Report of the Health Effects Research Review Group

U.S. Environmental Protection Agency
Science Advisory Board
February 1979

EPA NOTICE

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I. INTRODUCTION

The Congress required an evaluation of the health effects research efforts of the U.S. Environmental Protection Agency in section 8(d) of Public Law 95-155, enacted November 8, 1977.*

Subsequent to the passage of the Act, EPA's Science Advisory Board formed a special committee to perform the mandated evaluation. This Committee, named the Health Effects Research Review Group (HERRG) and composed of experienced scientists and research managers, began their task in May 1978.

The Act stated that the evaluation include the following:

1) The health effects research authorized by this Act and other laws;
2) The procedures generally used in the conduct of such research;
3) The internal and external reporting of the results of such research;
4) The review procedures for such research and results;
5) The procedures by which such results are used in internal and external recommendations on policy, regulations, and legislation; and
6) The findings and recommendations of the report to the House Committee on Science and Technology entitled "The Environmental Protection Agency's Research Program with Primary Emphasis on the Community Health and Environmental Surveillance System (CHESS): An Investigative Report."

The Act further stated that

> "the review shall focus special attention on the procedural safegards required to preserve the scientific integrity of such research and to insure reporting and use of the results of such research in subsequent recommendations. The report shall include specific recommendations on the results of the review to ensure scientific integrity throughout the Agency's health effects research, review, reporting, and recommendation process."

The word "research" takes on a broad meaning in a regulatory agency. For the purpose of this evaluation, health effects research will be defined as requested by Mr. Costle in his letter of June 17, 1978, to the Chairman of the Science Advisory Board. A quotation from that letter follows.

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*Section 8(d) of this Act requires that a special evaluation of EPA's health effects research be prepared by the Science Advisory Board (SAB) and the report be submitted to the Administrator, the President and the Congress.

"To delineate the Congress' charge more sharply, I urge the Study Group to define health effects research to include all planned activities, collection and analyses of data done within the Agency for the purpose of adding to the scientific basis for understanding the effects of environmental factors on human health. This definition would include those activities within the Agency which may be used to assess human risk, and which support standard setting and regulatory decision and any activity which gathers new knowledge about human health, or improves our understanding of human health either directly or which can be used to extrapolate to human health impacts."

In view of the limited time available to the Committee, this study focused on the collection and analysis of data primarily to add new knowledge. The analysis of existing information and data, which already satisfies generally acceptable criteria for scientific adequacy, was not considered to be within the scope of the charge to the Committee. Some requested data were unavailable or not provided to the Committee, therefore,the evaluation is not as complete as initially anticipated or desired.

II. SUMMARY AND RECOMMENDATIONS

A. Summary

The purpose of this report is to summarize the nature of health effects research in a regulatory agency, to describe the current status of that function in EPA, and to present conclusions and recommendations. Supporting data and reports relating to individual ORD facilities are available but are not included.

The Committee visited (either as a full or partial committee) all EPA laboratories performing health effects research. Interviews were conducted with senior laboratory staff, managers, and bench scientists as well as with senior managers in the Office of Research and Development (ORD) and in the Program Offices. For the purposes of this report, a "Program Office" refers mainly to the Offices of Water and Waste Management; Air, Noise, and Radiation; and Toxic Substances, as these are the offices responsible for developing regulations and setting standards or tolerances in response to specific legislative acts. A list of the facilities visited, Committee members visiting each facility, and those EPA employees interviewed or providing information can be found in Appendices C and D.

The Committee also utilized the services of SAB members, other scientists, and research managers on an ad hoc basis (Appendix B).

Programs and facilities were evaluated using a number of criteria relating to the objectives of the research and the quality of facilities, staff and results. Among these criteria were responsiveness of the research function, research influence in the decision making process, coherence of planning and goal-setting between ORD and the Program Offices, and quality assurance through peer review and publications.

The Committee interviewed many competent and dedicated people with a real desire to work in a more effective, efficient and involved way.

Research and development in a regulatory agency is a complex task, one requiring research targeted to regulatory requirements usually having short (six month to two year) time frames. Research and development must be related to specific regulatory needs. Identification of gaps in data and needed research effort necessitates cooperative planning between

program managers*, often unfamiliar with research, and research managers, who are often insensitive to regulatory pressures and requirements. Researchers, as professionals, may have difficulty in identifying results which will satisfy regulatory needs when these results are not in their scientific specialties. Constantly altering budgetary allocations to adapt to rapidly changing regulatory needs aggravates research-program staff relations. For these and other reasons, ORD has frequently been viewed as unresponsive by many program managers, who do not, in general, depend upon ORD to support their regulatory efforts. The Committee concluded that it would require far greater joint planning and coordination of ORD and Program Office staffs if ORD outputs, useful to regulation, were to be commensurate with the funds allocated. At present, it is not an effective or an efficient system. The dilemma of research in a regulatory agency is further treated in Chapter IV.

The most successful and useful research programs were found where there was a close working relationship and understanding between scientists in the laboratories and their counterparts in the Program Offices. Such communications are essential to an understanding of priorities, quality demands, timing and what was truly needed to back up the regulatory process in the short and long terms. Poor results were seen all too often, however, because close relationships did not exist.

Pilot research committees have helped to establish essential communications between those who have direct and indirect responsibilities. Where successful, the resulting agreements, e.g., Drinking Water and Pesticides, have helped to make research more responsive and have cut across jurisdictional barriers to establish objectives, goals and plans. The pilot research committees are one means to an end, but shorter and more direct communications lines are needed between data generators and data users.

Beyond a committee approach, there seemed to be little consideration of organizational structures designed to streamline decision making. Hopelessness was expressed many times by those concerned when faced with the seemingly obdurate character of the civil service system and the highly placed, inflexible, and sometimes less than adequate individuals who occupy unessential positions. Inflexibility makes it difficult, indeed, to place people properly and to transfer or get rid of people not performing up to expectations in their jobs.

*A program manager is defined as that person in the Program Office who is responsible for developing the regulatory or standard-setting activity for a specific program as mandated by legislation. A research manager is that person in ORD who is responsible for formulating, planning, and executing specific research programs.

