UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
THE ADMINISTRATOR

July 11, 1990

EPA-SAB-EPEC-90-019

Honorable William K. Reilly
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Mr. Reilly:

The Science Advisory Board (SAB) has completed its review of the Office of Research and Development (ORD) Ecological Core Research Strategy. Our review was based on a document entitled "Ecological Risk Assessment Program" provided to us in March of 1990 as a "working draft" and on a briefing and discussions with the ORD staff in a review conducted on April 2-3, 1990 by the Ecological Processes and Effects Committee (EPEC).

The review conducted on the Ecological Core Research Strategy was one of three SAB Reviews of EPA's Core Research Program which took place in April. The other two reviews involved the examination of Core Research for Environmental Health and Risk Reduction (Engineering) and were conducted by other SAB Committees.

The charge to this Committee identified three questions for their review of the Ecological Core Research Strategy:

1) Is the conceptual strategy clear?

2) Does it contain the appropriate major areas for research and does the plan ask the right questions?

3) Within each of the major topics, are the proper sub-elements identified?

The Committee unanimously supports the core research outlined in ORD's Ecological Risk Assessment Program as a new, innovative, and visionary approach to help meet the environmental needs of the future. The focus of the Ecological Risk Assessment Program is on the ecosystem. This is an essential and proper step in the advancement of environmental science. However, the emphasis on ecosystems should not be viewed at this time as superior to or as a replacement to community, population, individual, and sub-organismal level studies.

ORD's core research program should place a high priority on risk characterization. Much of the core research program is tailored to support the Ecological Monitoring and Assessment Program (EMAP). Methods to analyze data developed by EMAP should be developed in parallel with its implementation. EPA needs to plan how risk characterization will be carried out, in order to be sure that the data collected by EMAP are appropriate (in terms of type, quality, quantity and scale) for this purpose. The Committee is concerned that ORD is not ready, at present, to carry out such planning, with respect to the data needs for risk assessment, because of ambiguity and controversy over some aspects of methodology in risk assessment.

On the other hand, the Committee is encouraged that the Agency response to the Research Strategies report of the SAB has accorded a new and positive emphasis to the role of ecological research.

In order to maintain or, in some cases, establish credibility, the Agency must seek to increase its numbers of scientists and retain or acquire veteran expertise in the fields circumscribed by the Core Ecological Research Program.

The Committee commends the Agency for its involvement of other Federal and State agencies and academic institutions to produce much of the status and trends monitoring data for EMAP. The Committee recommends however that the Agency develop formal interagency agreements to establish commitments for monitoring and reporting wherever possible.

There must be an efficient "feedback" mechanism from EMAP to other portions of the Core Ecological Research Program to highlight knowledge gaps relative to natural variabilities, so that research efforts can focus on these issues. The Ecological Processes and

Effects Committee of the SAB will continue to review these issues as it focuses on the elements of EMAP and Ecological Risk Assessment.

We appreciate the opportunity to advise the Office of Research and Development on their core research proposals for ecological research. We are pleased to be of service to the Agency, and look forward to your response.

Sincerely yours,

Raymond C. Loehr, Chairman
Executive Committee
Science Advisory Board

Kenneth L. Dickson, Chairman
Ecological Processes and
Effects Committee
Science Advisory Board

EPA U.S. Environmental Protection Agency Washington, DC
EPA-SAB-EPEC-90-019

Report of The Ecological Processes and Effects Committee

Evaluation of The Core Research Program for Ecology

A SCIENCE ADVISORY BOARD REPORT July, 1990

U.S. ENVIRONMENTAL PROTECTION AGENCY

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EVALUATION OF THE CORE PROGRAM CONCEPT FOR ECOLOGICAL RESEARCH

1.0 EXECUTIVE SUMMARY

The Ecological Processes and Effects Committee of the Science Advisory Board met on April 2-3, 1990, to review the concept of the Core Ecological Research Plan. This Plan uses risk assessment as its organizational framework. Currently, the assessment focuses on protecting ecosystems. The Committee unanimously supports the use of risk assessment for organizing this plan; however, EPA should not limit itself to protecting ecosystems because most of the data on effects necessary to assess and quantify risks are derived from community, population, and sub-organismal studies.

