Water Committee (DWC), consulted with staff of the Office of Water and the Office of Radiation and Indoor Air (ORIA) on EPA's outline for a Congressionally mandated multi-media risk assessment for radon developed in response to the so-called "Chafee-Lautenberg Amendments" (Appendix B, Public Law 102-389) to the Agency's FY 93 Appropriation Act. This consultation took place during a series of four publicly announced conference call meetings (Appendix A, Report #37). The Committee as well as EPA staff found this consultation to be very valuable and mutually useful, and a number of important issues were raised that the Agency subsequently considered in developing its risk assessment.

The review of EPA's resulting document, "Uncertainty Analysis of Risks Associated with Exposure to Radon in Drinking Water", and related documents and public comments took place in February, 1993. In the document the Agency responded to Congress' directive to "conduct a risk assessment of radon considering the risk of adverse human health effects associated with exposure to various pathways of radon Such an evaluation should consider the risks posed by the treatment and disposal of any wastes produced by water treatment." Congress also required that "The Science Advisory Board shall review the Agency's study and submit a recommendation to the Administrator on its findings." The EPA's uncertainty analysis addressed four radon exposure pathways: inhalation of indoor radon from non-water sources, inhalation of radon outdoors, ingestion of waterborne radon, and inhalation of waterborne radon. The charge to the RAC was to review the adequacy of revisions of ingestion and inhalation risk from radon progeny and the adequacy of uncertainty analysis regarding risk assessment of waterborne radon, including health risk analysis and exposure analysis.

In its review of the Agency's document (*Appendix A, Report #40*), the Committee commended the EPA staff for having produced an excellent document that responded to previous SAB comments on uncertainty analysis and the exposure to radon gas at the point of use (e.g., showering). The EPA's response was all the more impressive given the constraint of tight deadlines imposed upon it by Congressional and Court mandates. Its quantitative analysis of uncertainties in the radon risk assessment represented a methodology that was essentially state-of-the-art. The Committee assumed that this reflected the EPA's recently stated commitment to a more rigorous approach to evaluating uncertainties in its risk analysis of radiological and other hazardous exposures in the future.

The revised estimates for ingestion and inhalation risks from radon in drinking water indicated that the risk from ingestion was approximately one-half of the risk from inhalation, and

both risks are considered scientifically acceptable. There was concern, however, that the uncertainties in the estimates of the ingestion risk could be larger than suggested by the quantitative uncertainty analysis. The Committee recommended that the EPA incorporate a qualitative discussion of known, but not quantified, uncertainties in its analysis and, given the larger uncertainty bounds associated with the ingestion risk, that consideration be given to keeping the ingestion and inhalation estimates separate in the Agency's deliberations on standards for radon in drinking water. The Committee also reiterated its previously stated concerns that the overall risk associated with radon in drinking water was small compared with the average radon exposures due to indoor air and that the drinking water risks be viewed in context with other radon risks in the summary documents developed by EPA.

In addition, the Committee provided comments and recommendations regarding the adequacy of the analysis and the approaches taken. Among these was the recommendation that EPA look at a range of water treatment technologies and include in the analyses risks from occupational radiation exposures and potential waste disposal issues. Finally, the Committee recommended that particular attention also be given to the uncertainties associated with the variance and shape of the probability density functions used by EPA to represent variability of exposures among individuals.

This review by the RAC constituted a part of a broader SAB assignment, and the above RAC report was attached to a report to the EPA Administrator from the SAB Executive Committee, entitled "SAB Review of Multimedia Risk and Cost Assessment of Radon in Drinking Water" (Appendix B, Report EPA-SAB-EC-LTR-93-010).

6. RADIOACTIVITY MANAGEMENT AND WASTE DISPOSAL

6.1 Idaho Radionuclide Exposure Study

In September, 1986, the ORP asked the RAC to review the work plan for the Agency's proposed study to assess the total integrated risk to the communities of Pocatello and Soda Springs, Idaho, from all radioactive emissions into the air and water and from the use of solid waste resulting from the nearby phosphorus industries. In describing the need for this study, the Agency pointed out that phosphorus ore contains approximately 60 times the levels of natural radioactivity normally found in the earth's crust; some of the radioactivity is released to air and water during processing of the ore, and some is distributed in the environment through the use of solid wastes. Besides stockpiles of slag, phosphogypsum, and phosphate ore at the phosphate fertilizer plants, slag containing elevated concentrations of naturally occurring radionuclides had been used as an aggregate material for paving and building throughout the communities. The original work plan was subsequently revised and the final document was sent to the Committee in March, 1987 and was reviewed at the June, 1987 RAC meeting.

The revised objective of the study was more limited than the original one, viz., "to determine the magnitude and relative importance of the various industrial sources of radiation and to estimate the dose to the populations of Soda Spring and Pocatello from these sources." The Committee found (*Appendix A*, *Report #10*) that the revised version of the study plan was of sufficient quality and detail to achieve the study's objective. This conclusion resulted primarily from changes made in approaches to sampling and measurements of radionuclides, enhanced use of existing data, and improved use of meteorological information.

The Committee made two additional comments, neither of which was felt to affect the ability of the proposed plan to achieve its objective:

- (1) In the absence of information on indoor/outdoor polonium-210 ratios, the Agency in its March, 1987 transmittal memo stated that it would assume the indoor polonium-210 concentration to be the same as the outdoor concentration and that this assumption would result in a conservative estimate of dose. However, this assumption could also be incorrect. A better approach would have been to take a conservative indoor/outdoor ratio based on literature values, rather than to assume a ratio of unity.
- (2) The Committee expressed the hope that, in the final report of the study, lung doses resulting from inhalation would be converted into effective dose equivalents so as to permit these doses to be added to the external doses from gamma radiation originating in slag. Because these two pathways were expected to be the principal modes of exposure, the Committee felt it to be important that they be expressed in comparable units.

In January, 1991, EPA asked the RAC to review the results of the completed Idaho Radionuclide Study. This study was originally designed to support the rulemaking on the radionuclide NESHAP, not for an explicit evaluation or remediation of individual

radiation exposures. However, the study did provide radiation exposure data that prompted the Agency's consideration of current and past uses of phosphorus slag. The matter was brought back to the SAB for a timely review to resolve the issues involved with slag reuse, because members of the general public could come in contact with the gamma radiation fields associated with the slag. The Agency's actions in this case had the potential to set important precedents for sites with residual radioactivity and/or elevated exposure rates resulting from past technological activities. In its report (*Appendix A*, *Report #28*) the Committee addressed the four questions asked by the Agency, to which it added its comments on the broader technical and policy concerns.

(1) Was the "Idaho Radionuclide Study" implemented consistent with the SAB's review of the study design?

Most of the components were implemented, with three exceptions: (a) Measurements were made in homes volunteered for participation in the study rather than in a representative random sample in each sector; this could potentially introduce a selection bias. (b) An actual indoor/outdoor polonium-210 ratio could not be established as planned, which may result in overestimation of lung dose; however, this was not viewed as significant since the primary radiation doses are principally from direct gamma exposure. (c) Indoor radon measurement data were not presented but, because the radon emanation rate from glassy phosphate slag was found to be small, the absence of these data was not viewed as significant.

(2) Were the study's exposure scenarios for "average" and "maximally exposed" individuals reasonable?

The gamma radiation exposure scenario for the "maximally exposed individual" was for a hypothetical person and it is highly unlikely that a single individual would be exposed to the maximum exposure rate in the home, workplace, and public sectors. The "average" exposure scenario incorporated a number of reasonable assumptions but, due to the limited number of indoor measurements, the non-random nature of home selection, and the uncertainties in exposure conditions based on aerial surveys, the calculated population dose was considered unreliable; furthermore, decisions on specific actions would require data on individual exposures.

(3) Are the results of the study sufficient to make reasonable estimates of the population radiation exposure due to slag?

No, because the study could not identify those members of the population receiving the highest exposures or quantify those exposures that may occur at various exposure ranges above background. The study did demonstrate (based on actual exposure rates measured in homes and on the ground) that elevated gamma radiation levels occurred in Pocatello and Soda Springs such that some persons could receive doses above 100 millirem per year in excess of natural background but did not provide the necessary data on which to base

potential regulatory initiatives or remedial actions for individuals exposed to elevated radiation levels.

The Committee further recommended that the Agency prepare a plan for obtaining reliable exposure determinations and provide it for technical review. The study plan should contain, at a minimum, means for determining reference background for each area, and means to determine dose rates and accumulated doses from various areas, especially residences.

(4) Were the cancer risk factors used in estimating potential health effect appropriate?

The Committee here referred to its earlier recommendation (*Appendix A*, *Report #15*) as to models to be used to estimate cancer risk but made the following concluding statement: "Although the study design did not suggest that risk determination would be made with the exposure data, such estimates were in fact made. Because the population dose estimate is flawed, the calculated risk estimates are not meaningful and [are] of little value as a basis for future actions."

In a closing section the Committee called attention to the considerable interest of the Idaho citizens, industry, and other members of the public in the Agency's deliberations on this issue, especially as they might affect potential disruption in people's lives, costs, and risks involved in actions for phosphorus slag. In the words of the Committee, "The Idaho Radionuclide Study was not designed to and does not provide a sufficient basis for removal or remediation actions. A much more detailed study would be required before such actions can be considered." The Committee went on to suggest that the Agency establish a set of graded decision guidelines based upon technical and economic factors for both short-term and long-term exposure of the public due to past uses of slag, and make them available for public and SAB review; it further suggested that past and current slag uses be considered separately, because the cost/risk considerations involved make them distinctly different technical issues for assessment and control, including selection of any action level.

As a final opinion the Committee made the following statement: "Numerous other situations exist where actual and potential exposure to residual radioactive substances may occur at similar levels and risks; therefore, the Committee urges the Agency to take the necessary steps to develop an overall policy for addressing situations of this type."

6.2. Residual Radioactivity

Simultaneous with its 1991 review of the Idaho Radionuclide Study the RAC prepared a self-initiated Commentary to the Administrator (*Appendix A, Report #24*) urging the Agency to develop Federal radiation protection guidance specially for removal or remediation actions for radioactive substances at various locations, including Superfund sites and Federal facilities. No radiation guidance directed to allowable residual radioactivity contamination at such sites then existed. The Committee's recommendation was directed toward residual radioactivity resulting

from human activities, not from naturally occurring distributions of radionuclides. The guidelines available for assessing cancer risk focused mainly on chemical contamination at Superfund sites.

Both the Department of Energy (DOE) and the Superfund program must deal with radioactive contaminants at more than a hundred sites of various types. The number has increased as Federal site evaluations proceed, and as radioactivity sources not previously considered gain public attention. The Congress had recognized this potential problem by directing the Agency to address this issue in a recent appropriation bill. The Agency had issued an Advance Notice of Proposed Rule-Making for residual radioactivity in 1986 but as of 1991 had made little progress in finalizing this notice.

The Committee's Commentary contained a list of technical issues to be considered in developing guidance. Such guidance could include residual contamination levels for individual radionuclides that should not be exceeded, or could perhaps set forth decision-making processes for establishing such levels. Superfund guidance suggested that any lifetime risk in excess of one in ten thousands was an obligatory (de maximus) basis for consideration of the feasibility of removal or remediation action. Once an action had begun, the risk goal could be as low as one in a million, representing a de minimis level for which no further action was indicated. From the RAC's perspective, the Agency needed to establish whether the de maximus and de minimis values used for Superfund actions for chemicals were justified for radionuclides as well and, if it were determined that these levels were not justified, such values and Applicable Relevant and Appropriate Requirements (ARAR) for radionuclides had to be established.

In October, 1992 the RAC met with ORIA staff to consult on the technical approach to radiation site cleanup regulations (*Appendix A, Report #42*). The staff gave a brief overview of EPA's technical support for development of cleanup regulations for radioactively contaminated soils, aquifers, and buildings. The SAB recognized the importance of EPA's role in setting these regulations, as decontamination and decommissioning of military bases and nuclear facilities were getting underway and were expected to be a major cleanup problem for the next several decades.

The ORIA staff provided brief discussions on EPA's approach to the cleanup of radioactively-contaminated sites covering a number of topical areas such as site categorization, Agency data and reference sites, various information sources, pathway models, cost assessment, individual, worker, and population risk assessments, cleanup and disposal costs, and a sensitivity analysis of a number of variables. At the time of writing of this retrospective review, the RAC was involved in follow-up interactions on technical aspects of the cleanup standards, including the scheduled review of draft documents.

6.3. Naturally Occurring Radioactive Materials (NORM)

At the request of the Office of Radiation and Indoor Air (ORIA, the successor of ORP), the RAC reviewed the Agency's May 1993 draft document "Diffuse NORM - Waste Characterization and Preliminary Risk Assessment." In its review (Appendix A, Report #44) the

Committee responded to six specific questions asked by the Agency and also provided a number of general comments and suggestions.

The NORM document was the latest draft in a series spanning several years and reflected the responsiveness of ORIA to comments by EPA internal reviewers, by the public, and by RAC. The Agency appeared to have accessed and summarized most of the information about diffuse NORM that was generally available at the time the document was prepared. However, in the opinion of the RAC, the document did not meet its stated goal of providing a scoping analysis of the NORM problem sufficient to determine the need for additional investigations or for regulatory initiatives.

In response to the six specific questions in the charge, the Committee provided the following findings:

- 1) "The NORM document does not adequately convey the deficiencies and uncertainties in the information available to characterize the sources of NORM. The choices of nominal values for volume and concentration used in the risk assessment are not sufficiently justified. Some values appear to be overestimates (especially for concentrations) while others appear to be underestimates."
- 2) "The justification provided for parameter values used in the risk assessment is not sufficient. In addition, the NORM document uses aggregate factors for food uptake and dose conversion that incorporate many other assumptions and parameter choices, making evaluation difficult. The RAC suspects that the food uptake factors may tend to underestimate exposures."
- 3) "With few exceptions, the NORM document has selected reasonable scenarios and pathways of exposure for analysis."
- 4) "The NORM document has used appropriate models for the most part. The RAC notes, however, that advective flow was not considered in the model for radon exposures, and suspects that this omission may have led to underestimates of exposures for radium in the waste."
- 5) "While the greatest uncertainties are in the estimates of risks from pathways that probably do not contribute much to total risk, the risks from specific sources are probably not known within a factor of three, despite what might be inferred from the language in the NORM document."
- "The RAC believes that if the EPA addressed the deficiencies identified in this review, the revised document could serve as a useful compilation of information for the public on NORM source terms and potential exposure pathways. However, to go beyond this limited use and to meet the goal of serving as a screening tool for identifying those categories that may require regulatory attention, it would be necessary for the Agency to

conduct its risk assessment analysis using a consistent approach in addressing uncertainties, such as the methodology suggested by RAC in its report."