Recent changes in the civil service laws were not seen as adequate to effect much improvement. Desirable changes can occur, but they will require enormous effort, training in, and application of the principles of management by objective and job performance evaluation to establish a clear understanding of what is expected of each employee.

B. Recommendations

The Committee recommends that:

> (1) ORD and Program Office leadership take immediate steps to coordinate all research planning and activities in the Agency. Joint planning to identify information needs must begin as soon as a decision is reached to prepare a regulatory proposal.

Immediately following a program decision to develop a regulatory proposal, Program Office and ORD staff should be assigned to review existing information needs. This group should be given authority to organize Program Office-ORD staff to identify regulatory needs for specific proposals and outline the required research to fill the gaps.

> (2) ORD continue to use appropriate research committees, but they should not be ORD's exclusive planning mechanism.

Research committees, initiated on a pilot scale in 1978 to help ORD plan and coordinate its research activities with the Program Offices, should be used sparingly. These research committees, really task forces, will be most useful when research needs relate to multiple Program Offices and laboratories.

The research committees should be used for identification and prioritization of needs. These committees should not be involved with research implementation.

Key managers within ORD should devise mechanisms to develop well understood objectives, goals, plans and measures of performance for how research should be conducted.

The Committee does not believe that it will be possible for ORD to fulfill its function without extensive agreement by key personnel on objectives, goals, plans, and measures of performance. It might be helpful for ORD to hire experienced management specialists, as consultants, to help address some of the difficult managerial problems which currently exist.

ORD leadership must take steps as soon as possible to work out an understanding with Assistant Administrators in the Program Offices to simplify and shorten lines of communication and to cut to a minimum the reprocessing of decisions by the Washington ORD staff.

(3) The scientific staff of ORD identify subject areas and establish active investigatory groups to pursue long term research essential to regulatory needs. (Implementation of recommendation 1 will ensure that long term research efforts remain relevant.)

There should be a long-term ORD investment in researchers and facilities to develop highly active and productive groups in those research areas which are central to large segments of the Agency's regulatory activity. Allocation of a specific percentage, at least 10%, of the ORD budget for relevant research in case subject areas seems to be reasonable.

(4) The incorporation of ORD research results into criteria, standards, and regulations be strengthened.

ORD must stress, at all levels, the importance of producing results and assisting with their incorporation into regulations and standards. ORD has neither fully recognized or accepted this criterion for judging its efficiency, nor developed mechanisms for efficient utilization of research results by Program Offices. ORD does not maintain records of results which have been incorporated into regulations.

The formation of the Environmental Assessment Groups is a step in the right direction. Part of the responsibility of these groups should be the documenting of which research results have been utilized, the continuing audit of the usefulness of ORD results to regulations and standard setting, and getting feedback from the Program Offices about the research and research planning activities. The Committee found the model, outlined on page 9 of Volume III of "Research and Development in the Environmental Protection Agency," to be still relevant for Agency use.

(5) Responsibility and authority for implementation of research and reporting of research be vested in the laboratory directors and the staff scientists, after agreement on research plans.

The Committee feels that too many specific directions regarding research implementation come from headquarters. This prevents the scientists from using their talents and diminishes the scientific climate for innovative research.

(6) After agreement on responsibilities for research implementation, laboratory directors and their scientific staff be permitted to performed their assigned tasks. (See recommendation 5.)

Laboratory staff need protection against unwarranted mandates, incursions into allotted time for research, and reorganizations and spurious changes in policies that occur with the all-too-frequent changes in leadership. The scientists also need a sense of the Agency's long range commitment to its stated goals.

(7) An expansion of the Interagency Regulatory Group (IRLG) activities be carried out. The excellent planning initiatives of IRLG should be extended to include environmental health research.

The IRLG is seen as an excellent beginning with the potential of reducing duplication and confusion among agencies. This effort should be extended to strengthen coordination of research planning by all agencies conducting environmental health research.

(8) A simple, easily understood accounting system be established for planning, assigning and monitoring use of funds and personnel relative to ORD's intramural and extramural programs.

Effective use of limited funds and personnel requires that they be carefully managed. The accounting systems now in use are inadequate. At the present time, analyses are not performed to place in perspective salaries, equipment costs, services, etc. Those cost breakdowns are necessary to give ORD information about responsive and nonresponsive work at the different laboratories performing health effects research.

(9) Standard procedures for awarding contracts, grants, and cooperative agreements, and monitoring extramural research be simplified and enforced.

Current elaborate rules for contract and grant awards should be reviewed and revised to promote efficiency and timeliness of extramural awards. All personnel must adhere to these new procedures. This would end the current abuses of the extramural award system. Procedures should be adopted to ensure adherence to the new requirements after revisions are made.

The monitoring procedures should indicate methods for evaluating the performance of contractors and grantees during and after completion of their work. Furthermore, the extramural research results should be published in peer reviewed scientific journals. EPA-published reports are no substitute for open literature publications.

Adequate travel funds should be allocated for proper site visits and for monitoring of extramural work. Presently, there is no routine, operational audit of the quality of extramural research.

Responsibility for extramural research (planning, awards, and monitoring) should be made according to the staff's capabilities to effectively plan and monitor such research. This should take into account the amount of independent in-house research expected from the staff scientists. Extramural monitoring assignments should only be made to scientists who have demonstrated professional competence and are thoroughly familiar with how research is conducted in the field being monitored.

(10) Scientific peer review of proposals, programs, and intramural and extramural research be greatly intensified.

Scientific credibility and defensibility of research done in support of regulations are key elements of the success and acceptance of the Agency's role by the public. The Committee feels that, to the maximum extent practical, scientific peer review mechanisms should be utilized to improve the quality of final research results.

All programs and organizational units should be periodically subjected to peer review by qualified scientists from outside the Agency. All proposals and completed research should be reviewed by peer scientists <u>within</u> the Agency, and representative items should be reviewed by scientists <u>outside</u> the Agency.

The quality of research in EPA is important not only because any research should meet standards acceptable to the scientific community but also for reasons derived from the regulatory nature of the Agency.