The Core Ecological Research Program, as presented to our Committee, appeared to place almost all its initial emphasis on the EMAP component of the program. The Committee recommended that ORD place higher priority than it now does on risk characterization in the early stages of this Core Research Program. Research to improve understandings of causal relationships underlying ecological impacts and to analyze ecological data should parallel the EMAP report to monitor ecological status trends.

The plan should identify those responsible for conducting research on the statistical foundations of risk assessment, quantifying uncertainty, and selecting and validating models used for risk assessment.

All of the components of the Core Ecological Research Program are interrelated. Figure 1 in the research plan is a diagram of the components of risk assessment which implies that risk assessment is a series of steps that can be addressed one at a time. The Committee recommends that EPA change this figure to a block diagram that reflects the component's interactions and to illustrate that risk communication is part of each component of the process.

The Committee recommends that the SAB review and monitor progress of the major components of EMAP.

2.0 INTRODUCTION

The Ecological Processes and Effects Committee of the Science Advisory Board met on April 2-3, 1990 to review the concept of the Core Ecological Research Plan of the US EPA Office of Research and Development (ORD). The research plan was described in a document entitled "Ecological Risk Assessment Program". The Committee was requested by ORD to review the proposed plan as a working draft and to provide reactions during the review process. In particular, ORD requested that the Committee consider whether the use of the risk assessment paradigm was appropriate for this plan, whether the plan covered all of the essential elements, and whether the sequence of steps outlined in the plan was appropriate.

The Committee's review was restricted to the concept and overall approach of the Core Ecological Research Plan. The Committee was advised during staff briefings that the research plan lacked an implementation strategy and contained only lists of candidate projects that could be conducted rather than specific commitments for research projects. This Plan divided the ecological risk assessment process into six steps which were considered to be largely sequential. The majority of the Committee's review was spend on monitoring activities that were included in the Ecological Monitoring and Assessment Program (EMAP). ORD estimated that 70% of the available budget would be spent on EMAP during the first two years of the Core program (fiscal years 1991 and 1992).

2.1 Statement of the charge

The Assistant Administrator of the Office of Research and Development (ORD) attended the January 9-10, 1990, Executive Committee of the Science Advisory Board and requested that the SAB review three ORD Core Research Plans: Ecological Research, Health Effects Research, and Risk Reduction Research. The Executive Committee assigned each Plan to a standing Committee with appropriate expertise. The Ecological Processes and Effects Committee (EPEC) was assigned the task of reviewing the planning document entitled, "Ecological Risk Assessment Program". ORD asked that EPEC review the proposed plan as a "working draft" and provide reactions to ORD staff during the review session. Specifically, ORD asked the Committee to address the following

questions:

1. Is the conceptual strategy clear?

2. Does it contain the appropriate major areas of research and does the plan ask the right research questions?

3. Within each of the major topics, are the proper sub-elements represented?

3.0 COMMENTS ON THE CORE ECOLOGICAL RESEARCH PLAN

3.1 General Comments

The Committee unanimously supports the research outlined in ORD's Ecological Risk Assessment Program as a new, innovative, and visionary approach to meet the future environmental needs. If it carried out properly, it is the type of long-term, proactive research program that should provide a technical basis to make informed, intelligent policy decisions. The Committee viewed the components of Environmental Monitoring and Assessment (EMAP), Ecological Exposure, Ecological Effects, Risk Characterization, Ecosystem Management, and Communication as an appropriate framework for the program. However, to achieve the desired results within and between these components, it will take innovative thinking and a management style not limited to traditional boundaries of expertise or agencies.

Risk assessment is proposed as the organizing framework for the Core Ecological Research Program. The Committee endorses this choice, since the combination of risk management (which is essentially a policy matter) and risk assessment (which is essentially a scientific matter) constitutes the central role of the Agency. To this end, it is important that the ecological research and monitoring efforts be focused on development of methodology and supply of data for risk assessments.

The Committee supports the overall program concept because an Core Ecological Research Program provides:

1. Career/intellectual stimuli by providing freedom to pursue

long-term research problems.

2. Support for investigator-initiated research proposals that address research needs in ecological risk assessment.

The Committee notes that the core strategy makes no reference or indicates any linkage to the Agency's proposed climate research program. This omission strikes us as incongruous in light of the fact that global climate change has been identified as a very important environmental/ecological issue.