The Committee believed that, in spite of its shortcomings, the NORM document nonetheless provided indications that some categories of NORM might produce risks that exceed those of concern from other sources of radiation. Consequently, the RAC was of the opinion that the issue of NORM deserved substantial attention within EPA, and was concerned that resolution of this issue would require an increased commitment of resources. The RAC pointed out the need for the Agency to distinguish between those categories of NORM that may be rated high with respect to individual risk and those that may be rated high with respect to population risk.

6.4. High-Level Radioactive Waste Disposal

In January, 1983 [before the establishment of the Radiation Advisory Committee], the SAB was asked to review EPA's proposed environmental standards for the management and disposal of spent nuclear fuel, high-level and transuranic radioactive wastes (40 CFR 191). A High-Level Radioactive Waste Disposal Subcommittee was formed to review the technical basis of the proposed standards.

In its report (*Appendix A, Report #1*) the Subcommittee accepted the general form of the proposed standards but recommended several changes in the standards as well as improvements in the supporting methodology. The principal recommendations are highlighted in the following text.

a) The Standard:

l) "The Subcommittee recommends that the release limits specified in Table 2 of the proposed standards be increased by a factor of ten, thereby causing a related ten fold relaxation of the proposed societal objective (population risk of cancer)."

The Subcommittee noted that the proposed release limits were directly related to the societal objective of not exceeding 1,000 deaths in 10,000 years, and thus, compliance with this recommendation carries with it a related ten fold increase in the societal objective. The relaxation in the release limits was, in the Subcommittee's opinion, justified for the following reasons. First, the proposed release limits in Table 2, and therefore the proposed societal objective, were considerably more stringent than those standards generally required or adopted in today's society. Second, in addition to the fact that some of the cancer deaths which might result from these releases were calculated using conservative assumptions that probably overestimated the number, some of these deaths would have resulted at least in part from the unmined ore from which the wastes were subsequently generated, and thus were substitutional rather than additional in nature. Third, the Subcommittee believed that the compounding of conservatism by EPA in the choice of probabilities and specific model parameters used throughout the analysis was not warranted.

- b) Uncertainty and the Standard:
- 1) "We recommend that the probabilistic release criteria in the draft standard be modified to read 'analysis of repository performance shall demonstrate that there is less than a 50% chance of exceeding the Table 2 limits, modified as is appropriate. Events whose median frequency is less than one in one-thousand in 10,000 years need not be considered'."
- 2) "We recommend that the use of a quantitative probabilistic condition on the modified Table 2 release limits be made dependent on EPA's ability to provide convincing evidence that such a condition is practical to meet and will not lead to serious impediments, legal or otherwise, to the licensing of high-level-waste geologic repositories. If such evidence cannot be provided, we recommend that EPA adopt qualitative criteria, such as those suggested by the NRC."
- c) The Time Frame 10,000 Years and Beyond:
- 1) "We recommend that EPA retain the 10,000-year time period as the basis for determining the adequacy of repository performance. We believe that the use of formal numerical criteria limited to this approximate time period is a scientifically acceptable regulatory approach."
- 2) "We recommend that the process of selection of sites for disposal systems also take into account potential releases of radioactivity somewhat beyond 10,000 years. Particular attention should be focused on potential releases of long-lived alpha-emitting radionuclides and their decay products."

This recommendation recognized that the potential for radionuclide releases would not stop after 10,000 years, but could continue in amounts equal to or exceeding those estimated for the initial period. The degree of confidence with which impacts could be modeled much further in the future was much less certain. The Subcommittee did not recommend detailed modeling calculations regarding post-10,000 year releases, but believed that estimates should be made, and should be considered as factors in disposal site selection.

- d) Population vs. Individual Risk
- 1) "We recommend that EPA retain the use of a population risk criterion as the measure of performance for the proposed standards."

The Subcommittee found that an approach employing individual dose limits, i.e., considering some "maximally exposed individual" or alternatively some "average exposed individual" would, in practice, make the standard difficult to meet with high assurance for very long times, and that use of a population risk approach would be more

practical. In its view, however, it is important that for the first several hundred years residents of the region surrounding a repository have a very great assurance that they will suffer no, or negligible, ill effects from the repository. For longer periods, the Subcommittee believed that EPA should rely on the existence of continuing requirements similar to its current [1983] drinking water standards to protect groups of individuals.

- e) Coordination of Policies and Standards:
- 1) "We recommend that EPA initiate action within the Federal Government for the establishment of an interagency council to coordinate the development of high-level radioactive waste disposal policy, standards and regulatory practices and to serve as a forum for exchange of scientific and technological information."

Several Federal agencies are involved in the process of establishing radiation protection policies, standards and operational requirements governing the disposal of high-level radioactive wastes, including EPA, NRC, DOE and DOD, together with states, appropriate entities of Congress and the judiciary. Overlapping and independent authorities and responsibilities exist under the present law. Coordination of Federal policies and practices is essential to the U.S. high-level radioactive waste disposal program. While the lead in coordination could be appropriate for the NRC or DOE, the Subcommittee feels that the obligation for achieving mutual interaction more appropriately belongs to EPA under its authority to issue environmental standards and Federal Radiation Protection Guidance.

- f) Research Needs A Matter of Priority:
- 1) "We recommend that EPA support, or encourage other agencies to support, continuing research in technical areas where major uncertainties still exist, particularly in the biological effects of radiation, the geochemical transport of radionuclides, and the characterization of rock-mass deformation."

6.5 Release of Carbon-14 in Gaseous Form from High-Level Waste

In 1987 a Federal Court remanded portions of the standards for disposal of high-level waste, spent fuel, and transuranic waste promulgated by the EPA in 1985 (see above). To satisfy the Court's ruling, EPA was required to revise and update the standard. The earlier analysis did not consider the potential for gaseous releases from high-level waste disposal (except as a consequence of volcanic eruptions), but it was not certain whether or not unsaturated sites could comply with the earlier standard with respect to releases of carbon-14. At the request of the ORP, the RAC in 1992 established the "High-Level Waste / Carbon-14 Subcommittee" to review the Agency's document entitled "Issues Associated with Gaseous Releases of Radionuclides for a Repository in the Unsaturated Zone." The summary that follows represents selected excerpts

from the Subcommittee's cover letter accompanying its report (*Appendix A, Report #39*) and contains its most significant findings and recommendations.

- a) "Releases of carbon-14 from a repository may produce an appreciable global population dose over 10,000 years, but the average individual dose would be very low. For a reasonable upper bound release of half the carbon-14 originally contained in a repository, the global population dose over 10,000 years is estimated to be 14 million person rem, and the corresponding average individual lifetime dose would be about 0.01 mrem. Based on the EPA's preliminary risk factor for carbon-14, these doses correspond to calculated lifetime individual risks of 3 x 10⁹, and population risks of less than one fatality every two years on average, or 4,000 cancer fatalities world wide over 10,000 years. Whether or not these doses constitute a public health concern is a fundamental issue of principle. The Subcommittee did not try to resolve this issue, but EPA must address it when considering carbon-14 releases. Consistent with the report "Reducing Risk" (Appendix B, EPA-SAB-EC-90-021), the Subcommittee recommends the predicted individual and population doses be considered in comparison with doses from other sources, with dose limits in other standards, and with other environmental and radiation risks.
- b) "The uncertainty analysis performed in the issues document is in a preliminary state and can be improved substantially. ... [It] is not possible on the basis of presently available information to predict with reasonable confidence whether releases from an unsaturated repository would be less than or greater than the Table 1 (40 CFR 191) release limits. ...
- c) "The issues document does not accurately characterize the potential for gaseous carbon-14 releases from the repository to the environment, although the Subcommittee notes it may not be possible to do so based on currently available information. The EPA document's assumptions about release mechanisms and rates of release from the wastes and containers, and the transport mechanisms and rates, do not appear to be supported by sound technical justifications.
- d) "The description of the effectiveness of engineered barriers designed to reduce or impede releases is not adequate because there has been little research and development of engineered barriers specifically designed to contain carbon-14 in unsaturated repository. ... (The significance of the reduction in the release would depend on the containment time relative to the 5,730 year half-life of carbon-14.) Therefore, the Subcommittee encourages investigation of the use of multiple barriers to retard migration of carbon-14 to the accessible environment.
- e) "EPA needs to revise the description in the document of the physical and chemical retardation and transport of carbon-14 from the waste repository to the surface, because the hypothesis that the principal transport mechanism in flat terrain would be diffusion is incorrect. ... "

f) "In responding to the broader issue of risk reduction, the Subcommittee notes that optimizing site selection on the basis of a single criterion may cause a change in optimal conditions for other criteria. For example, carbon-14 releases to an accessible environment would probably be less from a saturated site than from an unsaturated site, but risks from other radionuclides may be greater or smaller depending on a number of factors."

6.6 Low-Level Radioactive Waste Disposal

One of the first tasks assigned to the newly established RAC was the review of the ORP's "BID on Low-Level Radioactive Waste Disposal," initiated in February of 1985 (*Appendix A*, *Report #5*). The parts of the report dealing with the Agency's risk assessment methodology were discussed in Section 3.1 of this retrospective report. The present section deals primarily with the other issues covered in the RAC report and is based largely on the cover letter accompanying the submission of the report to the EPA.

The Committee was asked by the ORP to address 11 issues associated with the draft document: 1) sorption characteristics and environmental behavior of carbon-14; 2) behavior of carbon-14 and tritium in the disposal trench; 3) the reasonableness of time spans for risk assessment; 4) identification of disposal pathways from disposal of low-level wastes; 5) exposure pathways from unregulated disposal of "below regulatory concern" wastes; 6) generic characterization of disposal sites; 7) appropriateness of site-independent modeling parameters; 8) appropriateness of model scale and approach; 9) parameters investigated in sensitivity analysis; 10) uncertainty in risk assessments; and 11) adequacy of the range of low-level waste disposal methods.

The Committee's major findings were:

- 1) The Agency should explain how it would use the information in the document to arrive at and support a generally applicable radiation protection standard for the disposal of low-level radioactive wastes.
- 2) Risk assessments involve the use of a variety of complex models which are predicated on the legitimacy of certain assumptions and the appropriateness of the data that are utilized. It is important that the uncertainties in these data and calculational procedures be fully described at the outset.
- 3) The Committee believed that the time spans over which the analyses were made, 1,000 and 10,000 years, were unrealistically long and found the assumptions that social changes, advances in public health, and population growth will not occur over a 10,000 year period to be unpersuasive. ORP should select a time frame based on explicit engineering considerations, biological reasonableness, or preferably both.

- 4) [The recommendations regarding risk assessment have been dealt with in Section 3.1 of this retrospective report. The only additional point that should be made is that risk should be expressed in terms of risk to an individual and not in terms of numbers of death or genetic effects within populations of dissimilar size and demographic characteristics.]
- 5) The Committee identified some technical weaknesses that could be remedied by better use of existing information, and it presented some areas in need of additional research. These included: (a) Improved understanding of the geohydrology of long-lived, mobile radionuclides with particular attention given to tritium, carbon-14, technetium-99, iodine-129, and neptunium-237. The studies should include an evaluation of the transport of various chemical forms in a variety of soil types. (b) Better understanding of the behavior of long-lived mobile radionuclides in the disposal trench. Specific leach rates for these radionuclides in their various physical and chemical forms should be determined; these differences would affect the rate of movement of radiocarbon from the site and the time at which the maximum exposure rate occurs after closure. (c) The Committee further recommended that the Agency support research in the technical areas where major uncertainties exist. In addition, future studies on the biological effects of radiation should include particularly the assessment of human studies on low-dose risk estimation and the evaluation of dose response information and relative biological effectiveness (RBE) from human and other biological systems.

Overall, the Committee believed that, with incorporation of the recommended changes, the document would prove useful to the Agency and to the general public in promoting a wider understanding of the options for the disposal of low-level radioactive wastes.

7. RADON RELATED ISSUES

Over the period covered by the present review, issues related to radon have by far been most prominent, having been dealt with in 16 of the total 36 RAC reports. For convenience, this part of the retrospective report has been divided into several sub-categories.

7.1 Radon Epidemiology Proposal

In February, 1986, EPA's Office of Health Research in the Office of Research and Development (ORD) asked the RAC to review a proposal, from the Maine Medical Center and the University of Maine, for an epidemiological study of indoor radon entitled "Health Effects of Waterborne Radon," to be conducted in the State of Maine. A Radioepidemiological Subcommittee was formed to carry out the review. The ORD posed two main questions to the reviewers:

- 1) Can further epidemiological study contribute to an understanding of the risks of lung cancer associated with household exposures?
- 2) Is the proposed study under review by the ORD appropriately designed to address this risk?

The Subcommittee noted (*Appendix A, Report #7*) that the relationship between radon exposure and lung cancer in the domestic population was based on extrapolation from data on uranium miners and that epidemiological studies on people exposed in the home were only then being proposed or conducted. Since the proposed Maine study would be assessing a "middle range" of radon exposures, the Subcommittee concluded that data from a successful study combined with those from other studies to be conducted elsewhere could clarify the present understanding of risk vs. radon exposure.

The second conclusion, that the proposed study would not likely provide useful information on the issue of waterborne radon risks, was based on a number of perceived problems of the study, among which were the relatively low number of cases available and the difficulty of estimating indoor radon exposures, including those of deceased individuals. In addition, the Subcommittee noted that even in Maine, where the water in many wells contains high levels of radon, the radon in water is usually a minor contributor to radon in indoor air. Overall, while supporting the need for radioepidemiological studies on radon in indoor air, the Subcommittee recommended that the Agency not undertake the proposed study as then currently planned.

By way of follow-up information, the applicants resubmitted the study proposal to the EPA the following year and at that time the Agency assigned it to an outside group, not affiliated with the RAC, for a site visit and review. This latter group recommended funding of the study, with reduced budget, contingent on the resolution of a number of issues raised in the second review. The eventual outcome was that the proposed study was not funded.

7.2. Radon Measurement and Mitigation

In January 1986, at the time that the issue of environmental radon was beginning to be appreciated by the general public, the RAC was asked by EPA's Office of Environmental Engineering and Technology Demonstration (OEETD) to review the Agency's Radon Mitigation Research Plan. Two reports were prepared by the Radon Mitigation Subcommittee, which was established for this purpose (Appendix A, Reports #8 and #12). Overall, the Subcommittee found OEETD's general approach to be reasonable but made the recommendations that the number of cells in the mitigation test matrix be reduced by combining techniques which have similar effects, that increased attention be given to pre- and post-mitigation measurements, and that geological parameters relating to the source terms not be included in the mitigation matrix when not susceptible to mitigation. The Subcommittee also suggested a series of criteria for prioritizing the development of various mitigation techniques. Additionally, it commented on the need for being able to relate short-term to longer term measurements and how these may be compared to EPA's annual guidance level of 4 pCi/liter of radon in indoor air, an issue that would come up again (cf. Appendix A, Report #22 later in this Section). It was also recommended that greater emphasis be placed on new construction mitigation to prevent radon problems from developing in new construction on high-risk lands. Finally, reviews of existing literature and of the details of statistical testing were considered to be essential for judging the scientific merit of a mitigation approach.