To ensure acceptability of research results, the studies must be reviewed by one's scientific peers and published in reputable scientific journals. Failure to so treat results of research investigations involves the risk that review will occur at a later date, in a adversary situation, with possible refutation of results and embarrassment to the Agency.

> (11) A dual-ladder promotional system be implemented for qualified scientists to advance in grade and salary without having to undertake supervisory or managerial responsibilities.

Presently EPA has a promotion ladder inadequate to allow scientists to remain in the laboratory and be promoted strictly on the basis of their scientific excellence. EPA suffers from a poor reputation as far as the scientific quality of its health effects research is concerned. This reputation is not totally deserved. There does need to be a system whereby both qualified scientists and qualified managers can each advance and be rewarded in their own fields.

Well qualified personnel are the key ingredient to the conduct of a scientifically sound research program. At the present time, there are both formal and informal procedures that encourage scientists seeking promotions to accept supervisory and administrative responsibilities, thereby reducing the amount of time they have to spend on laboratory research.

When personnel are assigned to senior management positions, primary consideration should be given to individuals who have demonstrated scientific and managerial capabilities; an understanding of how research is planned, conducted and reported; and the ability to communicate research information and needs to both scientists and non-scientists.

> (12) Research management give immediate attention to instituting, in the laboratories, a variety of procedures to create an atmosphere conducive to scientific excellence.

Even though the laboratories are located on or near university campuses or other research institutions, EPA scientists were somewhat outside the mainstream of scientific events. The Committee, therefore, urges management to regularly schedule seminars in which both outside scientists and Agency scientists participate, invite outside scientists to spend time in EPA laboratories (in addition to use of the Interagency Personnel Agreement--IPAs), encourage EPA scientists to spend time in outside laboratories (an exchange program), sponsor workshops and symposia, and generally institute a closer interaction with geographically close institutions.

(13) ORD and senior Program Office staff rotate assignments, preferably on the basis of those ORD and Progam organizational units which consistently interact.

It is essential for effective performance that Program Office and ORD managers understand the problems and capabilities in each organization. Program managers are often unfamiliar with research planning, laboratory work and the inherent time constraints. Likewise, research managers are often unaware and insensitive to regulatory pressures and requirements and with the dilemma of how to present data in a form useful to the Programs.

(14) The research program using the clinical inhalation exposure facility at Chapel Hill, North Carolina, be fully staffed and a sound research program implemented as soon as possible.

The clinical inhalation facility at Chapel Hill is a unique facility, engineered to deliver the desired exposure levels; however, the scientific program, staffing, and plans to utilize the facility are totally inadequate--a very conspicuous waste, as it now stands.

ORD should immediately assess the future need for and use of this facility, establish goals and support for the facility, and assure that the facility is not wasted--even if EPA has to make it available to outside groups. This facility was designed for long range studies to accurately assess and predict the potential adverse effects of selected environmental chemical agents.

The inhalation program, once developed, should be scientifically peer reviewed and approved.

III. COMMITTEE MEMBERSHIP, APPROACHES AND PROCEDURES

A. Committee Membership

The Health Effects Research Review Group (HERRG) consisted of core members and consultants selected for their scientific expertise and research management skills. The consultants supplemented core members and were used to provide specific expertise for the evaluation of individual laboratory programs or special topics of research. A list of Committee members and consultants is Appendix B.

B. Approach to the Assessment of R&D and Procedures Used

It was apparent from the outset that the Committee needed a clear understanding of the mission of health effects research as seen from the viewpoints of the personnel in both the various Program Offices and ORD. Responsiveness of the research function to the pressing (often mandated) needs of the Program Offices has been inadequate in the past; this problem has been clearly described in a report by a committee of the National Academy of Sciences, Analytical Studies of the U.S. Environmental Protection Agency, Volume III: "Research and Development in the Environmental Protection Agency," 1977.

Of necessity, the Committee had to subdivide much of its investigation into small study group activities. A common approach was taken to make it easier to analyze and assemble the findings of the various study groups into an integrated final report. Thus, the research function of the Agency was to be analysed in the context of the regulatory responsibilities of the Agency, which in turn requires a reliable and defensible data base for decision making. The Committee agreed that research can only be understood if the reciprocal relationship between the users of the information (the Program Offices) and the generators of the information (ORD) was examined. The perceptions of both the generators and the users were, therefore, to be probed to determine if there were shared goals and a shared understanding of what is known, what is unknown, and what needs to be known. It was also necessary to determine whether there was a shared understanding of the time frame necessary to generate or assemble the needed data. These perceptions were to be examined at several hierarchical levels to determine if the intentions of the supervisors were accepted in a way that motivated the respective organizational units regardless of location or attitudinal preferences.

While conducting interviews and fact-finding sessions, Committee members tried to use some of the following checkpoints as they were appropriate for the various situa-tions. These points were the basis for the formulation of this report.

a. Checkpoints relating to the mission of health-related research as it supports short-term and long-term Agency needs:

1. Responsiveness of the research function (as defined at the outset)
2. Sense of urgency and commitment of the research function
3. Research influence on judgments made on the decision making process (level of influence and dependence by the program offices)
4. Coherence of planning and goal setting between the Program Offices and ORD (Are budgets really reconciled and supported by both the Program Offices and ORD?)
5. Examples of good and poor responses by ORD
6. How and by whom is the decision made to initiate and conduct specific research investigations?
7. How are information gaps identified? How are long-term trends with potential environmental impacts identified? How are long-term research needs defined and planned to assure budgetary support?
8. Beyond the Program Offices and the ORD functional organizations, what other factors help influence what research is to be done?

b. Checkpoints relating to the quality of health effects research as it supports short-term and long-term Agency needs:

1. Quality assurance:
   a) Good laboratory practices
   b) How is quality assurance implemented to improve the defensibility of results?
   c) Evidence of attention to detail and carefulness (facilities, work flow, housekeeping, attitude, safety program)
   d) Personal scientific integrity, including quality of planning and experimental design, rigor of analysis, courage to disprove one's hypotheses (or hypotheses of a superior), and acceptance of opinions of qualified peers
   e) Can the most qualified people be quickly identified?
   f) Is the civil service system seen as a positive factor in the encouragement of a good research program within EPA?