3.2 Risk Assessments

For many years the major approach to environmental assessment has been to focus on individuals in a population studies, mostly with laboratory/experimentally derived dose-effects data. The focus of the Core Ecological Risk Assessment Program is on the ecosystem. This is an essential and proper step in the advancement of environmental science. However, the emphasis on ecosystems should not be viewed at this time as superior to or as a replacement for community, population, individual, and sub-organismal level studies. Instead, we need to take this opportunity to calibrate and validate all the different types of studies that provide the "tools" for ecological risk assessment. Once this is done, these "tools" can be used with a better understanding of their uncertainty and usefulness for ecosystem protection.

As stated above, the current risk assessment orientation of the Core Ecological Research Program seems to focus on the protection of ecosystems. By their very nature, ecosystems tend to be resistant and resilient to the influences of stressors. Therefore, it may also be important to consider the protection of communities and populations as a goal of the risk characterization. In part, this is already reflected in the spectrum of exposure and response data that are collected for EMAP. These range from changes observed at the sub-cellular level through effects on individuals and populations to measures of community and ecosystem parameters. The basic challenge is to determine how changes observed at lower levels relate to changes at higher levels of organization, so that it becomes possible to improve the risk characterization process.

Ultimately, risk characterization procedures need to be validated. This is particularly important in an environmental context, because environmental observations detect change, but do not inherently prove causation. Validation of a prediction made in a risk characterization can be tested by intentionally perturbing an ecosystem with a stressor and comparing the effects with the prediction. A partial validation can be accomplished by routinely measuring the efficacy of a risk characterization procedure.

3.3 Risk Characterization

A critical need exists within EPA for integrative methods to perform ecological risk assessments at all levels of biological organization. ORD's core ecological research program should place a high priority on risk characterization. Risk characterization research should provide the methods for incorporation of effects and exposure information into a probabilistic statement of harm at the population, community, and ecosystem levels of organization. ORD should include ecological processes research on the fate of chemicals in ecosystems. Methods to analyze data developed by EMAP should be developed in parallel with its implementation.

Risk characterization is the process of analyzing data, via models and statistical means, to arrive at a quantified estimate of risk and a quantified estimate of the uncertainty of the risk estimate. This process, in other words, is the glue that holds the program together. In one way, this crucial role is recognized in the "pyramid" diagram in the draft plan, for there is a separate box, labeled "risk characterization", constituting one level of the pyramid (which has EMAP, as the data source at the base). But in other ways, it appears to the Committee, that risk characterization has been treated as an afterthought, without due regard for its critical role in the planning process.

In particular, if risk characterization really is the "way that the data from EMAP will be used" there is an absolute need from the start in the process of planning EMAP, to ensure that the data collected by EMAP are appropriate data (in terms of type, quality, quantity and scale) for this purpose. Evidence

was not presented to the Committee of attempts to carefully anticipate the data needs by "mocking up" the risk characterization as part of the planning for EMAP.

Further, there is concern on the part of the Committee that ORD is not ready, at present, to carry out such planning, with respect to the data needs for risk assessment, because of ambiguity and controversy over some aspects of methodology in risk assessment. The Committee believes that it might be wise to place a higher priority on resolving these methodological problems before making too great a commitment to operational components of EMAP. That is to say, resolution of the methodological problems with respect to risk assessment must be part of the planning and design of EMAP; it should not be treated as a separate issue that can be dealt with after EMAP is already in place as a full scale ongoing monitoring program.

Finally, the Committee noted that in some respects ecology has in the past been somewhat of a poor relation within the Agency, fighting an uphill battle for credibility in competition with attention to human health and considerations of chemical toxicity. The Committee is encouraged that the Agency response to the Research Strategies report of the SAB (EPA-SAB-RSAC-89-033, September, 1989) has accorded a new and positive emphasis to the role of ecological research. It is desirable that the work on ecological risk assessment be sufficiently solid that it can continue to maintain unquestioned credibility, in this new and positive atmosphere. For this reason, it is important that the methodological work on ecological risk assessment be coordinated with methodological work on health risk assessment, to ensure that both share the same logical basis, and meet the same basic procedural standards.