In its subsequent report (*Appendix A, Report #12*) the Subcommittee expanded on several of the above points, such as the variables to be addressed by the test matrix, the collection and management of useful data, and data analysis. The issue of cost effectiveness was given a broad discussion and the committee endorsed the goal of OEETD to develop cost-effective, in preference to low-cost, mitigation techniques. The Subcommittee recommended that different definitions of cost-effectiveness be developed from the perspectives of the different interested groups: mitigators, homeowners, and policy makers.

Radon risk assessments and mitigation decisions both depend crucially on the ability to test for radon with reasonable accuracy. The RAC, in the fall of 1987, was asked to review ORP's "Radon Measurement Proficiency Program" which had been established in response to requests from private laboratories and State agencies to assist these initially in choice of methods and equipment, and to assure their measurement capabilities in the public interest. The RAC formed the Radon Measurement Subcommittee to conduct the review. The Subcommittee addressed performance standards, statistical methods, standard measurement protocols, participant's procedures, blind tests of passive devices, consensus standards and voluntary accreditation, and user fees. The Subcommittee's recommendations (Appendix A, Report #18) included the following points:

a) development of separate objectives for devices or methods used for screening, diagnostic measurements, and exposure evaluations;

- b) consideration of different testing protocols for passive devices and active measurements;
- c) design of the testing program to obtain independent measurements from each device or method tested;
- d) the need to conduct blind testing, wherever practicable, as in the instance of passive measurement devices; and
- e) the assignment of a full-time statistician to the measurement protocol program, at least until it was well established.

The Subcommittee recommended that serious consideration be given to establishing consensus standards and voluntary accreditation procedures. Finally, since a successful program would require adequate and continuous support, it recommended that EPA explore all possible avenues, including user fees.

The RAC had long recommended that radon measurements that were intended to be compared with the action level proposed by EPA for indoor air (i.e., an annual average of 4 pCi/liter) should preferably be conducted over a 12-month period. Practical considerations argued against such a long testing period which would not be acceptable to homeowners wanting to test for radon in their homes. In 1990 the RAC was asked to review the ORP's approach to analyzing the effects of substituting short-term tests for long-term tests in determining the concentration of radon gas in homes.

The Committee (*Appendix A, Report #22*) endorsed the use of along-term test conducted in the lowest lived-in space as the standard against which other test results should be judged; noted that the lower the radon level, the less accurately informed the homeowner is likely to be by results obtained with currently available test devices; expressed concern about the false positive and negative rates that are likely to result from short-term tests near an assumed action level of 4 pCi/L; and noted that the long-term test, when properly done, provides a more scientifically appropriate basis for mitigation decisions, particularly in the range of radon levels most commonly found in U.S. homes. The Committee observed that improving the methods and/or improving the means of estimating actual radon exposure could lead to a greater number of correct mitigation decisions.

During the second half of 1993, the RAC reviewed the study design for the Office of Radiation and Indoor Air's (ORIA's) "Radon Measurement Protocol Evaluation Study" (*Appendix A, Report #43*). An initial discussion of this proposed study was held with ORIA staff at the RAC meeting in November, 1992, at which a number of suggestions were made by the Committee, many of which were addressed in the final draft protocol. A number of the issues dealt with in the Agency's document may be viewed as having their origins in earlier EPA documents and RAC reviews, most notably in connection with the revised "*Citizen's Guide to Radon*" and the "*Homebuyer's and Seller's Guide to Radon*" (see Sections 7.6 and 7.7 of this review).

In the charge to the Committee, ORIA asked three questions, each of which is listed below, together with an abbreviated version of the Committee's response. In addition, the Committee's further discussion and recommendations for the study are summarized.

(1) Does the study accumulate data pertinent to further investigating the use of shortterm measurements for making mitigation decisions?

"Overall, the study design will gather data that will permit pertinent comparisons of results from the different measurement methods with the long-term (annual) average. Because the study population is those houses that participated in the "National Residential Radon Survey" (see Section 7.4 of this report), the collection of additional long-term data will permit the Agency to examine the degree of temporal variability in the long-term average radon concentration. Since there are very few data enabling such comparisons, the Committee believes this will be a very useful result of the study."

(2) Are the Data Quality Objectives (DQOs) reasonable?

[The DQOs for the study were: (a) Detect false positive and false negative errors with probability of at least 0.80, if the error rates are 0.03 or higher; (b) Have a 95% upper confidence bound no higher than 0.05 for each study cell, if no false positive or false negative errors are observed for that particular cell; (c) Have power of at least 0.80 for detecting a difference between a false positive or false negative error rate of 0.05 and an error rate of 0.15.]

"The Committee believes that the DQOs are reasonable for comparison to the Agency's guideline of 4 pCi/L."

(3) Does the study design seem reasonable to achieve the Data Quality Objectives (DOOs)?

"The limiting case in each of the DQOs is the design cell for which the Agency expects 70 responses, and as the study protocol document states, this sample cell will not meet the third DQO, although the design does maximize the power for this one cell. The Committee does not believe that the failure to meet this DQO for only one of the cells is an important limitation to the study design. The ability for this design cell to meet the first two DQOs depends critically on whether the projected 70 percent response rate is achieved. ... However, at a sample size of 70, both these DQOs are just met. Thus the Committee is concerned that, should the response rate fall below that projected, meeting one or both of these DQOs will be more difficult. In all other design cells, the sample size is sufficient to meet the DQOs."

Among its additional concerns, the Committee believed that the study document was incomplete in that it did not discuss the statistical analyses proposed for the data resulting from the study; in particular the comparisons to be made among the different testing devices, methods,

locations and seasons. No mention had been made as to how the data analysis pertinent to each question would be conducted. The Committee recommended that, as the Agency completed its planning for the evaluation study, ORIA discuss with the Committee the hypotheses and/or specific questions to be addressed by the study. It was also not clear to the Committee how the final results were to be presented; in particular, it appeared to the Committee that the metric for comparison among the results was "mitigation decision-making" rather than a direct comparison of measured radon concentrations. In order to evaluate the results of this study across all seasons, testing devices, method and device locations, the RAC recommended that the results of each measurement be presented in units of concentration or as ratios of concentrations with their attendant uncertainties (both precision and accuracy), and that the raw data be preserved in such a format.

A further recommendation of the Committee was that the Agency not examine the effect of climate based on the present study design since it did not appear that the climate zone effects could be determined by the use of surrogate analyses of the data obtained by house structure type, even though there appeared to be some geographical overlap between the two parameters. With regard to the comparison of short-term testing results with annual average concentrations, the Committee believed that the Agency should consider apportioning the study houses on the basis of whether the first-floor concentration was above or below 4 pCi/L, rather than using the "lowest level" as this division criterion. In addition to the issue of potential differences in radon concentration dynamics, using the first floor concentration as a division point provides a uniform basis for this decision across all houses in the study. All houses have a "first floor," which is often the level most frequently occupied by the inhabitants.

Finally, the Committee suggested that the resources for the part of the study that included the 2-day measurements might be better allocated to another short-term testing method for which the comparison data set would currently be less extensive, and it further encouraged the Agency consider to whether there should be a small sub-study conducted with continuous radon monitors in view of the fact that the "Homebuyer's and Seller's Guide to Radon" acknowledged their use as a short-term measurement technique.

7.3 Radon Science Initiative

In the early part of 1993 the RAC established a Radon Science Subcommittee to carry out the self-initiated task of providing EPA with information and advice regarding the expanding field of radon research. Most of the Subcommittee's ten members were individuals actively engaged in research on radon and who were recruited from outside the RAC and came to the Subcommittee with distinct and varied views about radon research. The Subcommittee met in February, 1993 to initiate discussion of radon research activities and the needs of importance to EPA in this area. At that time, the Subcommittee identified three broad areas of concern in the radon field for which they believed additional research was required:

- 1) Radon exposure and risk assessment
- 2) Radon risk control/reduction/mitigation strategies
- 3) Radon risk communication.

The Subcommittee strongly believed that all three of these areas need to be addressed by EPA or by other agencies. This was considered to be particularly true in view of the recommendations set forth in the SAB's document: "Reducing Risk: Setting Priorities and Strategies for Environmental Protection" (Appendix B, EPA-SAB-EC-90-021), which argues that resources should be allocated on the basis of opportunities for the greatest risk reduction and concludes that radon is among the environmental problems posing the greatest potential health risk. In a self-initiated letter to the Administrator (Appendix A, Report #38), the Subcommittee expressed concern that funding within EPA for additional research on mitigation of radon risk appeared to have been reduced to zero. This action was deemed to create a void in further radon mitigation research that would not be easily filled by current or planned research activities in this or in other agencies. The decision to discontinue funding by the Agency for radon control research would, in addition to terminating efforts with substantial potential for risk reduction, effectively disperse the expertise developed within the Agency.

The full report of the Radon Science Initiative Subcommittee was substantially completed in the Fall of 1994 and will be forwarded to the Administrator early in calendar year 1995 (*Appendix A, Report #45*). The Subcommittee's goal was to develop a comprehensive view, both of radon research undertaken within or for the EPA and, to the extent possible, of research efforts underway or sponsored by other agencies. This appraisal sought to determine what further research would be needed to improve the scientific basis of our understanding of the occurrence, behavior, health effects and exposure reduction methods for radon and its radioactive decay products. Overall, the Subcommittee considered research that would lead to reduced radon risks and/or reduced uncertainty about radon risks to be important to EPA's mission of protecting public health and the environment.

In the area of <u>risk reduction</u>, the Subcommittee agreed with the principle articulated in SAB's "Reducing Risk" report (EPA-SAB-EC-90-021). Recommended areas of radon research that addressed risk reduction generally related to radon-resistant construction of new homes, identification of homes with elevated radon levels, mitigation of homes, and public participation. As to <u>uncertainty reduction</u>, the Subcommittee, like RAC and the SAB in general, believed that quantitative uncertainty analysis (and disclosure of that analysis) was increasingly important to scientists and that it would become the norm for those making decisions based, at least in part, on science. Recommended radon research aiming at uncertainty reduction generally related to radon measurement, exposure and dose assessment, dose rate effects, risk assessment, and factors such as smoking or genetic susceptibility that would affect the individual's likelihood of developing cancer.

A broad range of research topics was identified, based on the assembled expertise of the Subcommittee members, and through discussions with colleagues and staff members of the EPA and other Federal agencies. Through further Subcommittee discussion, a consensus list of specific

research recommendations was developed; the list of broad research areas is shown below. The Radon Science Initiative report should be consulted for a more detailed list and description of individual research items.

1) Factors Affecting the Bases for Radon Risk Estimates:

Epidemiology

Mechanistic studies

Dosimetric studies

General issues In radiation biology pertinent to radon

2) Factors Affecting Concentrations, Exposures, and Exposure Assessment:

Regions with high radon susceptibility

Measurement and interpretation methods

Factors affecting total exposure and dose

3) Risks from Ingestion of Radon in Drinking Water:

Gastrointestinal and non-gastrointestinal cancer

4) Exposure/Dose/Risk Reduction Methods:

Source control for retrofit and new applications

Radon and/or progeny reduction methods

Reduction in water-borne radon concentrations

5) Risk Communication:

Communicating technical information and scientific uncertainty

Motivating public action: goals for risk communication

Public participation

The Subcommittee further endeavored to prioritize the research and to select high- and medium-priority topics. In discussing priorities, an approximate 3 year time horizon was used as the distinction between short- and long-term research, recognizing that in some cases, certain research areas would not fall easily into either category. The recommendations that follow represent the Committee's combined expert judgment as to the areas in which a significant reduction in either the uncertainty of current risk estimates, or in domestic radon risk itself, can potentially be obtained.

High Priority - Short term:

1) Durability and performance of active and passive

mitigation systems

High Priority - Long Term:

1) Smoking and radon synergism and effects in non-

smokers

2) Risks at low cumulative doses and low dose rates

Medium Priority - Short Term:

- 1) Development of methods to determine high radon areas
- 2) Improvements in the accuracy and precision of radon measurement methods and protocols
- 3) Better characterization of mine exposure comparison to home exposure stressing differences as well as similarities

Medium Priority - Long Term:

1) Development of potential physical and biological markers of exposure or dose

An overarching area of research is the combined topic of continued research the communication of technical information along with the uncertainties associated with the information. Because it covers a number of issue areas, not just radon, it was not included in the list of research priorities. This area is an extremely important part of the link between policies to reduce radiation exposures and obtaining public action. Studies to improve the communication of information about radon should contribute to the overall goal of reducing radon risk while generally improving knowledge and awareness of the issue. The Subcommittee felt that the goals of improving the technical content of public information and improving the communication process with the public are not incompatible and that research in these areas is vital to providing the basis for decision-making by members of the public.

7.4 National Residential Radon Survey

In June, 1986, the ORP asked the SAB's RAC to review the design for a national radon survey. A National Radon Survey Subcommittee was established to carry out this review. At the Subcommittee's first meeting, in September, it became apparent that the design being presented was to be viewed as a "preliminary" document and that the Agency planned substantial revisions. The Subcommittee therefore did not prepare a report at that time. It did, however, offer a number of suggestions to the Agency, the most important being that if the Agency wanted a clear understanding of indoor radon distribution it would have to do a rigorous probability-based survey independent of the state surveys that the Agency had hoped might be used to supplement the national survey. The revised survey design document was transmitted to SAB the following spring and the Subcommittee reconvened on June 12, 1987. According to the ORP, the primary objective of the national radon survey was to determine the frequency distributions of the radon concentrations in residential structures. This would provide data on the average indoor residential radon levels to which the population of the United States is exposed. It would also provide information on the number of homes that exceed various radon levels.

The Subcommittee found (*Appendix A*, *Report #11*) that the document presented a valid approach to designing a national radon survey. It did express strong concern, however, about the bias that might arise if only owner-occupied housing were to be sampled since at most 60% of dwelling units in the U.S. fall into this category, and it urged the Agency to include rental units as well in the study. A summary of the Subcommittee's other major conclusions and recommendations follows:

- a) The primary objective of the survey, that of determining the nationwide frequency distribution of radon concentrations in residential structures, is important and achievable with adequate precision within the study design. Achievement of secondary objectives, such as regional distribution estimates, is also possible.
- b) A pretest should be conducted to determine the relative advantages of a telephone survey versus face-to-face interview.
- c) Occupancy figures for individuals should also be obtained since this will allow estimates of effective dose equivalent that provides a better representation of the radon exposure than concentration and can be readily translated in terms of potential health effect to the public.

The national radon survey could also be a valuable mechanism for investigating correlations between radon and certain variables which would constitute a major contribution of the national radon survey. To realize this possibility, additional data should be collected including bedrock geology, climate, basement radon levels, housing characteristics, and household heating/air conditioning practices.

Only residential structures were included in the objectives covered in the ORP's original memorandum to the SAB. It was noted by the Subcommittee that the Superfund Amendment and Reauthorization Act (SARA) stated that EPA was to include "structures where people normally live and work, including educational institutions" in the national assessment of radon gas.