2. Publication of results (reporting)
   a) In journals requiring scientific peer review, internal government publications, journals or meetings not requiring scientific peer review
   b) Methods for approving manuscripts before release or publication
   c) Is publication seen as helpful to career development?

With these checkpoints in mind, the Committee conducted its assessment through a series of fact-finding sessions and public meetings in Washington and in various EPA laboratories (see Appendix C). The Committee chairman and co-chairman first discussed the charge and the plans for accomplishing the evaluation with the appropriate Congressmen and their staffs. Subsequently, the Committee met with the Administrator, the Assistant Administrators and other senior EPA policy and management staff in various Program Offices, and with representatives from the regions, laboratory directors, senior science managers, and individual laboratory scientists (Appendix D). The Committee members reviewed legislative mandates, various EPA documents, and other papers and memoranda relating to the Committee's charge.

IV. RESEARCH IN A REGULATORY AGENCY: THE CONFLICT DEFINED

A. Present and Future Agency Needs for Data

Volumes have been written on regulatory agency research needs in general and on EPA research needs in particular. Therefore, the Committee approached the subject of the research and development needs of EPA with trepidation and elected initially to describe the pressures and constraints imposed generally upon a research and development group in a regulatory agency and those imposed upon EPA in particular.

Program administrators in regulatory agencies are captives of the calendar deadlines imposed for regulation by the specific statutes they enforce. These agencies routinely deal with Congress, irate constituents, citizen groups, the media, and others. The professional skills which contribute to their success and/or survival are all devoted to integrating immediate pressures and existing knowledge into a set of regulations acceptable to all. This is a difficult situation, one requiring sensitivity to human behavior and appreciation for the relevant available data base. Regulations are usually compromises, their political socio-economic impact and whether they can be enforced. The scientific and technical bases for a regulation will be put to rigorous test if, and only if, the regulation is challenged. Judicial review will incorporate and consider all relevant data; an administrative "gamble" made in the absence of sufficient data to support regulation will very likely lead to remanding the rule to the Agency. Development, promulgation and enforcement of regulations, particularly in an area as underdeveloped and evolutionary as environment, is a difficult exercise.

The formal challenges to regulation are cyclical. Because of inflationary pressures on regulatees since 1976, there has been an increasing trend toward challenging environmental regulatory promulgations. The courts have been sympathetic to the innovative promulgations of EPA, but the economic impacts of EPA administrative interpretations of enabling statutes have led to regulatee demands for more complete substantiating data for promulgated rules; those demands will increase in the future. Even those sympathetic to prudent Federal environmental regulations are demanding higher standards of proof during this highly inflationary period of increasingly demanding and varied Federal regulation. Because environmental rules are still perceived by many as a luxury affordable only by a prosperous private sector, EPA must anticipate continuous, more sophisticated private sector challenges because of inflationary pressures.

These challenges will be overcome only by convincing arguments for regulation, arguments drawing upon defensible data. These data will have to relate specifically to improvements in human health if EPA is to fulfill its mandate as an Agency. In the future EPA will increasingly have to document health gains anticipated from allocation and expenditure of large sums of money for regulation and control of environmental pollution.

B. Investigatory Time Frames

Specific statutes include timetables for regulation assigned by Congress. The Agency has formulated a table of regulations scheduled or in progress (Appendix E). Program administrators will formulate these regulations with whatever data are available prior to and until the scheduled completion date. In general, schedules for EPA to write regulations are short; 6-12 months is normal, while 18 months is considered long. These are short time frames for generation of new information in the laboratory or in the field. EPA Research and Development Office (ORD) personnel have had enormous difficulty responding within the time allotted. It is essential that ORD and Program Office personnel carefully evaluate information needs critical to implementation of scheduled regulations. This must be done as soon as a statute is assigned to EPA for enforcement. In this way, ORD will be able to utilize the maximum available time to generate needed data for regulation. We did not perceive that research needs are routinely approached in this manner.

C. Investigator and Program Staff Interactions

The perceived needs of program managers are usually very specific and often conflict with needs perceived by researchers. For example, researchers may regard experiments requiring toxicity data from animal exposure to pollutant agents at concentrations far in excess of those likely to occur under normal exposure as of little relevance to scientific understanding. Program personnel, however, may regard demonstrated toxicity data, even at unrealistically high exposure levels, as a rationale for regulation. Sorting out these differing perceptions requires personal interchange if ORD is to respond in a timely and meaningful manner. Too often in the past the Program Offices have perceived ORD as unresponsive because results were of a kind different from what had been anticipated and because research time frames were too long to allow the Program Offices to use the data produced. Under these circumstances, program administrators did not look to ORD for solutions to their problems.

Principal Program Office and ORD administrators are located in Washington, D.C. ORD investigators are located in laboratory facilities throughout the nation. Specific administrative mechanisms are required to ensure that communications occur between Program Office administrators and ORD investigators as research in support of specific regulations progresses. In 1978 five research committees were initiated on a pilot basis to help ORD plan and coordinate its research activities and become more responsive to the needs of designated Program Offices. These pilot research committees have helped to provide an essential communication function; furthermore, they have helped to establish understanding and commitment to objectives, goals, and plans. Carefully selected research committees are seen as a means to an end, although a cumbersome one, because their meetings help to educate those who need to know. In the long run, however, the functions served by the pilot research committees need to be institutionalized so that laboratory directors are not excluded from key roles in leadership or from maintaining a high level of competence in their respective laboratories.

Program administrators frequently have their primary training in the legal or engineering professions; they are often not familiar with the state-of-the-art of ORD scientific research. ORD utilizes scientifically trained personnel at all levels of the organization, those working at science on a daily basis. One can draw flow diagrams of the decision making processes in a regulatory agency, diagrams illustrating ORD and Program Office personnel interactions. However, in the final analysis, exchange of information and resolution of issues is required of persons with essentially different bases of understanding. There will be a major built-in obstacle to communications between ORD and Programs Offices as long as ORD relies entirely on scientific managers and the Program Offices on managers who pride themselves on their pragmatic approach, managers grounded in law and/or engineering sciences. By one mechanism or another (rotation of assignments, creation of new positions for complementary professionals in each Program Office and ORD), there must be promotion of ORD-Program Office communication by ensuring that senior managers have a common language(s).