The Committee believes that a number of specific questions should be addressed to integrate the risk characterization theory and practice into the planning and design of the Core Ecological Research Program. Examples are as follows:

- What group is taking responsibility for research on the logical, mathematical and statistical foundations of risk assessment in general?

- In particular, what attention is being devoted to the quantification of uncertainty?

- How will EPA determine when a professional consensus has been reached on the research foundations of risk assessment?

- What group is taking responsibility for developing protocols for ecological risk assessment?

- How do the ecological risk assessment protocols relate to the protocols developed for health risk assessment?

  - How does ecological risk assessment relate to the work on the foundations of risk assessment?

- Are there any important differences between ecological risk assessment and other forms of risk assessment?

  - How are these differences justified?

- How can the concurrence of the broader risk assessment community be obtained on this justification, to preserve credibility?

- What models will be employed in processing data into a risk estimate and an uncertainty estimate?

  - Have the models been selected?

  - Have the models been validated? Is there an identified methodology for validation?

  - Have the data needs for calibrating the models been identified?

- If needed calibration data are missing, are there plans for pilot studies to obtain these data?

  - Have the data needs for using the models been identified?

  - How do these data needs translate to specifications in the design for data gathering?

- Is there an identified methodology for incorporating the estimate of the model's predictive power into the uncertainty quantification for the risk characterization?

- What statistical operations will be carried out in processing data into a risk assessment and an uncertainty estimate?

- How do sampling and measurement error in the data carry through to uncertainty in the risk assessment?

It is possible that many of these questions will need to be addressed concomitantly in a separate research effort.

3.4 Risk Communication

The Committee thought that communication of technical programs (what, why, how, benefit, timing, etc.,) in each of the program components is critical if the final research plan is to be of benefit to the decision makers, society in general, and the environment in particular. Risk communication is placed at the top of the pyramid in Figure 1 of the planning document. It would be better to incorporate risk communication as a part of each component. The Committee encourages the Agency to explore and use creative means to communicate the objectives and activities of the proposed program to the public in ways not traditionally considered by scientists.

3.5 Interrelationship of Program Components

All of the components of the Core Ecological Research Program are interrelated to various degrees. For instance, the design of the EMAP program requires a knowledge of the risk characterization process for the selection of monitoring parameters, and simultaneously the risk characterization process requires an understanding of the strengths and limitations of the information that can be provided by EMAP. A careful consideration of their interrelationship should allow for an optimal use of these two components. However, they are also related to all of the other parts of the program, and therefore, their interactions need to be taken into account as well, and it will likely require their simultaneous consideration, rather than a sequential one. From this perspective, the pyramidal

presentation (Figure 1 of the Core Research Report) of the relationship of the components of the overall program, with EMAP at its base is misleading, because it implies a conceptual primacy for EMAP. A block diagram with arrows denoting relationships would avoid this problem.

3.6 Maintenance of ORD Scientific Capabilities

The core research program emphasizes an ecological risk assessment approach to environmental problems. It asks questions that need to be addressed on a broad front by the environmental sciences that, in addition to all aspects of ecology, include environmental engineering, atmospheric science, environmental chemistry, epidemiology, geography among others.

It is clear that from a recent study conducted by ORD (ORD, 1990) on the mix of skills within the office and its laboratories that the Agency is woefully short of the personnel necessary to accommodate all of the research outlined in the Core Ecological Research Program. The intent is, of course, to contract with non-EPA laboratories and scientists to conduct much of the research. However, since the research must lead directly to the goals of the program, ie., ecological risk assessment, human health risk assessment and risk reduction, an interactive relationship between extramural investigators and intramural expertise must exist.

The best way to accommodate this relationship is to make certain that intramural staffing consists of the appropriate mix of scientific competence to develop and maintain these communication links. This competence must be at a respected senior level, so that whatever guidance it proffers will be accepted and followed by both intramural and extramural workers. The staff skills must also be of an integrative quality that can successfully plan and implement complex, multidisciplinary efforts and that can analyze, evaluate and synthesize effective protocols to meet the goals of the Core Ecological Research Program. Such scientists frequently are not satisfied with a role of simply monitoring and supervising research efforts but usually must be active in their own research to keep their state of knowledge and interest current with advances in their respective fields.