The Subcommittee identified some additional areas of concern and also recommended that the Agency consider how the results of the survey would be used and how the information derived would be reported. Both the RAC and the Subcommittee concluded that the study was important from a national health point of view and that all efforts must be made to insure that a survey of high quality was conducted; an inadequate national radon survey would be a disservice because it might well prevent the execution of any future study of significant scientific value.

7.5 National School Radon Survey

In June, 1990, the National Radon Survey Review Subcommittee reviewed the ORP's design options for the National School Radon Survey. These design options attempted to respond to the requirements and constraints set by Congress in the Indoor Radon Abatement Act and Section 118 (K) of the Superfund Amendments and Reauthorization Act. Since the survey was scheduled to take place during the 1990-91 school year heating season, the ORP utilized the preliminary findings of the Subcommittee to revise part of its study plan. The data collection was completed on schedule and the report (*Appendix A, Report # 27*) was submitted after-the-fact.

The survey document presented two alternative options to be considered. The Subcommittee found that the document presented statistically valid sampling designs for selecting school districts for the survey. Design Option II was considered preferable because, while it was

not much more complex or costly than Design Option I, it provided for 25 probability sampling units within which alpha track detector measurements for both residences and schools would be available for comparison. However, the Subcommittee raised concerns about the primary radon measurement method chosen for a study of this importance. The original proposal to use shortterm charcoal canister measurements was expected to produce results of tenuous reliability because they could be defended only as screening data and not as valid measurements from which realistic exposures might be derived. In response to these concerns, ORP decided to extend the charcoal canister deployment period from 2 to 7 days. The SAB was pleased by this revision but still wished to stress that conclusions from screening data and the preparation of technical documents using such data to support national programs could compromise the positive aspects of the school survey. It should be emphasized, however, that short of a continuous measurement with alpha detectors or repeated short-term measurements during the school year, the Agency's decision to use measurements made over a longer period that included the school week instead of the originally planned weekend measurements constituted a greater improvement in the survey design than could be achieved with any other single design change. The Subcommittee also noted that consideration of how the results were to be used, prior to initiating the survey, would greatly enhance the data collection protocol and thereby strengthen the quality and defensibility of the study.

7.6 Citizen's Guide to Radon

In June, 1988, the Agency published its initial "Citizen's Guide to Radon" as a means to inform the public about risks associated with exposure to radon in indoor air and to provide guidance in regard to when mitigation efforts should be considered. Although the RAC received a briefing on the guide, it was not asked to review the document as a committee but was invited to submit comments as individuals. In 1991 ORP drafted a revised "Guide to Radon," and at this time the SAB was requested to provide a review of the draft document. Supplemental material relating to the "Guide" was provided at the RAC meeting in September, 1991. In the charge from the ORP, RAC was asked to address specifically 1) whether the document properly reflected current scientific knowledge on radon, particularly in the area of short- and long-term testing of radon, and 2) whether the Agency had appropriately incorporated the available technical information in reaching the policy recommendation embodied in the test protocol.

The Committee in its review (*Appendix A, Report # 29*) accepted the premise that measurements on the lowest living level are the most relevant since they best reflect residential radon exposures to humans. The Committee continued to affirm that a long-term test was the best basis for a mitigation decision; however, if a short-term measurement were to exceed the 4 pCi/L action level several fold, the RAC recommended that a short-term confirmatory test be made immediately. The "*Guide*" should make it clear that a single short-term test is not decisive and at least two short-term tests are needed before a decision to fix a home is made.

In regard to comparing the risk of fatalities from different causes, the Committee recommended that a clear distinction be made (in Fig. 1 of the "Guide") between the <u>calculated</u> fatalities from radon based on mathematical models and the <u>actuarial</u> deaths from other causes.

The Committee also expressed concern about the Agency's other risk comparison charts; e.g., to compare radon risk to risk from chest X-rays (a risk that most people do not understand) might increase the fear of a medically beneficial diagnostic procedure. The risk from a hazardous waste site would be equally poorly understood by the public. If risks such as heart attacks are dependent on smoking status, the appropriate risk should be used when comparing with radon risk. To some Committee members automobile accident deaths was a more acceptable risk comparison. The Committee also urged that the greater risk from radon exposure to smokers be further emphasized in some specific places of the report.

7.7 Homebuyer's and Seller's Guide to Radon

In January, 1992, the RAC was asked to review the scientific basis of the real estate testing protocol options proposed in ORP's draft revised "Homebuyer's and Seller's Guide to Radon." A briefing by the Agency was given at the February, 1992 RAC meeting. This document was anticipated in the revised Citizen's Guide and was to be considered a companion to that earlier document.

The Committee had long held the view that all radon remediation decisions should be based on estimates of exposures to individuals. The Committee had for some time advocated a year-long integrated radon concentration measurement, taken in the lowest lived-in space, because this measurement most accurately reflected the average annual radon concentration in a home (exposure depending also on the time spent in a particular area). The Committee realized, however, that the scientifically best option was not the currently most realistic one for real estate transactions where decisions may be made in matters of days or weeks. In proposing real estate testing protocols, the Committee noted that EPA must also consider a number of practical concerns that are not strictly part of science; for example: tampering or interference with the test will make it invalid; a testing protocol that is too complicated or costly will discourage testing; in addition, in warm weather home sellers without air conditioning are unlikely to comply with the requirement to close up their houses for several days during testing.

Overall, the Committee recommended (*Appendix A, Report #33*) that the real estate testing protocols should be consistent with the "*Citizen's Guide to Radon*" but that the protocols should not be constrained by those adopted for the Citizen's Guide. Where the two protocols differ the Agency should provide an explanation for this difference. In reviewing the five protocols presented by EPA, the Committee considered the many variables affecting radon concentration: location within the home; use patterns of heating, ventilation and air conditioning; and variations over time (time of day, season and weather). The Committee found that the data and analyses made available to it were insufficient to make decisions about the protocols, and its recommendations therefore included the professional judgment of the Committee. Some controversy existed about the location for testing, the commercial radon testing community having routinely tested on the basement level where test results generally were less variable but more likely to give higher radon concentration values than in the lowest lived-in area. In its report the Committee recommended that short-term testing be conducted "at the lowest level of

the home that is finished in a manner suitable for occupancy, whether or not the seller lives in that area."

Two simultaneous tests run side-by-side would improve the precision of the measurement applicable to the time period of the measurement; two sequential tests would improve the accuracy of estimating an annual average concentration by increasing the time period over which measurement is made. The material presented to the Committee did not provide a conclusive basis for choosing between simultaneous and consecutive testing.

With short-term testing, both false positive and false negative results will occur at a higher frequency than with long-term testing properly performed. If short-term testing is chosen, the Committee recommended that:

- a) Short-term testing should be conducted on the lowest level of the home that is finished in a manner suitable for occupancy, whether or not the seller lives in that area.
- b) Two measurements should be conducted if passive short-term integrating monitors are used; each measurement should span at least two days or preferably longer.
- c) A non-passive continuous radon monitor could also be used, with data collection over a time period sufficient to minimize the effects of daily and day-to-day variations in radon concentration. Again the time period should be at least two days and preferably longer.
- d) Methods should be employed to reduce or eliminate inadvertent or deliberate interference with the measurement devices or violation of the closed-house condition to ensure the integrity of the results.
- e) The "Homebuyer's and Seller's Guide to Radon" should carefully portray 4 pCi/L as the recommended EPA action level for an annual concentration and stress that a 4 pCi/L short-term test result does not necessarily translate to an annual average concentration of this magnitude.
- f) The Committee recommended that the "Guide" address alternate approaches such as escrow account or "radon insurance" type arrangements under which long-term testing and any resulting mitigation would be conducted after the sale of the home and at no further monetary expense to the homebuyer, and
- g) Finally, the Committee believed that the Agency should conduct studies directed toward improving the analyses of both the precision and accuracy of the various measurement methods, testing protocols, and interpretive procedures.

8. NON-IONIZING RADIATION

8.1 Earlier Concerns about the Non-Ionizing Radiation Program

The issue of non-ionizing radiation has concerned the SAB for a number of years and the initial report in this area (Appendix A, Report #2) in fact preceded the establishment of the RAC, having been prepared by a subcommittee appointed by the Executive Committee of SAB to review EPA's document "Biological Effects of Radiofrequency Radiation." This document was prepared for the ORP as a BID for the Agency's development of radiation protection guidance, for use by Federal agencies to limit exposure of the general public to radiofrequency radiation.

The Subcommittee found the document, as amended in response to its earlier comments, to be "an adequate review of the scientific literature" that could serve as a basis for the development of the intended radiation protection guidance. In its further comments the Subcommittee stated that EPA ought to use its own professional staff to keep abreast of developments in this field and that it "should continue to strengthen its program of extramural research and also its in-house research on the health effects of radiofrequency radiation." In addition, the Subcommittee identified certain research areas that it believed needed the Agency's attention.

At the first meeting of the newly established RAC, on February 4, 1985, the Committee learned that the ORP's resources had been repeatedly reduced. At its second meeting, the Committee learned that EPA's Health Effect Laboratory's non-ionizing radiation research program would be eliminated in FY 1986. The Committee subsequently addressed a letter to EPA Administrator Lee M. Thomas expressing its reaction to the latter information (*Appendix A*, *Report #4*). The following paragraphs are quoted from that letter:

- a) "We would like to convey to you our strong concern that this unique research capability will be lost if this action is carried out. The decision to cease research in this area goes counter to the advice given by the SAB earlier and counter to the Agency's need to maintain an analytical and research capability if it is to make informed regulatory decisions. In addition, advances in the field of non-ionizing research are changing our understanding of the biological mechanisms at work.
- b) "EPA should continue and strengthen its program of extramural research and also its in-house research on the health effects of radiofrequency radiation. This is necessary not only to keep abreast of the field but also because the research itself is invaluable to the nation, as attested by the fact that a considerable part of the scientific results reported in its recent (1984) review of the field derives from work done at EPA's own laboratories."

In addition the Committee reiterated the list of non-ionizing radiation research areas needing attention, as originally presented in its earlier report (*Appendix A, Report #2*).

Within a relatively short time thereafter, the RAC was appraised of the ORP's proposal "to 'defer' all Agency involvement in non-ionizing radiation after the Guidance to limit exposure (now being developed) is issued." The phasing out of this area of activity was considered despite renewed national interest in the effects of non-ionizing radiation as a possible cancer promoter. Presumably this decision was made on the basis of budget constraints and the need to focus on larger tasks with perceived higher priorities. With the encouragement of SAB's Executive Committee, the RAC submitted a letter (*Appendix A, Report #14*) to the EPA Administrator drawing attention to the need for EPA to maintain a viable Federal presence in the area of non-ionizing radiation and to provide technical assistance to other agencies in their implementation and compliance with its Guidance. A copy of the Committee's previous report (*Appendix A, Report #2*) was appended.

In May, 1990, RAC again expressed its concern in regard to EPA's lack of attention to non-ionizing radiation and it submitted a letter (*Appendix A, Report #20*) to the Administrator, pointing out that the earlier Guidance development and the Agency's own research in this area had been terminated despite objections from other Federal agencies, the academic community, and the Agency's own Science Advisory Board. The following two paragraphs are quoted from the letter:

- a) "It is the Board's present view that its earlier recommendations have lost none of their force. In addition, new circumstances have arisen that further support these recommendations. Recent research has focused attention on nonionizing electric and magnetic fields well below the usual range, down to 60-Hz power line and lower frequencies, as well as fields modulated at these extremely low frequencies (ELF). Reports in recent issues of scientific journals have suggested the possibility that ELF and power frequency fields may produce detrimental health effects. Some of these studies suggest that cancer is associated with exposure to alternating current magnetic fields. The Agency's Human Health Assessment Group is expected to draw attention to this possibility in its forthcoming report.
- b) "All these circumstances reinforce our view that the Agency should resume its efforts in this area. It is entirely appropriate for EPA actively to conduct research on nonionizing radiation, including ELF effects. Even though the Department of Energy and the National Cancer Institute conduct research on ELF effects, EPA will be called upon to address the public health and environmental issues involved. The fact that other agencies, state and local authorities, and foreign governments have looked to EPA for assistance on this issue reinforces the need for EPA to actively undertake this ELF research."

8.2 Potential Carcinogenicity of Electromagnetic Fields

In October, 1990, the SAB was asked to review the draft report "Evaluation of the Potential Carcinogenicity of Electromagnetic Fields" which had been prepared for the Agency by an outside contractor. By this time the question of whether or not electric power transmission lines could cause cancer had been elevated to an issue of great public concern. The RAC appointed a "Nonionizing Electric and Magnetic Fields Subcommittee" with extensive

participation of outside experts to carry out the review (Appendix A, Report #31). The Subcommittee found serious deficiencies with the EPA document, including internal inconsistencies, that could not be remedied by editing alone, and recommended "logical reorganization" and complete rewriting. Based on the available information, however, the Subcommittee nevertheless expressed its viewpoints on several scientific issues and responded to a number of questions posed to it in the Agency's charge. In the area of epidemiology it found the evidence "suggestive of an association between surrogate measurements of magnetic field exposure and certain cancer outcomes" (such as childhood leukemia), but refrained from drawing the inference of cancer causality from these associations at this time. The Subcommittee also pointed out that low-frequency electric and magnetic fields do not carry enough energy to break chemical bonds and produce mutations directly, but allowed that the incidence of cancer might well be affected by an agent that does not produce mutations.

In response to the Agency's charge, the Committee stated that currently available information is insufficient to conclude that electric and magnetic fields are carcinogenic although some of the data suggested the existence of mechanisms by which other human health effects might be inferred. It also concluded that the Agency's carcinogen classification system is not applicable to electric and magnetic fields because of present major uncertainties. Further, there was insufficient information to designate specific values of magnetic field strength as hazardous to human health.

Two specific policy recommendations were volunteered by the Subcommittee:

- a) "... the question of electric and magnetic field effects on biological systems is important and exceptionally challenging, and ... the report should be rewritten by EPA, and then reviewed by the Science Advisory Board."
- b) "EPA should complete its efforts in regard to RF electromagnetic fields (including microwaves) and issue exposure guidelines independent of present issues pertaining to lower frequencies."

8.3 Research Strategy for Electric and Magnetic Fields

As a follow-up activity to the above review, the Subcommittee was asked to review EPA's document "A Research Strategy for Electric and Magnetic Fields: Research Needs and Priorities." The Subcommittee's response was submitted in a letter report (Appendix A, Report #32). It concluded that all of the topics identified in the Agency's document were relevant to EPA's mission but that a number of important topics were missing if the "Research Strategy" were to represent a national research agenda, a point that was not clear from the document itself. Although well-written and informative, the document provided insufficient details for setting specific research goals and priorities and for ensuring implementation of the strategy.