D. Evaluating the Responsiveness of ORD

The responsiveness of ORD is judged by a variety of groups and individuals, including EPA program managers, Congress, citizen groups, and the media, to name a few. The Committee probed primarily EPA program managers' perceptions of ORD's responsiveness to their needs. Senior program managers have indicated that there have been recent improvements, but much

remains to be done. In the past, many Program Offices did not participate in ORD planning. Recent joint ORD-Program Office research planning exercises, such as the pilot research committees, have caused Program Offices to be more favorably disposed toward ORD activities.

Ultimately, ORD's response to the Program Offices will be more stringently judged by how effectively the research results meet the specific needs of the regulators in a timely and scientifically rigorous fashion. The current auspicious climate for ORD pilot research committee planning must not be confused with future ORD outputs necessary to satisfy hard-pressed Agency program managers. For this reason, the major ingredients of ORD research that would allow ORD to be considered "responsive" to regulatory program needs will be briefly discussed. Following this discussion will be comments on the current EPA research process from the planning stages to the final utilization of results by Agency Program Office staffs.

The timing of the delivery of research results to a Program Office is a major factor contributing to the perception of ORD's responsiveness to Agency needs. Regardless of the quality of research results, they are viewed as only marginally useful if available after statutory deadlines have passed. One can argue that in the long run "late" results will be integrated into environmental programs, but this does not engender Program Office staff confidence in or support for ORD.

The scientific and technical soundness of ORD results is crucial if EPA Program Offices are to sustain their regulatory positions. Transfer of weak results by ORD will lead either to rejection of these results by administrators or to utilization with subsequent public embarrassment upon disclosure of a weakly supported position and/or reversal of the Agency position by the Courts.

In addition to being scientifically defensible, research results must be targeted to meet Program Office needs. Needs must be commonly perceived and agreed upon by researchers and program administrators. Dictation of needs by regulatory staff to researchers can result in untimely and fruitless investigations; likewise, researchers with inadequate understanding of program needs may pursue scientifically sound studies which are irrelevant to the Programs.

The understanding of ORD results by potential users is probably a major ingredient of the perception of responsiveness. ORD must not only deliver sound results in a timely manner, but must also translate these results into terms and concepts understandable to the users, i.e., the Program Offices. ORD has a responsibility to assist its users in understanding the strengths, weaknesses and full significance of those research results transmitted for Agency use.

The above ingredients of "responsiveness" relate to the research function as it serves regulatory needs. Each ingredient must be carefully developed and nurtured, literally on a project basis, if expectations of ORD efforts are to be fulfilled.

With this brief introduction to the demands placed upon ORD, specific aspects of performance of health effects research and development in the Agency will now be discussed.

E. What is an Investigatory Product in a Regulatory Agency?

The investigatory product in a regulatory agency is that body of scientific information and data base which is either available to or resides with the scientific staff. The product must be provided to the Program Office in a form that is useful, understandable, and defensible in setting reasonable standards and for writing regulations.

This scientific information can be provided to the Program Offices in many ways. The best way would undoubtedly be to have the research described and published in professionally peer reviewed journals, but information can also be provided through monographs, letters and verbal presentations. The key to the desired investigatory product is for the Agency to have an in-house core of capable scientists who understand the regulatory and standard setting requirements, who can perform the necessary literature searches, can perform their own research and evaluation, and can freely attend professional scientific meetings where discussions and information exchanges occur.

V. OBSERVATIONS OF CURRENT EPA RESEARCH AND DEVELOPMENT

A. Identification of Research Needs

ORD can be viewed as a large multifunction apparatus capable of responding in a variety of modes if appropriate planning of the necessary dynamics and a complete "tune-up" occur prior to "start-up." The initial step is to identify the required outputs. ORD outputs should be responsive to regulatory needs, in the short or long term. At present and, indeed, during the entire history of EPA, short term R&D needs have been stressed. We do not see any conflict between simultaneously sustaining research programs with long (years) and short term (months to years) goals, provided Program Office-ORD concurrence is reached as to these goals.

Historically, Program Offices outlined needs according to their perceptions of the problem. It was a hierarchical planning process which gave the scientists at the laboratory little understanding of what was needed or why. Laboratory scientists often communicated with lower level Program Office staff who did not fully understand the needs and priorities of their program.

There seems to be no systematic identification of information gaps (research needs) in the Agency. This identification should take place as soon as EPA receives legislation on which it must act; it requires close cooperation between the appropriate Program Office and ORD scientists, especially those in the laboratories. These staff members should carefully analyze the Act to assess what the Agency must do to gather the needed information and to fulfill the requirements of the Act. Additional research needs come from the process of drafting regulations and from writing the criteria documents when perceived needs for information are recognized. Better identification of needs takes place when there is a close association between ORD and the Program Office, but this must be directed throughout the Agency in a systematic way.

Long-term (anticipatory) research in subject areas central to Agency responsibilities should be planned as a natural extension of the identification of gaps in the data base. It cannot be designed in a vacuum, as an activity to be initiated or terminated at will. When effective cooperation occurs between ORD laboratory and Program Office personnel and when effort is expended to define common objectives, goals, and plans, opportunities are likely to arise for defining relevant, long-term research programs.

The perception of needs for longer term research arises from the interaction of key regulatory people and creative researchers who are in touch with the issues and the scientific literature. People who do research, read scientific literature,

attend meetings and work cooperatively with the Program Offices are those with the best resources to define needs. The Committee believes that the stress on identifying long-term research needs must come from ORD and that more attention must be devoted to identifying these needs and pursuing the associated research studies.

The pilot research committees have helped to identify gaps deserving further research effort, to date only short term; but even this has helped to gain better insight into Agency priorities. Because of the large number of people involved, these pilot research committees are cumbersome, but they have forced a meeting of minds among key people in the Program Offices and ORD. In fact, the identification of research needs by individuals with diverse backgrounds and responsibilities is a very strong feature of the pilot research committee effort and should be retained regardless of the ultimate fate of the activities of these committees. This should be expanded to include identification of long term needs.