The intramural effort must be at least as strong as the extramural effort in order to maintain technical leadership and manage the research program. The Agency must seek to increase its numbers of scientists in the fields circumscribed by the Core Ecological Research Program. EPA has some opportunity to do this with replacement of those who retire, but this is not enough. It must seek new positions as well as the money necessary to conduct credible intramural research.

3.7 Capabilities of EMAP

It is important to clearly state what types of results and data analysis EMAP can definitely deliver, what it may deliver, and what it cannot do. For instance, if EMAP is fully implemented it will provide a critically needed national census of land use patterns and a census of biomes and ecosystems. It will be able to detect changes in the distribution of these features over time. By itself, this information will be enormously useful for policy makers concerned with a broad range of environmental issues. EMAP can also assist in the analysis of broad range of anthropogenic impacts. It cannot supplant compliance monitoring for local situations. These strengths and weaknesses should be elaborated in the report.

3.8 Coordination Concern for EMAP

The Committee commends EPA for its involvement of other Federal and State agencies and academic institutions to produce much of the status and trends monitoring data for EMAP. However, formal arrangements between EPA and other agencies must be developed and agreements made to their scope and commitments to reporting results if complete and timely state-of-the environment reports are to be published.

3.9 Use of Existing Data in EMAP

EMAP provides for incorporation of data from other monitoring networks. The Committee wishes, however, to stress the importance of making adequate provision, both in time and resources, for incorporating, interpreting, and synthesizing all relevant information, including historical data. No matter how

well EMAP is designed, its ability to interpret the findings will be greatly enhanced if they are viewed in the light of other existing information. An emphasis on integration and synthesis will enable the program to begin to issue useful interpretative reports and findings early on. This will help assure continued interest and support for the major budgetary expenditures necessary to implement EMAP.

The Committee recognizes that there is a natural tendency to want to view the EMAP data as internally produced, so that their consistency and quality can be assured. Synthesis of information from various sources will raise difficult questions of extrapolation and interpretation which make many scientists feel uncomfortable. However, commitment of time and resources to such an effort is likely to benefit the program.

3.10 Statistical Design of EMAP

The Committee was not presented information that allowed an evaluation of the EMAP statistical design, but wishes to raise issues believed to be central to the success or failure of the program. Assuming that the appropriate parameters or indicators are selected for measurement, the central issue is whether or not the spatial density, frequency, and distribution of sampling points is adequate to detect significant change--and if so, at what level? Further, if statistically significant changes can be detected, it is necessary to separate the influences of anthropogenic change from natural variability and ecological succession to interpret the change.

All of this involves the need to incorporate in the sampling design current understandings of the extent and causes of spatial and temporal variability of the various measurement indicators. The degree of variability may differ widely between different ecosystems, thus further complicating the problem of sampling design. The EMAP scheme, in this regard, presents a much more difficult challenge than the design of the acid deposition network, which is the basis for the EMAP concept.

The Committee understands that the EMAP designers are reviewing these issues in depth and look forward to the specific results of these reviews.

3.11 Indicators in EMAP

There was general agreement that a critical issue in exposure and effects evaluations is related to how well indicators are chosen and how well they relate to the ultimate determination of ecosystem health. Many indicators are very specific with regard to anthropogenic insult, such as bioaccumulation of toxics or specific types of symptoms observed on foliage in forests. Others, however, especially biomarkers such as altered enzyme activity or ethylene release, can also be the result of natural biotic and abiotic stresses, such as insects and pathogens, or even frost. The Committee strongly encourages careful evaluation of indicators used in EMAP [1] so they can be diagnostic of stressors of the environment.

3.12 Natural Variability Versus Anthropogenic Change

Fundamental to the success of EMAP will be the ability to separate natural changes or natural variability from anthropogenic changes. The importance of understanding natural variability has been recognized by the Agency. It must be stressed, however, that without an estimation of such changes or differences in individuals, populations, communities, and ecosystems or natural changes or differences in chemical fluxes or concentrations, the uncertainties in estimates of status and trends will be great. There must be an efficient "feedback" mechanism from EMAP to other portions of the Core Ecological Research Program to highlight knowledge gaps relative to natural variabilities so that research efforts can focus on these issues. Results may indicate that existing sampling designs must be modified to accomplish specific goals or that certain conclusions cannot be made with existing designs.