Whereas priorities for broad research categories were identified, the EPA document did not establish specific research priorities or provide estimates of resources or time needed to undertake the research. Finally, the Subcommittee recommended that research needs and priorities ought to be identified within a broad interagency scope which would then provide the basis for effective interagency cooperation and communication.

9. MISCELLANEOUS GENERIC REPORTS

Over the years, the RAC has generated a number of self-initiated reports on issues that were not limited to a single document or subject under review. Three of these are reviewed below, in chronological order.

9.1 Status of EPA Radionuclide Models

The following text represents excerpts of a letter submitted to the EPA Administrator in January, 1992 (*Appendix A, Report #23*). The comments in the letter specifically addressed the documents produced in support of potential rulemaking for NESHAP (*Appendix A, Reports #17 and #19*) and for radionuclides in drinking water (*Appendix A, Report #26*).

"Many Science Advisory Board reports submitted to the Agency have included constructive criticisms of the models, databases, and uncertainty analyses used by EPA. These criticisms have not been unique to the radiation-related activities of the Office of Radiation Programs, but they are pertinent to those activities. Therefore, the Radiation Advisory Committee of the SAB would like to share with you its view of the limited progress it has seen in this area and problems that remain. The Committee does so because outmoded or inappropriate models, supported by inadequate data and executed to produce conservative results, can lead to significant overestimates of impact for specific potential hazards.

"In addition, selection of regulatory limits based on overestimates may lead to remedial actions unwarranted by actual risks and thus deprive other activities of the resources needed for protection of public health and the environment. The Committee strongly recommends that the EPA at this time assign a high priority to the development of comprehensive models and data sets for the transport of radionuclides in the environment.

"This commentary focuses on three principal topics: (1) models used for predicting radionuclide transport, (2) data sets used as bases for prediction, and (3) lack of uncertainty analysis.

"The Radionuclide Transport Models: The models employed by the ORP to predict the transport of radionuclides in the environment are often inappropriate. Specific models are either outdated or are not the best choice for the specific task. During recent years, improvements in model platform, development, selection and peer review have been inadequate. [Several examples followed.]

"<u>Data Used for Prediction</u>: The data sets used by the ORP as the bases for prediction of the effects of proposed regulatory actions are not adequate. They often do not include the best and most complete information available within the time and budget constraints posed by specific problems, or by the general needs of the Agency. Sensitivity analysis should be

used to determine the data sets most in need of supplementation. During recent years the Committee has found little Office of Radiation Programs support for collection of adequate data. [Several examples followed.]

"Inadequate Uncertainty Analysis: ORP documents using the results of modeling generally do not include detailed presentation of uncertainty analyses. The multiple levels of conservatism often built into a particular analysis are usually not apparent from the document. Specific results often reflect the high end of a range of possible modeling results. Rather, a modeling result should in most cases be presented as an average (reflecting average input data) and a range (which may include a zero health risk at the low end). Presentation of the range of uncertainty is often helpful to the decision maker. The Committee has observed improvement in uncertainty analysis in specific cases in recent years; however, in general, few Office of Radiation Programs reports present their results properly bounded. [Several examples followed.]

"Finally, given the eventual selection of a suite of appropriate models, adequate supporting data sets, and development of a well-designed sensitivity and uncertainty analysis protocol, two more topics must be considered by the ORP.

- "1. The selected models must be adequately validated, i.e., their ability to predict must be tested against actual environmental measurements.
- "2. An ordered approach to the selection, from the above suite, of specific models most appropriate to specific problems must be developed. For example, single, one-dimensional models are best suited for screening tasks. Given a good understanding of input/output uncertainty ranges, a simple model may provide an adequate, cost-effective prediction for many cases. More complex models, with more complex data requirements, should logically be specified only when the increased accuracy of resulting predictions is truly required to solve a problem, and when an adequate input data base is available to support the complex input requirements of the model.

"In summary, many of the recommendations found in recent RAC reports echo those in the August 1984 report of the Science Advisory Board Subcommittee on Risk Assessment for Radionuclides [Appendix A, Report #3] and the SAB generic "Resolution on Use of Mathematical Models by EPA for Regulatory Assessment and Decision-Making" (Appendix B, EPA-SAB-EEC-89-012). The ORP has discussed these problems on numerous occasions in the interim, and has assured the SAB it will develop the techniques and data sets to allow state-of-the-art risk assessments as the basis for regulation, but much of the basic framework of problems remains.

"The Committee hopes that by drawing this persistent problem to your attention, specific work, such as development of validated environmental assessment models with integral uncertainty analysis capability, will be emphasized. These models must be well-

documented, peer-reviewed personal computer implementations, capable of producing uncertainty-bounded best estimates for a range of increasingly detailed input data. They must be made generally available to other researchers, and should have associated generic and region-specific input data sets based on research programs. Development of this comprehensive and defensible model/data set will improve the scientific basis of impact assessments for the next round of radiation-related regulations."

9.2. Harmonizing Chemical and Radiation Risk-Reduction Strategies

This self-initiated report was prepared and submitted to the EPA Administrator in May, 1992 (*Appendix A, Report #34*; see also the published literature on this topic, Appendix B, Report #2). The following summary is taken from the cover letter accompanying the report, with minor editing.

"The RAC would like to bring to the Agency's attention the need to develop a more coherent policy for making risk-reduction decisions with respect to radiation and chemical exposures. The regulation of radiation risks has developed under a different paradigm than for regulation of chemical risks, and a significant potential exists for EPA decisions on radiation risk reduction to be seen as unjustified by the health physics community, the chemical risk management community, or both. Our concern has been stimulated by three recent reviews that the committee has conducted: the Idaho Radionuclide Study [Appendix A, Report #28], the Radionuclides in Drinking Water BID [Appendix A, Report #29]. In the first two reviews, the Committee observed that application of the chemical paradigm to radiation issues was questioned by many in the radiation protection community. The Agency's treatment of radon in indoor air has been more in line with traditional radiation risk management, but is inconsistent with the Agency's proposals for control of radon in drinking water.

"Although the reason for the differences between the two paradigms are historical as well as scientific, an important feature of radiation risk assessment and reduction is the existence of a natural background of radiation in the range of 70 to 250 millirem per year exclusive of indoor radon. With standard risk assessment assumptions, the average background ... say, 100 millirem per year ... is estimated to produce a cancer risk of between 2 and 3 per thousand of people over a lifetime of exposure. To many radiation scientists, reducing *excess* exposures much below 100 mrem/yr seems unnecessary and in any case exceedingly difficult to monitor for compliance because it is within the natural variability of background. By contrast, most EPA programs aimed at reducing risk from *chemical* exposures strive for risks of one in ten thousand or lower. When this paradigm is applied to radiation exposures, such as from radon in drinking water or radionuclides at Superfund sites, the reduction in radiation exposure is in the vicinity of 3 to 5 percent of the total exposure, a figure far below the variability of natural background exposures. The ORP appears to use the radiation paradigm, however, in the case of guidelines for radon mitigation in homes. The current benchmark criterion for remediation of radon in homes

is 4 picocuries per liter of air, which translates (again with standard risk assessment assumptions) to a lifetime cancer risk near one in one hundred.

"The landmark Science Advisory Board report, *Reducing Risk: Setting Priorities and Strategies for Environmental Protection* [Appendix B, EPA-SAB-EC-90-021] (subsequently referred to as *Reducing Risk*), clearly enunciates the principle that EPA's priorities should be directed to reducing the greatest risks first, especially when that can be accomplished economically. The corollary to that principle is that similar risks should be treated similarly, which calls for the harmonization of risk-reduction strategies between chemicals and radiation.

"The resolution to the seeming discrepancy between the radiation paradigm and the chemical paradigm could be achieved in any of several ways: bringing risk-reduction strategies for excess radiation exposures consistently in line with the chemical paradigm (as appears to be happening in some parts of the Agency); bringing chemical risk-reduction strategies more in line with the radiation paradigm; or creating a synthesis between the two systems that places more emphasis on what can reasonably be achieved. In the last case, the importance of background risk could be incorporated and the balancing of the benefits and costs of risk-reduction measures could be strengthened while retaining much of the Agency's current approach to chemicals. If none of these approaches seems appropriate, the Agency should at least explain why the risks from radiation and chemicals are treated differently under specified conditions. The Committee appreciates the Agency's difficulty in establishing a coherent risk-reduction strategy under the variety of statutes governing EPA.

"The ideas in this letter have been discussed with two other SAB committees, Environmental Health and Drinking Water. While not necessarily in agreement about the virtues of various approaches to the problem, those committees agree that the issue is important and should be addressed by the Agency."

9.3. Quantitative Uncertainty Analysis for Radiological Assessments

The following paragraphs are excerpted from the RAC's Commentary submitted to the EPA Administrator in July, 1993 (*Appendix A, Report #41*).

"During its history, the Radiation Advisory Committee (RAC) has on numerous occasions expressed its strongly held view that EPA should incorporate uncertainty analysis as a routine part of its scientific work. Uncertainty analysis is a necessary element of the scientific support for policy actions taken by the EPA. The EPA has recently made significant advance in adopting this practice through the analysis of uncertainties in its assessment of the risks of radon in drinking water. This joint effort was conducted by the staff of the Office of Groundwater and Drinking Water, the Office of Radiation and Indoor

Air, and the Office of Policy and Program Evaluation. This analysis [document] was recently reviewed by the RAC and was the subject of a separate report (*Appendix A*, *Report #40*). This letter is to provide a commentary on uncertainty analysis and urge its widespread use.

"Quantitative uncertainty analysis should be an integral part of performing human health and ecological risk assessments for toxic chemicals, radionuclides, physical stressors, and biotic stressors. Uncertainties associated with both exposure and effects must be accounted for in risk assessments and subsequent risk management decisions and communications. Approaches developed and used by the Offices identified above in their analysis of quantitative uncertainties associated with radon risks have application to risk assessment activities in a variety of EPA program Offices.

"Quantitative uncertainty analysis is relatively straightforward when there is reasonable confidence that the data are of acceptable quality, when crucial relevant risk factors have not been omitted, and when there is a reasonable well-accepted body of literature on the parameter values that would be used to define the uncertainties. The tools needed to accomplish such analysis are readily available.

"Uncertainty analysis is more difficult when data are seriously deficient in quality, when they simply do not exist, or when important risks have not been studied. A formal uncertainty analysis must be preceded by an understanding of these factors. ... An evaluation of the integrity of the data and the sources of information being used to make both central estimates and uncertainty bounds should be done as part of the analysis. When there are unquantified risks (such as synergism which can reasonably be expected but have not been studied), then these should be qualitatively discussed as a complement to the quantitative uncertainty analysis.

A few of the elements that the Committee believed would aid the EPA in performing the quantitative aspects of uncertainty analysis are highlighted below.

"Databases exist for many parameters needed for exposure assessments. The Agency should consider review of distributions of important parameters in criteria and guidance documents to determine if the information needed to perform formal uncertainty analysis for particular assessments is present. Bounds on parameter values and the specified shape of the distribution of plausible values are used in the analysis of uncertainty. Sensitivity analysis will reveal any important dependence upon the form of the distribution. The absence of data does not mean that uncertainty analysis cannot be performed. In the absence of data, quantitative estimates of parameter uncertainties can be obtained by consulting with an appropriately diverse group of experts. However, in some cases, the resulting analysis may be controversial externally, especially if the range of expert opinion is not wide enough.

"Computer software is available for quantitative uncertainty analysis, both for mainframe and personal computers. ... Inexpensive ... software has been developed for either Macintosh or IBM-type computers. Many assessment models can be implemented in spreadsheet format. ... Of course, whenever using any piece of software, efforts should be undertaken to benchmark and verify the calculations to ensure that the software is not producing erroneous results. Efforts should also be made to ensure that the algorithms in the software are appropriate to the specific environmental problem at hand.

"Several general guides to quantitative uncertainty analysis that are applicable to exposure, dose, and risk assessment are available [consult Appendix A, Report #41 for specifics].

"The SAB strongly encourages the increased use of uncertainty analysis as exemplified by its recent use in analyzing the cancer risks of radon in drinking water. The Committee strongly urges that the EPA incorporate the results of this analysis in its overall drinking water risk assessment. Additionally it urges that such uses of uncertainty analysis be expanded to include all EPA programs. In approximately one year the SAB would like to receive an update on how uncertainty analysis has been used by the Agency across its programs."

10. LESSONS LEARNED - EXPERIENCE AND OPINIONS

During its decade of operation, the RAC has evolved and has attempted to evaluate its own performance as well as its interactions with various parts of EPA, including the Science Advisory Board. In the sections to follow, these issues - performance and interactions - will be reviewed and critiqued from the RAC's vantage point.

Broadly, the comments will fall in the categories of the Committee's view of itself, its interaction with the SAB, dealing with the Agency, and other issues.

10.1 The Committee

The RAC believes that it serves a useful function as a sounding board and monitor of the EPA's science base on radiation-related issues. Whereas the Committee fully appreciates the Agency's in-house expertise, a basic principle of the scientific method is the independent evaluation of the scientific work by peers external to that work. If EPA wants strong science to develop sound environmental policy, its science, like that of any institution of individual scientists, must pass through the tests of peer review. The increased utilization of the RAC by the Agency over the years, and the indications that EPA may increasingly be looked upon as the national focal point for information and rule-making in radiation matters, have strengthened the Committee members' conviction that RAC serves an important function and that their own efforts are worthwhile. Even though the expertise of individual RAC members would make them valuable participants on other SAB committees, it is as a whole, and through the interactions among the members, that the Committee achieves its greatest scientific strength.

The RAC itself has evolved over the years, as reflected in its reports to the Agency. The composition and expertise of the Committee have changed, to accommodate the needs of the Agency, and in particular those of the Office of Radiation and Indoor Air (ORIA) and its predecessor, the Office of Radiation Programs (ORP). From an initial, heavily radiobiology-oriented membership, the Committee has broadened its span, now including more representation from the physical sciences and engineering.

An issue of great concern to the Committee is the timeliness of the reports submitted to the Agency. On occasion there has been significant delays before a requested review was forwarded to the Administrator. Although this has not always been the fault of the Committee members (see later comment), the Committee has increased its efforts to complete its review activities in a timely manner.

Looking back over the reports of the RAC and its 1984 predecessor Subcommittees, the Committee believes that the recommendations submitted to the Agency have been quite consistent, making allowance for the few cases when advice later had to be modified in view of developments in the science base. Whereas the bulk of the Committee's reports have dealt with reviews of background information documents, it may be justified to say that the Committee's

greatest impact may well have been the result of its self-initiated communications, such as the ones dealing with residual radioactivity (*Appendix A, Report #24*), consistency in the treatment of radon risk from different environmental sources (*Appendix A, Report #30*), and harmonizing chemical and radiation risk reduction strategies (*Appendix A, Report #34*), to mention a few. Less successful in terms of impact, but equally important in the RAC's opinion, have been the self-initiated reports on the status of the non-ionizing radiation program (*Appendix A, Reports #4*, #14, and #20), and on the status of EPA's radionuclide models (*Appendix A, Report #23*).