Several efforts at identifying research gaps and implementing research should be highlighted. The Drinking Water Program has been an example of effective cooperation in identifying and implementing research needs, whereas the Human Inhalation Exposure program at HERL, RTP (Chapel Hill) and the Animal Exposure Program at HERL, Cincinnati are examples of very poor coordination. In the area of pollutant inhalation studies on human subjects, the scientists of the Chapel Hill facility have attempted to implement longer range studies to predict and assess more accurately the potential adverse health effects of selected chemical agents. In general, ORD administrators have been sympathetic to funding short-term inhalation projects, but have not been supportive of longer term inhalation research programs. The Inhalation Toxicology (animal model) Program at HERL, RTP, on the other hand, was enthusiastic about its relationship with the Program Office. This group is well supported, largely as a result of a sustained effort by the section leader to keep close contact with ORD and Program Office personnel in Washington. Development of new methodologies was considered to be a major responsibility of the group working on animal inhalation toxicology; they expressed the desire to be involved in toxic substances support as well. This group also supervised contracts and grants. Management of both grants and contracts in addition to the "in-house" responsibility was seen as a desirable component of the total job done by the Inhalation Toxicology Section. A key element of this program seemed to be the desire on the parts of the Program Office and the laboratory to engage in cooperative planning and goal setting. The result is a very spirited and productive group of researchers.

Scientists in the Diesel Exhaust Program at Center Hill (Cincinnati) clearly foresaw the emerging importance of diesel engines and attempted to start long-range research several years ago. These projects were turned down by ORD staff members in Washington, who have recently recognized the need for such studies. Work is now frantically underway to obtain needed results to meet the statutory deadline for establishment of diesel emissions criteria.

B. Planning Research Projects

1. Budget Formulation

During the period of our Committee review, the Agency was in the second year of zero based budgeting (ZBB), i.e., fiscal years 1979 and 1980 budgets were in progress. Funds are authorized and appropriated directly to ORD in categories related to enabling legislation or special projects.

Prior to the introduction of the ZBB process, senior ORD personnel often established project allocations without communicating with Program Office managers. The zero based budgeting process has been an exasperating (but probably desirable) experience for all concerned--Program Offices, ORD, and laboratories alike. It has forced a certain amount of communication and has led to some good, though tortured, outcomes, especially in the pilot research committees. However, communications are still occurring only between ORD and Program Office personnel of relative seniority. We perceive that many bench scientists in ORD do not understand the relationship of their work to overall ORD and Agency goals. If communication involved the laboratory investigators doing the work, even more effective decisions could be reached, while simultaneously gaining the commitment of the researchers to the work.

An additional budgeting problem is the mismatching of personnel ceilings and funding for specific programs and laboratories. Numerous examples were found in which program areas in specific laboratories had very few or no people assigned and relatively large amounts of funds available. In a few instances, relatively large numbers of personnel were assigned with limited funds available. At the headquarters level, the view was frequently expressed that OMB had minimized management's latitude for shifting personnel between programs to better match program needs and fund allocations. Laboratory personnel expressed a feeling of hopelessness in dealing with the problem and were, on occasion, forced into the unrealistic posture of showing, for the record, programs with substantial funding managed with zero personnel; obviously this does not happen. The people who are assigned to manage the program simply charge their time to some other program that has a more adequate manpower ceiling. The result is manpower accounting by progam that is suspect, at best, and probably of limited value.

Clearly, if laboratory directors are to be effective research managers, they must be given the latitude to utilize assigned personnel without rigid program area constraints. A change in approach should allow laboratory directors to place increased emphasis on developing the appropriate mix of disciplinary skills of their staffs to better serve current and future program needs.

Allocation of travel funds is another budget problem. When travel funds are allocated to the laboratories, consideration should be given not only to the number of scientists in the laboratories, the degree of participation in extra laboratory Washington mandated activities, and the required extramural program monitoring required, but also to the geographic location of the laboratories with respect to these activities and to the location of national scientific meetings. Furthermore, increased flexibility should be given to the laboratory directors for control and utilization of travel funds. For example, the laboratory director at the ERL in Duluth should be authorized to approve travel for his staff to go to Canada. One of the major functions of this laboratory is scientific cooperation with their counterparts in Canada. Yet this collaboration is minimal because travel to the Canadian laboratory in Thunder Bay is considered foreign travel and must be approved each time, well in advance, by ORD headquarters in Washington.

2. Research Program Formulation

The Committee senses that the major contribution of the pilot research committees in program formulation has been to overcome previous inadequacies in planning and to initiate discussions of research by the many individuals with an interest in the outcome and utilization of the work. The previous "old system" of hierarchical planning failed to establish understanding and commitment by those who should have been involved. The pilot research committee approach to planning has been warmly endorsed by laboratory staffs because they, personally, provided inputs and gained familiarity with and perspective of the entire program and an awareness of their projected contributions to the entire program. This type of "grass-roots" motivation must be retained, but the leadership must also be involved in the process. Methods need to be established to institutionalize the involvement and commitment of the staff through proper involvement of laboratory directors, as well. Pilot research committees are a useful means to an end, but they are no substitute for accountable leadership, which must be responsible for the integrity and quality of the final product.

When laboratory personnel did feel that they had an influence in setting priorities, they became involved with input to the Program Offices, became involved in the objective

setting, and became involved in the design of protocols to meet objectives. The drinking water projects are outstanding examples and illustrate many of the elements of success that need to be emulated by others. The reputation of the people, their professional standing, and the history of performance stemming from the Cincinnati laboratory and its predecessor, the Taft Center, are influential factors which command the respect and attention of the Program Office. A critical factor in responsive and quality programs is the need to maintain a continuum of qualified, knowledgeable personnel. Also, it is important to recognize that, in the drinking water program office, there are counterparts to ORD staff who understand the scientific and technical issues.

3. Pre-project Evaluation of Productivity and Costs

The laboratories in ORD are mostly media oriented, and scientific program projects and resources are assigned accordingly without assessment of the cost-effectiveness of performing research in each specific laboratory.