3.13 Broad Spectrum Chemistry

The chemical analyses conducted in EMAP should be designed to quantify substances which have biological relevance (e.g. priority pollutants, nutrients, etc). For these chemicals, accurate and precise analytical methodologies should be utilized.

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[1]The Ecological Monitoring Subcomittee of EPEC reviewed the "Ecological Indicator Report for EMAP" on May 8-9, 1990. A report should be available after October 1990.

The quantitative nature of the analyses should be emphasized. A major weakness in this is that only those substances deemed important will be detected and quantified.

Consideration should be given to including broad spectrum analyses with sample extraction and extract fractionation to keep as many anthropogenic chemicals as possible and collection and storage of all instrumental analytical signals generated. This approach will yield less accurate quantitative information but will increases the probability of detecting new compounds or substances entering the system by emphasizing the qualitative output of the analyses. The advantages of such a program were discussed previously in the SAB review of the surface water monitoring (SAB-EETFC-88-006, 1987).

It is also recommended that EMAP incorporate environmental specimen banking in the program (i.e., storing samples in a manner to preserve chemical integrities). There is no doubt that analytical methodologies will improve over time and new problems will emerge related to chemicals which are impossible to foresee. Therefore having the ability for retrospective analysis by removing specimens from storage and subjecting them to "new" analyses will be of paramount importance.

3.14 Role of SAB in overall review of EMAP

EMAP is a major element in ORD's Core Ecological Research Program. It is recommended that the SAB review the EMAP program and its major components. The review should address the components of the program, implementation plans and its long-term strategies. The Committee expressed the concern that while many different groups are reviewing and commenting on portions of EMAP, no overall review of how the parts fit together appears to be programmed.

4.0 SUMMARY OF RECOMMENDATIONS

The Committee unanimously supports the research outlined in ORD's Core Ecological Risk Assessment Program as a new, innovative, and visionary approach to help meet the environmental needs of the future. The focus of this program is on the ecosystem. This is an essential and proper step in the

advancement of environmental science. However, the emphasis on ecosystems should not be viewed at this time as superior to or as a replacement to community, population, individual, and sub-organismal level studies. Risk characterization procedures need to be validated.

ORD's core research program should place a high priority on risk characterization, including more research on the fate of chemicals in ecosystems. Methods to analyze data developed by EMAP should be developed in parallel with its implementation. There is an absolute need from the start in the process of planning EMAP, to understand exactly how risk characterization will be carried out, in order to be sure that the data collected by EMAP are indeed the right data (in terms of type, quality, quantity and scale) for this purpose. There is grave suspicion that ORD is not ready, at present, to carry out such planning, with respect to the data needs for risk assessment, because of ambiguity and controversy over some aspects of methodology in risk assessment.

The Committee is encouraged that the Agency response to the Research Strategies report of the SAB (SAB-RSAC-89-033) has accorded a new and positive emphasis to the role of ecological research and ecological risk assessment. To support that emphasis the Committee recommends that a higher priority be placed on research in support of risk characterization. Risk communication should be better incorporated into every component of the risk assessment process. In addition, the Agency must seek to increase its numbers of scientists in the fields circumscribed by the Core Ecological Research Program.

The Ecological Monitoring and Assessment Program is a valuable and promising initiative, but it is important to clearly state what EMAP can definitely deliver, what it may deliver, and what it cannot do. The Committee is concerned over the dependency of EMAP on other agencies to produce much of the status and trends monitoring data. The Committee recommends that the Agency develop formal interagency agreements to clarify the monitoring and reporting responsibilities of parties outside the Agency wherever possible.

The Committee wishes to stress the importance of making adequate provision both in time and resources for incorporating,

interpreting, and synthesizing all relevant information, including historical data for reporting the status and trends data from EMAP. There must also be an efficient "feedback" mechanism from EMAP to other portions of the Core Ecological Research Program to highlight knowledge gaps relative to natural variabilities, so that research efforts can focus on these issues. Consideration should also be given to also including broad spectrum chemical analyses with collection and storage of all analytical signals. It is recommended that the SAB review the overall EMAP program.

5.0 LITERATURE CITED

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