The Committee believes that in order to best serve the Agency, it should, when appropriate, alert the Agency to the scientific and technical ramifications of various policy choices. In some of its self-initiated reports, and also in other communications to the Agency, the RAC has sometimes come close to (and perhaps even crossed) the line separating science from policy. The interesting point is that in cases in which the Committee has done this, it was orally commended and was encouraged by EPA Administration members to call attention to apparent inconsistencies in the Agency's handling of environmental risk factors.

However, the RAC declined a request to review the adequacy of testing for suspected radioactive contamination at a Superfund landfill. Since this review would have been site-specific rather than applicable to generic scientific information, the Committee feared that accepting this charge would set an undesired precedent for reviews of other site-specific problems. [In the case of another site-specific situation, the Idaho Radionuclide Study which involved exposures to radioactivity concentrated in slag from elemental phosphorus processing (*Appendix A, Reports #10 and #28*), the RAC saw a broader issue embedded in the site specific problem.]

10.2 Dealing with the SAB

The RAC is currently one of ten standing Committees of the SAB and is dependent on the SAB staff for administrative support and on the SAB Executive Committee for scientific oversight. A possible weakness affecting the interaction between the individual Committees and the rest of the SAB is the relative ignorance on the part of some Committee members in regard to the SAB's overall scope of operation. Thus, with the exception of the Committee chairs, who serve on the Executive Committee, few members of the standing Committees are aware of the activities of the other SAB Committees. Part of the blame for this may fall on the individual Committee chairs, but more might be done by both the Committee chairs and the SAB staff (including the DFOs) to inform the Committee members about the overall activities of the SAB.

The SAB staff by and large handles the identification and nominations of members for the various expert Committees. A greater involvement of the individual Committee members, and in particular the Committee chairs, in this process might have positive ramifications, both from a scientific and a psychological point of view.

Perhaps the greatest practical problem in the relationship between the Committees and the SAB is the periodic shortage, and sometimes unpredictability, of staff support for the preparation of Committee reports. This has on occasion caused unfortunate delays in the completion of reports; an extreme example of this was manifested when a backlog of ten reports by the RAC

was submitted to the Administrator during the month of January, 1992. This may well have been the result of Committee overload, but it may also signal a need for more SAB personnel and/or for a more flexible system of back-up support within the SAB.

Finally, the SAB's budget imposes limits as to the number of Committee and Subcommittee meetings that can be allocated to the individual SAB Committees. This makes the decision as to which requests for reviews to accept a critical issue, again a process that might involve the Committee members to a greater extent than is currently the case.

10.3 Dealing with the Agency

Originally there appeared to be a reluctant acceptance of the RAC by the ORP (later the ORIA), the EPA operating unit with which the Committee has had its major interaction. Fortunately, ORP's attitude improved as it was realized that the RAC could be a help rather than a hindrance to ORP's activities. At times, the Agency had disregarded, and/or disagreed with, the Committee's recommendations; such disagreements have led to the resignation of two Committee members who concluded that they were wasting their time giving unwanted advice. In general, however, the RAC believes that the Agency has valued the Committee's advice in the overwhelming number of cases and that the Committee's interaction with the program Offices has been considered beneficial to the Agency. It can be difficult, sometimes, to accept the fact that the Agency is not required to comply with what a Committee considers scientifically valid advice; in these situations it is important that the Agency, in its response to the Committee, describe its reason(s) for not following the Committee's recommendation(s). After an early period during which the EPA did not regularly provide responses, the Agency has been very conscientious in acknowledging and responding to RAC reviews.

A potential risk to be guarded against is the assumption, or perception, that a review by an SAB Committee implies complete endorsement of the document reviewed, which many times is not the case. Although the RAC is well aware that the Agency, in its decision making, needs to consider factors beyond the SAB's recommendations, the Committee is still concerned that its role in such cases will be misunderstood. Reference to SAB review in EPA publications should not be phrased as to imply complete endorsement by the SAB unless essentially all recommendations have been incorporated.

To get the most out of the Committee's interaction with the Agency, early information should be provided about the issues in which the Agency plans to involve the Committee and, to the extent possible, the Committee should be involved at an early stage of the process, as well as occasionally thereafter, depending on the complexity or significance of the issue at hand. In the case of the RAC, any "early warning" is generally accomplished through the periodic meetings between the Committee chair and the EPA Program or Office Director or her/his representatives. Early involvement is usually achieved through presentations by Agency staff at the official Committee meetings but, in a number of instances, the use of the consultation process has been quite successful. Since the Committee cannot be expected to address every issue that relates to its expertise (nor is this desirable), it would be useful for the Committee from time to time to be

informed about issues on the Agency's agenda that it will not be asked to review. To a certain extent this is already being done in the case of ORIA and the RAC, with the result that the Committee may be able to view its involvement in the context of the Agency's overall agenda.

In a number of instances, the quality of particular documents, especially when prepared by outside contractors, has been less than desirable for an efficient review. In the opinion of the Committee, the Agency should more thoroughly preview contractor-generated documents for adequacy, thus saving the Committee's time and effort and ensuring a better and more timely review. Unfortunately, a limited budget and limited time for oversight may prevent such careful previews from becoming the rule. An additional way to facilitate the Committee's effort is to make the 'charge' accompanying the request for a review as specific and clearly stated as possible.

10.4 Other Issues

Not only the overall operation of the SAB but also the organizational structure and functions of the EPA itself may be relatively little understood by the typical RAC member. While presentations by the ORIA staff allow the Committee members a reasonably good understanding of the radiation activities of that Office, the connections with other indoor air programs, other program offices, and the staff offices of the EPA are less apparent. For example, the relationships of the Office of Research and Development (ORD), and the Office of Policy, Planning and Evaluation (OPPE) to the radiation programs of ORIA are rarely explained in RAC meetings. In fact, the Committee has never been requested to review any of the internal radiation research programs of ORD, such as its early work on the biological effects of low frequency electric and magnetic fields. Thus, some potential benefits to EPA of Committee thinking appear to have been missed.

Regardless of whether or not the RAC becomes more widely utilized by the Agency, it could improve on its current scope by becoming more familiar with the totality of EPA either through written material or through briefings by staff. Such briefings ought to include information about how internal and extramural research programs are developed and managed. A better understanding of these issues might help the Committee in its providing advice to the Agency.

10.5 Continuing Concerns Regarding Issues Reviewed

Among the issues that the RAC has addressed in its history and which the Committee believes are still important for the Agency to consider are the following:

- 1) the need to distinguish more clearly between the risk assessment and risk management aspects of the radiation standards development process;
- 2) the need for quantitative uncertainty analysis for radiological and other assessments of risks;

- 3) the need to highlight the importance of continued development and application of computer models, especially for radionuclide transport;
- 4) the need to address risk in a multi-media manner and to maintain a comparative perspective on risk, even when legislation may not do so;
- 5) the importance of distinguishing between population and individual risks, as well as between organ-specific risks versus total cancer risk;
- 6) the importance of cross-Agency partnerships in addressing radiation concerns;
- 7) the difficulties resulting from a failure to pursue selected research issues; e.g., radon mitigation and effects of non-ionizing radiation; and
- 8) the need to develop a coherent approach for addressing risks from radiation and the risks from chemicals. (In this regard, the RAC is pleased to see that the Agency has recently appointed an intra-Agency task force to address this question.)

The need to give continuing attention to some of these issues was reinforced during the RAC's preparation of its report entitled "Future Issues in Environmental Radiation," (Appendix A, Report #46; EPA-SAB-RAC-95-006) which has been submitted as the Committee's contribution to the SAB's Environmental Futures Project. [The futures report has not been addressed in this retrospective review.]

10.6 Concluding Comments

Some of the comments and suggestions in this section of the report are not necessarily new, and may well have been discussed in other reports, such as the "Mission and Functioning of the EPA Science Advisory Board" (See this and related references in Appendix B). Nevertheless, the RAC felt justified in including in this retrospective report all of the above opinions and conclusions resulting from its own experiences.

APPENDIX A - EPA-SAB-RAC REPORTS REVIEWED

1) Pre-RAC Report A	Review of Proposed Environmental Standards for the Management and Disposal of Spent Nuclear Fuel and Transuranic Wastes (Jan. 1984).
2) Pre-RAC Report B	Biological Effects of Radiofrequency Radiation (Letter, Jan. 31, 1984).
3) Pre-RAC Report C	Report on the Scientific Basis of EPA's Proposed National Emissions Standards for Hazardous Air Pollutants for Radionuclides (Aug. 1984).
4) SAB-RAC (no Nmbr)	Non-ionizing Radiation Research Program (RAC-initiated letter, Apr. 26, 1985).
5) SAB-RAC-86-002	Review of the March 13, 1985 Draft Background Information Document on Low-Level Radioactive Waste Disposal (Oct. 28, 1985).
6) SAB-RAC-86-005	Emergency Criteria Applicable to Elevated Indoor Radon Concentrations in Structures Built on the Reading Prong (Nov. 5, 1985).
7) SAB-RAC-86-028	Review of Proposal Entitled Health Effects of Waterborne Radon (Sept. 5, 1986).
8) SAB-RAC-87-016	Review of EPA Radon Mitigation Test Matrix (Jan. 12, 1986).
9) SAB-RAC-87-035	Review of the Office of Drinking Water's Assessment of Radionuclides in Drinking Water and Four Draft Criteria Documents: Man-Made Occurrences, Uranium, Radium, Radon (July 27, 1987).
10) SAB-RAC-88-001	Review of Revised Plan for the Idaho Radionuclide Exposure Study (Oct. 9, 1987).
11) SAB-RAC-88-002	Review of the Office of Radiation Programs' National Radon Survey Design (Oct. 9, 1987).
12) SAB-RAC-88-009	Review of the Radon Mitigation Research Program (Dec. 22, 1987).

13) SAB-RAC-88-026	Use of the Effective Dose Equivalent Concept (RAC-Initiated letter, Apr. 27, 1988).	
14) SAB-RAC-88-031	Non-Ionizing Radiation Program (RAC-initiated letter, July 19, 1988).	
15) SAB-RAC-88-041	Review of Office of Radiation Programs' Low-LET Risk Estimate for Regulatory Purposes (Sept. 9, 1988).	
16) SAB-RAC-88-042	Review of Office of Radiation Programs' Radon Risk Estimate (Letter Report, Sept. 9, 1988).	
17) EPA-SAB-RAC-89-003	National Emission Standards for Hazardous Air Pollutants (NESHAP): Standards for Radionuclides -Review of Assessment Methodologies (Nov. 10, 1988).	
18) EPA-SAB-RAC-89-017	Review of the ORP's Radon Measurement Proficiency Program (Apr. 25, 1989).	
19) EPA-SAB-RAC-89-024	Review of the Office of Radiation Programs' NESHAPS Background Information Document (June 30, 1989).	
20) EPA-SAB-LTR-90-003	Non-Ionizing Electromagnetic Fields Research (RAC-initiated letter, May 4, 1990).	
21) EPA-SAB-LTR-91-001	ter Report on Radon Risk Estimates for General ulation and Smokers, Non-Smokers, and Children (Letter Jan. 22, 1991).	
22) EPA-SAB-RAC-92-008	Report on Correlation of Short- and Long-term Test Results for Indoor Radon (Dec. 9, 1991).	
23) EPA-SAB-RAC-COM-92-001	Status of EPA Radionuclide Models (RAC-initiated commentary, Jan. 9, 1992).	
24) EPA-SAB-RAC-COM-92-002	Commentary on Residual Radioactivity (RAC-initiated commentary, Jan. 9, 1992).	
25) EPA-SAB-RAC-LTR-92-003	Revised Radon Risk Estimates and Associated Uncertainties (Letter report, Jan. 9, 1992).	

26) EPA-SAB-RAC-92-009	Review of the Office of Drinking Water's Criteria Documents and Related Reports for Uranium, Radon, and Man-made Beta-Gamma Emitters (Jan. 9, 1992).
27) EPA-SAB-RAC-92-012	Review of the ORP's Design for the National Survey for Radon in Schools (Jan. 9, 1992).
28) EPA-SAB-RAC-LTR-92-004	Review of Idaho Radionuclide Study (letter report, Jan. 21, 92; mis-dated 1991).
29) EPA-SAB-RAC-LTR-92-005	Review of Draft Revised Citizen's Guide to Radon (letter report, Jan. 29, 1992).
30) EPA-SAB-RAC-COM-92-003	Reducing Risks from Radon; Water Criteria Documents (RAC-initiated commentary, Jan. 29, 1992).
31) EPA-SAB-RAC-92-013	Review of the ORD's Potential Carcinogenicity of Electromagnetic Fields (Jan. 29, 1992).
32) EPA-SAB-RAC-LTR-92-009	Review of A Research Strategy for Electric and Magnetic Fields Research: Needs and Priorities [EPA/600/9-91/016A] (letter report, May 11, 1992).
33) EPA-SAB-RAC-LTR-92-010	Review of the Draft Revised <i>Homebuyer's and Seller's Guide to Radon</i> (letter report, May 22, 1992).
34) EPA-SAB-RAC-COM-92-007	Harmonizing Chemical and Radiation Risk-Reduction Strategies (RAC-initiated commentary, May 18, 1992).
35) EPA-SAB-RAC-LTR-92-018	Drinking Water Treatment Wastes Containing NORM (letter report, Sept. 30, 1992).
36) EPA-SAB-RAC-LTR-93-004	Evaluation of EPA's Proposed Methodology for Estimating Radiogenic Cancer Risk (letter report, Dec., 1992).
37) EPA-SAB-RAC-CON-93-002	Notification of a Consultation on a Congressionally Mandated Study of Radon in Water (Jan. 29, 1993).
38) EPA-SAB-RAC-COM-93-001	Radon Mitigation Research: Preliminary Finding (RAC-initiated commentary, Apr. 16, 1993).
39) EPA-SAB-RAC-COM-93-010	Review of the Release of Carbon-14 in Gaseous Form from High-Level Waste Disposal (Apr. 29, 1993).

40) EPA-SAB-RAC-93-014	Review of Uncertainty of Risks Associated with Exposure to Radon - "Chafee-Lautenberg Multi-Media Risk Study" (July 9, 1993). [cf. EC-93-010 (July 30, 1993)].		
41) EPA-SAB-RAC-COM-93-006	Quantitative Uncertainty Analysis for Radiological Assessments (RAC-initiated commentary, July 23, 1993).		
42) EPA-SAB-RAC-CON-94-001	Consultation on Cleanup Standards (Dec. 9, 1993).		
43) EPA-SAB-RAC-LTR-94-006	ORIA's Radon Measurement Protocol Evaluation Study (letter report, Jan. 28, 1994).		
44) EPA-SAB-RAC-94-013	Review of Diffuse NORM Draft Scoping Document (May 16, 1994).		
45) EPA-SAB-RAC-95-XXX	Report of the Radon Science Initiative Subcommittee (RAC-initiated report, 1995).		