ORD, or an outside agency, should perform a yearly assessment of each laboratory's past performance with respect to the quality of the research information produced, the timeliness of delivery of research results, the cost-effectiveness of the laboratory, and other factors which deal with a laboratory's performance and productivity. Only after such assessment has been performed and deficiences corrected should the scientific work (decision units) and resources be assigned to a specific laboratory.

4. Good and Poor Planning

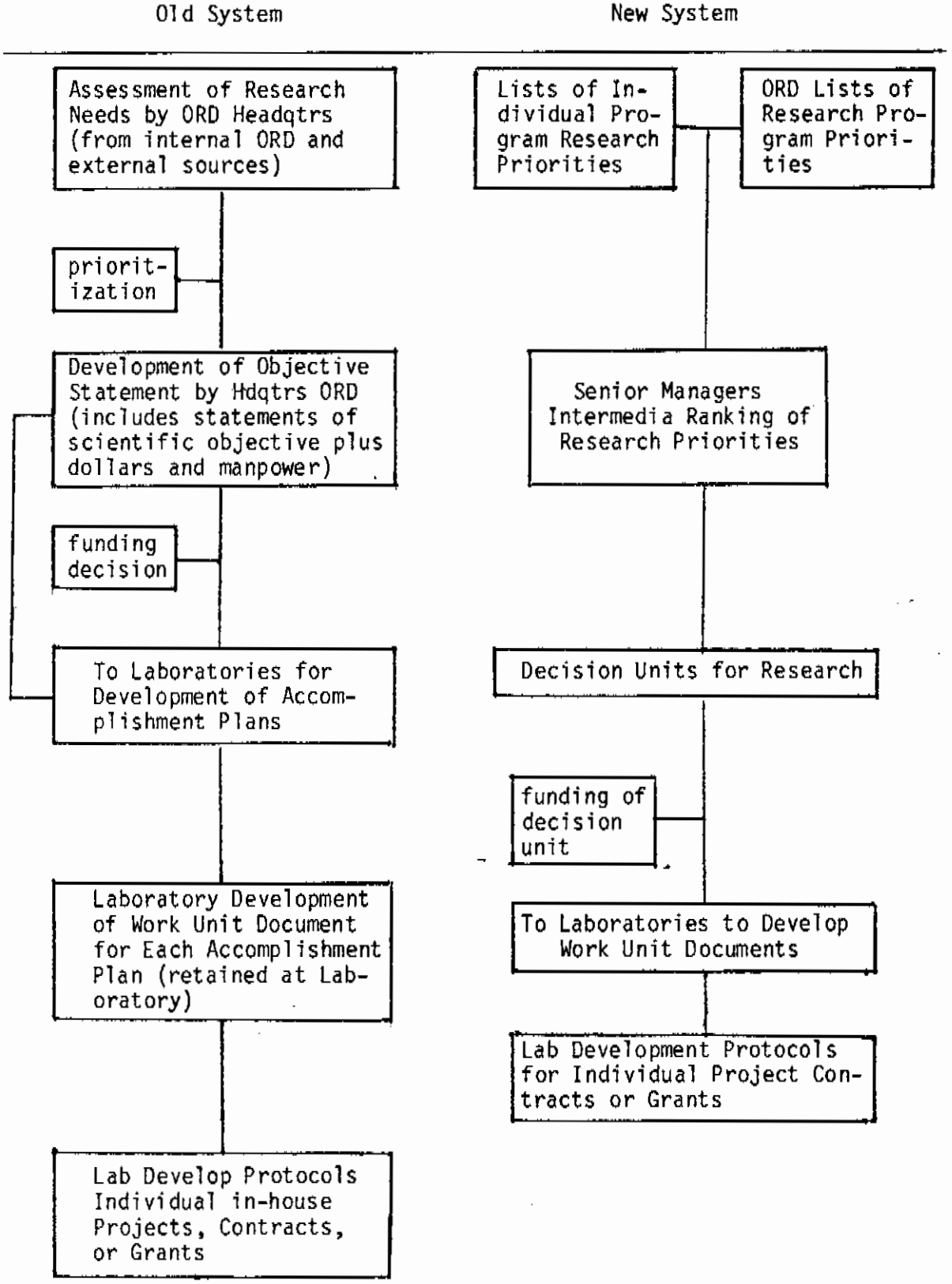
a. Some examples of good responses by ORD

- -The drinking water program at Cincinnati
- -The animal inhalation toxicology program at RTP
- -The pesticide pilot research program involving program and laboratory personnel
- -The Wenatchee Laboratory studies of field exposure of applicator to pesticides (relevant work goes back in history and should be better utilized)

These good responses all have a very important common element; namely, the participants work at good communication. Objectives, goals and plans are understood by the affected parties. Solid scientific approaches are being utilized and researchers in the laboratory are involved with personnel in the Program Offices.

Figure

Diagrammatic Representation of Old and New Systems to Develop Experimental Protocols at Bench Level of Investigation



b. Some examples of poor responses by ORD

The Human Inhalation Facility at Chapel Hill is an unusual facility, engineered to deliver the desired exposure levels, but the scientific program or plan to utilize it is totally inadequate-- a very conspicuous waste.

The Diesel Exhaust Program at Center Hill was prevented from doing adequate dosage response tests because of directives from Washington. The Epidemiology Program associated with the Diesel Emissions Program lacked adequate and mature direction.

C. Performance of Research

EPA's intramural health effects research is conducted in two major laboratories and in portions of three other laboratories, which were established primarily for other purposes. The major laboratories are Research Triangle Park, North Carolina, and Cincinnati, Ohio. Small programs are in effect at the environmental biology laboratories at Duluth, Gulf Breeze, Narragansett, and the Environmental Monitoring and Support Laboratory, Las Vegas. There are also health-related field laboratories in Wenatchee, Washington and W. Kingston, Rhode Island.

All of the laboratories have close relationships with neighboring universities; in some cases the laboratories are located on university campuses (the main Cincinnati Laboratory, the W. Kingston Laboratory, and the Human Inhalation Facility at the University of North Carolina, Chapel Hill).