(NOTE: The RAC Futures Report listed below is referred to, but not reviewed in this report.)			
46) EPA-SAB-RAC-95-006	Report of the Radiation Environmental Futures Subcommittee (1995).		

NOTE: The above Appendix A report numbers refer to the corresponding section/subsection numbers below.

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1: 6.4
                                              2: 8.1
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    8: 7.2

    10: 6.1, 10.1
    11: 7.4

    13: 3.1, 5.1
    14: 8.1, 10.1

    16: 3.2, 4
    17: 4,9.1

    19: 4, 9.1
    20: 8.1, 10.1

    22: 7.2
    23: 9.1, 10.1

    25: 3.2, 5.1
    26: 5.1

    28: 6.1, 9.2
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43: 7.2
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46: 10.5 (RAC Futures Report - referred to, but not reviewed in this report.)

APPENDIX B - RELEVANT REFERENCES

- Boice, J.D., Jr. and J.F. Fraumeni, Jr., editors, "Radiation Carcinogenesis: Epidemiology and Biological Significance," Raven Press, New York, 1984
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APPENDIX C - RADIATION ADVISORY COMMITTEE CHARTER

PREAMBLE: The Administrator of the Environmental Protection Agency (EPA) has asked the Science Advisory Board (SAB) to establish a standing committee on environmental radiation. The formation of such a committee was recommended by the SAB Subcommittee on Risk Assessment for Radionuclides as part of its review of the scientific basis of EPA's proposed standards for airborne radionuclides. The newly-created committee is expected to provide independent scientific advice to EPA as it carries out its mandated activities.

Objective: To review and evaluate the scientific basis and quality of the Agency's risk assessments, research, and other scientific activities related to environmental radiation.

Charge: To establish, on a continuing basis, a committee constituted of a group of scientists knowledgeable in matters related to the impact of radiation on the environment and human populations. The committee is expected to provide a review of the scientific quality of the Agency's radiation activities and to offer advice on how its scientific capabilities may be maintained at a high level. Specifically, the committee is expected to review and comment on the adequacy of scientific information and analyses used in developing risk assessments and other scientific documents on radiation matters.

Scope of Activities: Areas of current and planned committee activity include: (1) providing independent review of scientific analyses used to estimate the impact of radiation on the environment and human populations for EPA's rulemaking activities; (2) carrying out peer reviews and providing advice to EPA on the state-of-the-art of evolving dispersion and transport models and risk assessment methods development; and (3) identifying priority research, monitoring, and other scientific needs to support regulatory activities.

Procedure: The committee will meet at least twice annually or more frequently, if necessary, to carry out its assigned responsibilities. It may hold public meetings to obtain scientific information to assist the committee. The committee will report to the Administrator through the Executive committee of the SAB.

[Authority for Charter: see *Appendix A, Report #3* (Appendix G of the RAC "forerunner report," dated August 17, 1984)]

APPENDIX D - LIST OF RADIATION ADVISORY COMMITTEE CHAIRS, COMMITTEE MEMBERS AND CONSULTANTS

Committee Chairs:

- **1985:** Dr. William J. Schull, Director and Professor of Population Genetics, University of Texas Health Science Center, School of Public Health, Houston, TX
- **1986:** Dr. William J. Schull, Director and Professor of Population Genetics, University of Texas Health Science Center, School of Public Health, Houston, TX
- **1987:** Dr. William J. Schull, Director and Professor of Population Genetics, University of Texas Health Science Center, School of Public Health, Houston, TX

[NOTE: During 1987, Dr. John Till, Radiological Assessments Corporation, Neeses, South Carolina, served as Acting Chair of RAC, during Dr. Schull's sabbatical to the Radiation Effects Research Foundation, Hiroshima, Japan.]

- **1988:** Dr. William J. Schull, Director and Professor of Population Genetics, University of Texas Health Science Center, School of Public Health, Houston, TX
- **1989:** Dr. William J. Schull, Director and Professor of Population Genetics, University of Texas Health Science Center, School of Public Health, Houston, TX
- **1990:** Dr. Oddvar F. Nygaard, Professor of Radiology, Division of Radiation Biology, Department of Radiology, Case Western Reserve University, School of Medicine, Cleveland, OH
- **1991:** Dr. Oddvar F. Nygaard, Professor of Radiology, Division of Radiation Biology, Department of Radiology, Case Western Reserve University, School of Medicine, Cleveland, OH
- **1992:** Dr. Oddvar F. Nygaard, Professor Emeritus, Department of Radiology, Case Western Reserve University, School of Medicine, Cleveland, OH
- **1993:** Dr. Genevieve M. Matanoski, Professor of Epidemiology, The Johns Hopkins University, School of Hygiene and Public Health, Department of Epidemiology, Baltimore, MD
- **1994:** Dr. James E. Watson, Chair, RAC, Professor, Department of Environmental Sciences and Engineering, University of North Carolina, Chapel Hill, NC

Committee Members - 1985:

Dr. William J. Schull, Chair, RAC, Director and Professor of Population Genetics, Center for Demographic and Population Genetics, School of Public Health, University of Texas Health Science Center, Houston, TX

Dr. Seymour Jablon, Director, Medical Follow-up Agency, National Research Council, Washington, D.C.

Dr. Terry Lash, Department of Nuclear Safety, Springfield, Illinois

Dr. James V. Neel, Lee R. Dice University Professor of Human Genetics, The University of Michigan Medical School, Department of Human Genetics, Ann Arbor, Michigan

Dr. Oddvar Nygaard, Professor of Radiology and Director, Division of Radiation Biology, Department of Radiology, Case Western Reserve University, School of Medicine, Cleveland, Ohio

Dr. Warren Sinclair, President, National Council on Radiation Protection and Measurements, Bethesda, Maryland

Dr. Charles Susskind, Professor, Electrical Engineering & Computer Sciences Department, College of Engineering, University of California, Berkeley, California

Dr. John Till, Consultant, Radiological Assessments Corporation, Neeses, South Carolina

Executive Secretary 1985: Ms. Kathleen W. Conway, Science Advisory Board, Washington, D.C.

Committee Members - 1986:

Dr. William J. Schull, Chair, RAC, Director and Professor of Population Genetics, Center for Demographic and Population Genetics, School of Public Health, University of Texas Health Science Center, Houston, TX

Dr. Seymour Jablon, Director, Medical Follow-up Agency, National Research Council, Washington, D.C.

Dr. Terry Lash, Department of Nuclear Safety, Springfield, Illinois

Dr. James V. Neel, Lee R. Dice University Professor of Human Genetics, The University of Michigan Medical School, Department of Human Genetics, Ann Arbor, Michigan

Dr. Oddvar Nygaard, Professor of Radiology, Division of Radiation Biology, Department of Radiology, Case Western Reserve University, School of Medicine, Cleveland, Ohio

Dr. Warren Sinclair, President, National Council on Radiation Protection and Measurements, Bethesda, Maryland

Dr. Charles Susskind, Professor, Electrical Engineering & Computer Sciences Department, College of Engineering, University of California, Berkeley, California

Dr. John Till, Consultant, Radiological Assessments Corporation, Neeses, South Carolina

Executive Secretary 1986: Ms. Kathleen W. Conway, Science Advisory Board, Washington, D.C.

Committee Members - 1987:

Dr. William J. Schull, Chair, RAC, Director and Professor of Population Genetics, University of Texas Health Science Center, School of Public Health, Houston, TX [On leave with Radiation Effects Research Foundation, Hiroshima, Japan.]

[NOTE: During 1987, Dr. John Till, Radiological Assessments Corporation, Neeses, South Carolina, served as Acting Chair of RAC, during Dr. Schull's sabbatical to the Radiation Effects Research Foundation, Hiroshima, Japan.]

Dr. Seymour Jablon, Director, Medical Follow-up Agency, National Research Council, Washington, D.C.

Dr. Terry Lash, Department of Nuclear Safety, Springfield, Illinois

Dr. James V. Neel, Lee R. Dice University Professor of Human Genetics, The University of Michigan Medical School, Department of Human Genetics, Ann Arbor, Michigan

Dr. Oddvar Nygaard, Professor of Radiology, Division of Radiation Biology, Department of Radiology, Case Western Reserve University, School of Medicine, Cleveland, Ohio

Dr. Warren Sinclair, President, National Council on Radiation Protection and Measurements, Bethesda, Maryland

Dr. Charles Susskind, Professor, Electrical Engineering & Computer Sciences Department, College of Engineering, University of California, Berkeley, California

Dr. John Till, Private Consultant, Radiological Assessments Corporation, Neeses, South Carolina [Acting Chair, RAC.]

Executive Secretary 1987: Ms. Kathleen W. Conway, Science Advisory Board, Washington, D.C.

Committee Members - 1988:

Dr. William J. Schull, Chair, RAC, Director and Professor of Population Genetics, University of Texas Health Science Center, School of Public Health, Houston, TX

Dr. Seymour Jablon, Director, Medical Follow-up Agency, National Research Council, Washington, DC

Dr. James V. Neel, Lee R. Dice University Professor of Human Genetics, University of Michigan Medical School, Ann Arbor, MI

Dr. Oddvar F. Nygaard, Professor of Radiology, Division of Radiation Biology, Department of Radiology, Case Western Reserve University, School of Medicine, Cleveland, OH

Dr. Keith J. Schiager, Professor, Department of Radiological Health, University of Utah, Salt Lake City, UT

Dr. Warren Sinclair, President, National Council on Radiation Protection and Measurements, Bethesda, MD

Dr. Charles Susskind, Professor, Electrical Engineering & Computer Sciences Department, University of California, Berkeley, CA

Dr. John Till, Private Consultant, Radiological Assessments Corporation, Neeses, So. Carolina

Executive Secretary 1988: Ms. Kathleen W. Conway, Science Advisory Board, Washington, D.C.

Committee Members - 1989:

Dr. William J. Schull, Chair, RAC, Director and Professor of Population Genetics, University of Texas Health Science Center, School of Public Health, Houston, TX

Dr. Seymour Jablon, Director, Medical Follow-up Agency, National Research Council, Washington, DC

Dr. James V. Neel, Lee R. Dice University Professor of Human Genetics, University of Michigan Medical School, Ann Arbor, MI

Dr. Oddvar F. Nygaard, Professor of Radiology, Division of Radiation Biology, Department of Radiology, Case Western Reserve University, Cleveland, OH

Dr. Keith J. Schiager, Professor, Department of Radiological Health, University of Utah, Salt Lake City, UT

Dr. Warren Sinclair, President, National Council on Radiation Protection and Measurements, Bethesda, MD

Dr. Charles Susskind, Professor, Electrical Engineering & Computer Sciences Department, College of Engineering, University of California, Berkeley, CA

Dr. John Till, Private Consultant, Radiological Assessments Corporation, Neeses, So. Carolina

Mr. Paul Voilleque, Science Applications International Corporation, Idaho Falls, Idaho

Executive Secretary 1989: Ms. Kathleen W. Conway, Science Advisory Board, Washington, D.C.

Committee Members - 1990:

Dr. Oddvar Nygaard, Chair, RAC, Professor of Radiology, Division of Radiation Biology, Department of Radiology, Case Western Reserve University, Cleveland, OH

Dr. Kelly H. Clifton, Professor, Department of Human Oncology and Radiology, University of Wisconsin, Clinical Cancer Center, Madison, WI

Dr. James E. Martin, Assistant Professor of Radiological Health, University of Michigan, School of Public Health, Ann Arbor, MI

Dr. Genevieve M. Matanoski, Professor of Epidemiology, The Johns Hopkins University, School of Hygiene and Public Health, Department of Epidemiology, Baltimore, MD

Dr. Keith Schiager, Professor, Department of Radiological Health, University of Utah, Salt Lake City, UT

Dr. Warren K. Sinclair, President, National Council on Radiation Protection and Measurements, Bethesda, MD

Mr. Paul G. Voilleque, Science Applications International Corp., Idaho Falls, ID

Dr. F. Ward Whicker, Professor, Department of Radiology and Radiation Biology, Colorado State University, Fort Collins, CO

<u>Designated Federal Official 1990:</u> Ms. Kathleen W. Conway, Science Advisory Board, Washington, D.C.

Committee Members - 1991:

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Dr. Kelly Clifton, Professor, Department of Human Oncology & Radiology, University of Wisconsin Cancer Center, Madison, WI

Dr. James E. Martin, Assistant Professor of Radiological Health, University of Michigan, School of Public Health, Ann Arbor, MI

Dr. Genevieve M. Matanoski, Professor of Epidemiology, The Johns Hopkins University, School of Hygiene and Public Health, Baltimore, MD

Dr. Richard G. Sextro, Staff Scientist, Building Ventilation and Indoor Air Quality Program, Lawrence Berkeley Laboratory, Berkeley, CA

Mr. Paul G. Voilleque, MJP Risk Assessment, Inc., Idaho Falls, ID

<u>Designated Federal Official 1991:</u> Ms. Kathleen W. Conway, Science Advisory Board, Washington, D.C.

Committee Members - 1992:

Dr. Oddvar F. Nygaard, Chair, RAC, Professor of Radiology, Division of Radiation Biology, Department of Radiology, Case Western Reserve University, Cleveland, OH

Dr. Stephen L. Brown, ENSR Consulting & Engineering, Alameda, CA

Dr. Kelly H. Clifton, Professor, Department of Human Oncology and Radiology, University of Wisconsin, Clinical Cancer Center, Madison, WI

Dr. James E. Martin, Assistant Professor of Radiological Health, University of Michigan, School of Public Health, Ann Arbor, MI

Dr. Genevieve M. Matanoski, Professor of Epidemiology, The Johns Hopkins University, School of Hygiene and Public Health, Department of Epidemiology, Baltimore, MD

Dr. H. Robert Meyer, C.N.S.I., Harrisburg, PA [Now Vice President, Keystone Scientific, Fort Collins, CO]

Dr. Richard G. Sextro, Staff Scientist, Building Ventilation and Indoor Air Quality Program, Lawrence Berkeley Laboratory, Berkeley, CA

Mr. Paul G. Voilleque, MJP Risk Assessment, Inc., Idaho Falls, ID

Dr. James E. Watson, Jr., Professor, Department of Environmental Sciences and Engineering, University of North Carolina, Chapel Hill, NC

<u>Designated Federal Official 1992:</u> Ms. Kathleen W. Conway, Science Advisory Board, Washington, D.C.

Committee Members - 1993:

Dr. Genevieve M. Matanoski, Chair, RAC, Professor of Epidemiology, The Johns Hopkins University, School of Hygiene and Public Health, Baltimore, MD

Dr. Stephen L. Brown, ENSR Consulting and Engineering, Alameda, CA [Director, R2C2 (Risks of Radiation and Chemical Compounds), Oakland, CA]

Dr. June Fabryka-Martin, Staff Scientist, Chemical Science and Technology Division, Los Alamos National Laboratory, Los Alamos, NM 87545

Dr. Ricardo Gonzalez, Associate Professor, University of Puerto Rico, School of Medicine, San, Juan, Puerto Rico

Dr. F. Owen Hoffman, President, SENES Oak Ridge, Inc., Center for Risk Analysis, Oak Ridge, TN

Dr. Oddvar F. Nygaard, Emeritus Professor, Department of Radiology, Department of Radiology, Case Western Reserve University, Scholl of Medicine, Cleveland, OH

Dr. Richard G. Sextro, Staff Scientist, Building Ventilation and Indoor Air Quality Program, Lawrence Berkeley Laboratory, Berkeley, CA

Dr. James E. Watson, Jr., Professor, Department of Environmental Sciences and Engineering, University of North Carolina, Chapel Hill, NC

<u>Designated Federal Officials</u> 1993: Ms. Kathleen W. Conway, and Dr. K. Jack Kooyoomjian, Science Advisory Board, Washington, D.C.

Committee Members - 1994:

Dr. James E. Watson, Chair, RAC, Professor, Department of Environmental Sciences and Engineering, University of North Carolina, Chapel Hill, NC

Dr. William Bair (Retired), Battelle Pacific Northwest Lab., Richland, Washington

Dr. Stephen L. Brown, Director, R2C2 (Risks of Radiation and Chemical Compounds), Oakland, CA

Dr. June Fabryka-Martin, Staff Scientist, Chemical Science and Technology Division, Los Alamos National Laboratory, Los Alamos, NM 87545

Dr. Ricardo Gonzalez, Associate Professor, University of Puerto Rico, School of Medicine, San, Juan, Puerto Rico

Dr. David G. Hoel, Chairman & Professor, Department of Biometry & Epidemiology, Medical University of South Carolina, Charleston, SC

Dr. F. Owen Hoffman, President, SENES Oak Ridge, Inc., Center for Risk Analysis, Oak Ridge, TN

Dr. Bernd Kahn, Professor, School of Nuclear Engineering and Health Physics and Director, Environmental Resources Center, Georgia Institute of Technology, Atlanta, GA

Dr. Arjun Makhijani, President, Institute for Energy and Environmental Research, Takoma Park, MD

Dr. Oddvar F. Nygaard, Emeritus Professor, Division of Radiation Biology, Department of Radiology, School of Medicine, Case Western Reserve University, Cleveland, OH

Dr. Richard G. Sextro, Staff Scientist, Building Ventilation and Indoor Air Quality Program, Lawrence Berkeley Laboratory, Berkeley, CA

<u>Designated Federal Official 1994:</u> Dr. K. Jack Kooyoomjian, Science Advisory Board, Washington, D.C.

SAB Consultants:

NOTE: The SAB members, when their terms expire, become SAB Consultants, and some members served as consultants prior to becoming a member. The following list is an alphabetic compilation of those who served <u>only</u> as consultants, liaisons, or Federal experts to the SAB's RAC. If a person served at <u>any</u> time as a member, they are listed in the member listing, and not on the following consultant listing.

- 1) Dr. Abdul Karim Ahmed, Science and Policy Associates, [and also Community for National Institute for the Environment (NIE)], Washington, D.C. (EMF Subcommittee)
- 2) Dr. Julian Andelman, Graduate School of Public Health, University of Pittsburgh, Pittsburgh, PA (Radionuclides in Drinking Water Subcommittee)
- 3) Dr. David V. Bates, Professor Emeritus of Medicine, Department of Health Care and Epidemiology, University of British Columbia, Vancouver, BC CANADA (EMF Subcommittee)
- 4) Dr. Gilbert W. Beebe, (liaison), Health Statistician, Clinical Epidemiology Branch, National Cancer Institute, Bethesda, MD (Dose and Risk Subcommittee)
- 5) Dr. Ann Bostrum, School of Public Policy, Georgia Institute of Technology, Atlanta, GA (Radon Science Initiative Subcommittee)
- 6) Dr. David Brenner, Centre for Radiological Research, Columbia University, N.Y., N.Y. (Radon Science Initiative Subcommittee)
- 7) Dr. Patricia A. Buffler, Ph.D., M.P.H., Dean, School of Public Health, University of California, Berkeley, CA (EMF Subcommittee)
- 8) Dr. Craig V. Byus, Associate Professor of Biomedical Sciences and Biochemistry, University of California, Riverside, CA (EMF Subcommittee)
- 9) Dr. Douglas Chambers, SENES Consultants, Richmond Hill, Ontario CANADA (Radon Science Initiative Subcommittee)
- 10) Dr. John DiGiovanni, Associate Director, Department of Carcinogenesis, University of Texas, M.D. Anderson Cancer Center, Smithville, TX (EMF Subcommittee)
- Dr. William E. Feero, Electric Research and Management, State College, PA (EMF Subcommittee)

- Dr. Thomas F. Gesell, (Liaison), U.S. Department of Energy, Idaho Operations Office, Idaho Falls, ID (Radionuclides in Drinking Water Subcommittee)
- Dr. Raymond Guilmette, Inhalation Toxicology Research Institute, Albuquerque, N.M. (Radon Science Initiative Subcommittee)
- Dr. John H. Harley, Hoboken, N.J. (Deceased) (Radionuclides in Drinking Water Subcommittee and Predecessor Review)
- Dr. Robert Harris, Department of Environmental Science and Engineering (School of Public Health, University of North Carolina, Chapel Hill, N.C. (EMF Subcommittee)
- 16) Dr. Clark Heath, American Cancer Society, Atlanta, GA (EMF Subcommittee)
- Dr. Graham Kalton, Institute for Social Research, University of Michigan, Ann Arbor, MI (National Radon Survey Review Subcommittee)
- 18) Dr. Thomas Kirchner, Natural Resources Ecology Lab., Colorado State University, Fort Collins, CO (Modeling Study Group Subcommittee)
- 19) Dr. Nan Laird, Department of Biostatistics, Harvard School of Public Health, Boston, MA (EMF Subcommittee and Radon Measurement Proficiency Subcommittee)
- 20) Dr. Charles E. Land, (liaison), National Cancer Institute, Bethesda, MD (Dose and Risk Subcommittee)
- 21) Dr. Chung Liu, Southcoast Air Quality Management District, El Monte, CA (Modeling Study Group Subcommittee)
- Dr. Leonard LoSciuto, Institute for Survey Research, Temple University, Philadelphia, PA (National Radon Survey Review Subcommittee and Subsequent Radon in Schools Survey)
- Dr. Jacqueline Michel, Research Planning Institute, Columbia, SC (National Radon Survey Review Subcommittee)
- 24) Dr. M. Granger Morgan, Head, Department of Engineering and Public Policy, Carnegie-Mellon University, Pittsburgh, PA (EMF Subcommittee)
- Dr. Mary Ellen O'Connor, Psychology Department, University of Tulsa, Tulsa, OK (EMF Subcommittee)
- Dr. Donald Pierce, Department of Statistics, Oregon State University, Corvallis, OR (EMF Subcommittee)

- 27) Dr. Michael Reimer, (Liaison), U.S. Geological Survey, Denver Federal Center, Denver, CO (Radon Science Initiative Subcommittee)
- Dr. Donald Schutz, Teledyne Isotopes, Westwood, N.J. (National Radon Survey Review Subcommittee, and Subsequent Radon in Schools Survey)
- 29) Dr. Steven Simon, Department of Environmental Sciences, University of North Carolina, Chapel Hill, N.C. (Sources and Transport Subcommittee)
- 30) Dr. Alan Siniscalchi, Coordinator of Radon Program, State of Connecticut Department of Health Services, Hartford, CN (Radon Science Initiative Subcommittee)
- 31) Dr. Kenneth W. Skrable, University of Lowell, Lowell, MA (Invited Speaker)
- 32) Dr. Jan A.J. Stolwijk, School of Medicine, Department of Epidemiology and Public Health, Yale University, New Haven, CT (Radon Risk, Radon Citizen's Guide)
- 33) Dr. William L. Templeton, Battelle Pacific Northwest, Richland, WA (Sources and Transport Subcommittee)
- 34) Dr. James D. Werner, Senior Research Associate, Natural Resources Defense Council, Washington, D.C. (Invited Speaker on Radiological Waste Issues)
- 35) Dr. Barry Wilson, Battelle, Pacific Northwest Laboratory, Richland, WA (EMF Subcommittee)
- 36) Dr. Richard Wilson, Department of Physics, Harvard University, Cambridge, MA (EMF Subcommittee)
- 37) Dr. Rebecca T. Zagraniski (Liaison), Assistant Commissioner, Division of Occupational and Environmental Health, New Jersey Department of Health, Trenton, N.J. (Modeling Study Group Subcommittee)

NOTE: There were a number of SAB members or consultants serving on different standing committees that provided support and liaison activity to the RAC, such as the following (there were others): Dr. James W. Mercer, President, GeoTrans, Inc., Sterling, VA (EEC liaison on consultation dealing with Groundwater Modeling); Dr. Arthur Upton, New York University Medical Center, NY, NY (Dose and Risk Subcommittee), and others.

Previous and Current Secretaries:

Ms. Dorothy M. Clark, Secretary (Served RAC 1984- 1993) Ms. Diana L. Pozun, Secretary (RAC 1993 to Present)

SAB Staff Directors:

Dr. Thomas Bath, Staff Director from 1975-1977*

Dr. Richard Dowd, Staff Director from 1977-1981*

Dr. Terry Yosie, Staff Director from 1981 to 1988

Dr. Donald G. Barnes, Staff Director from 1988 to the present

SAB Executive Committee Chairs:

Dr. Emil Mrak (University of California)	$1974 - 1978^*$
Dr. John Cantlon (Michigan State University)	1979-1981*
Dr. Earnest Gloyna (University of Texas-Austin)	1981-1983*
Dr. Norton Nelson (New York University)	1983-1988
Dr. Raymond Loehr (University of Texas-Austin)	1988-1993
Dr. Genevieve Matanoski (The Johns Hopkins	1993 - present
University)	

* Denotes SAB Staff Directors and/or SAB Executive Committee Chairs prior to NOTE: formation of the Radiation Advisory Committee.

APPENDIX E - GLOSSARY OF TERMS AND ACRONYMS

A-Bomb <u>Atomic Bomb</u>

AIRDOS-EPA Acronym for a Computer Program (Dosimetry & Modeling)

ALARA <u>As Low As Reasonably Achievable (EPA's Federal Guidance on Popula</u>

tion Exposu re)

ARAR <u>Applicable, Relevant and Appropriate Requirements</u>
BEIR <u>Biological Effects of Ionizing Radiation</u>

BID Background Information Document

CASAC <u>Clean Air Scientific Advisory Committee</u> (U.S. EPA/SAB)

CFR <u>C</u>ode of <u>F</u>ederal <u>R</u>egulations

Ci <u>Curies</u> (3.7x10¹⁰ disintegration per second)

cm <u>C</u>enti<u>m</u>eter

COM <u>Commentary</u> (a U.S. EPA/SAB Commentary) CON <u>Con</u>sultation (a U.S. EPA/SAB Consultation)

DFO

Designated Federal Official

U.S. Department of Defense

DQO

Data Quality Objective(s)

DREF

Dose Rate Effectiveness Factor

EMF

Electric and Magnetic Fields

EPA U.S. Environmental Protection Agency (U.S. EPA, or "The Agency")

ELF <u>Extremely Low Frequency</u> f_1 Gut-to-blood absorption factor

FY <u>Fiscal Year</u> Hz Hertz

ICRP International Commission on Radiological Protection

L Liter

LET <u>Linear Energy Transfer</u>

LTR <u>Letter Report</u> (a U.S. EPA/SAB Letter Report)

m Meter (also milli, as in mrem)

m³ Cubic meter

NAAQS <u>National Ambient Air Quality Standards</u>

NARM <u>Naturally-Occurring and Accelerator-Produced Radioactive Material</u>

NAS National Academy of Sciences

NCRP <u>National Council on Radiation Protection and Measurements</u> NESHAP <u>National Emissions Standards for Hazardous Air</u>

Pollutants

NIH <u>National Institutes of Health</u>

NORM <u>Naturally-Occurring Radioactive Material</u>

NRC <u>Nuclear Regulatory Commission (also National Research Council - in</u>

reference to NAS and BEIR)

APPENDIX E - GLOSSARY OF TERMS AND ACRONYMS: CONTINUED:

OEETD <u>Office of Environmental Engineering and Technology Demonstration (U.S.</u>

EPA/ORD)ORD Office of Research and Development (U.S. EPA)

ORIA Office of Radiation and Indoor Air (U.S. EPA)

ORP Office of Radiation Programs (U.S. EPA - Forerunner of ORIA)

p pico-, [10⁻¹²] in combination with specific units

PA <u>P</u>ennsylvani<u>a</u>

Po Polonium, as an element or as an isotope of thorium or uranium alpha-

decay chains (e.g., Po-210)

Quality Factor (for high LET radiation)

R Roentgen (unit of exposure)

Ra Radium, as an element or as an isotope of thorium or uranium alpha-decay

chains (e.g., Ra-223, Ra-224, Ra-226)

RAC <u>Radiation Advisory Committee (U.S. EPA/SAB/RAC)</u>

rad Abbreviation for <u>radiation</u> (a unit of absorbed dose of ionizing radiation

equal to an energy of 100 ergs per gram of irradiated material)

RBE <u>Relative Biological Effectiveness</u>
RCRA <u>Resource Conservation and Recovery Act</u>

rem <u>r</u>oentgen <u>e</u>quivalent <u>m</u>an

RF Radio Frequency

Rn Radon, as an element or as an isotope of thorium or uranium alpha-decay

chains (e.g., Rn-219, Rn-220, Rn-222)

RPT <u>Report</u> (a U.S. EPA/SAB Report)

RSIS <u>Radon Science Initiative Subcommittee (U.S. EPA/SAB/RAC)</u>

SAB Science Advisory Board (U.S. EPA)
SARA Superfund Amendments and Reauthorization Act

 $\begin{array}{ccc} \text{SDWA} & \underline{\textbf{S}} \text{afe } \underline{\textbf{D}} \text{rinking } \underline{\textbf{W}} \text{ater } \underline{\textbf{A}} \text{ct} \\ \textbf{S}_{v} & \underline{\textbf{S}} \text{ievert (equal to } 100 \text{ rem)} \\ \textbf{TSCA} & \underline{\textbf{Toxic Substances Control } \underline{\textbf{A}} \text{ct}} \end{array}$

Uranium, as an element or as an isotope (e.g., U-234, U-235, U-238)

U.N. <u>United Nations</u>
U.S. <u>United States</u>

UNSCEAR <u>United Nations Scientific Committee on the Effects of Atomic Radiation</u>

μR/hr micro-Roentgen per hour (see rem)

U.S. <u>U</u>nited <u>S</u>tates

U.S.A. <u>United States of America</u>

U.S. EPA United States Environmental Protection Agency (also EPA, or "the

Agency")

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