1. Adequacy of Facilities for Research

The facilities of the health effects laboratories are generally excellent. The major exceptions are the RTP laboratory and the W. Kingston facility, neither of which was built for biomedical research purposes. Some laboratory buildings, on the other hand, were constructed for biomedical research within the past five years (e.g., Cincinnati). In spite of limitations of physical plant, such as the absence of modern animal care facilities at Research Triangle Park, EPA laboratory staff have improvised and created the physical conditions necessary for good research. The laboratories are, in general, notably well-equipped for physical and chemical analysis and modern biologic research; they also appear to have adequate library, data processing and statistical services on the premises or conveniently accessible.

The Committee did not conduct a formal audit of good laboratory practice at any laboratory visited. However, the Committee did consider as part of their general review many of the items that would be considered in such an audit. It was the

Committee's perception that additional attention is needed in this area if EPA laboratories are to achieve the same standards that EPA expects from research conducted outside the Agency and submitted to the Agency.

Some of the specialized physical facilities are unique in the cabability of their chambers to provide accurate concentrations of gasses and aerosols at very low concentrations for human exposure. The inhalation facilities at Cincinnati for experimental animal exposures and the Inhalation Exposure Facility at Chapel Hill for controlled human exposures are good examples.

Housekeeping and safety programs were generally quite satisfactory. Animal facilities in only two laboratories were examined (Cincinnati and RTP). The facilities at Cincinnati have been approved by a national animal facility accreditation committee, while no such accreditation has been attempted at RTP due to its many deficiencies. Our Committee agrees with the findings of the accreditation committee and suggests that EPA devote the necessary resources to bring the RTP animal facility into similar compliance.

2. Staffing for Research

The Committee recognizes the role of history in present EPA staffing, not only the legacies of personnel from the predecessor agencies and programs that were coalesced into EPA in 1970 but also the effects of legislative actions, OMB decisions, and civil service regulations. The Committee, therefore, addressed only limited aspects of the total problem, including the effects of imbalance between funds available for extramural research and professional staff available to monitor the research, the availability of research staff to make effective use of special facilities, and the utilization of scientists from academic institutions to supplement EPA research staff.

Over the past three years, there have been several increases in research appropriations, without proportional increases in personnel (Energy-Environment Act, TOSCA, CAA amendments, etc.). One result is an increase in the burden of monitoring extramural grants and contracts. We found great variability from one research program to another in the distribution and intensity of the monitoring load. There was also much variability in attitudes toward an extramural program. Ideally an extramural project should complement and enrich the intramural scientific endeavor. The individual research worker may or may not wish to expand his (her) own research effort through an extramural grant or two.

The Committee found that some EPA scientists were attempting to monitor six or more extramural projects and had no time for their own research. In one instance, every member of a laboratory division was fully occupied monitoring grants or contracts; there was no intramural research. This is an unsatisfactory method for establishing and maintaining a program of high quality; it is made even worse when appropriations are increased without additional staff increases, as frequently happens.

EPA's special inhalation facilities were costly to build and are expensive to maintain (over $1 million annually for one facility). It is important that such facilities be competently and fully staffed to be effectivly used. In fact, these facilities are seriously underutilized, due both to lack of skilled personnel and to lack of funds for research projects. At the same time multi-billion dollar decisions are being made which would benefit greatly from the kind of information these laboratories could provide (for example, the standard setting for ozone and NO_2).

One practice which increases available manpower and promotes intellectual quality is the exchange of staff between universities, industry, and the Agency (Interagency Personnel Agreement-IPA). The exchange is largely from academic institution to research laboratory, and we found universal enthusiasm for this arrangement within the laboratories. However, there seems to be little systematic effort to recruit IPAs; most of the arrangements develop out of personal acquaintances. While these arrangements are mutually benefical and should be encouraged, EPA has recently adopted a policy which will make university recruitment much more difficult--an academic institution must guarantee a position for a returning IPA. This would severely limit opportunities for young scientists in the early post doctorate period of their careers.

3. Accountability for Expenditures

The Committee did not discover any managerial accounting and auditing efforts within ORD to (a) analyze the success or failure of research projects after their conclusion or (b) apply accounting methods to individual projects to determine dollar allocations to equipment, salaries, travel, and services. There is a remarkable and conspicuous lack of managerial auditing procedures in the ORD operation. After initial formulation of the decision units and their overall budgets, the laboratories are assigned the implementation of projects. In general, it is at the laboratory level that work unit productivity and costs must be tracked on a continuing basis and evaluated for effectiveness and adherence to or departure from categorical costs of ORD operations. The insensitivity to project evaluation after completion of effort was reflected by attitudes of managers and bench scientists. The unawareness of costs was also widespread.

D. The Quality of Health Effects Research

The quality of research in EPA is important not only because any worthwhile research should meet standards acceptable to the scientific community but also for reasons derived from the regulatory nature of the Agency. Presumably all research supported by EPA should be related in the short or long term to the development of a regulation or standard. In this context scientific information is likely to be examined critically in an adversary relationship. Any sloppiness in conduct or interpretation of the work is likely to weaken or destroy EPA's position.

Another characteristic of a regulatory agency is the importance of the credibility of research supported by the Agency. Just as research supported by industry is often suspected of bias, whether justified or not, so research supported by EPA is often alleged to be biased toward the overzealous protection of public health. This question of credibility is a difficult one and is never easily solved. For EPA it implies a great need not only for the highest standards of quality in scientific work but also for active and constant efforts of EPA scientists to participate in and have the support of the scientific community.

It was our experience in visiting the health effects research laboratories and Program Offices that EPA has many scientists who would be welcome in the nation's universities and private research institutions. Many of the scientists we talked to were clearly dedicated to the best traditions of public service in carrying out the missions of EPA. The Committee found areas of high morale and sense of accomplishment, but was disturbed to find areas of low morale and frustration from frequent changes of research direction or even the absence of a sense of direction, often stemming from frequent changes in leadership.

In trying to assess quality, the Committee used what it could of the usual criteria for evaluation. The legal counsel's interpretation of the Privacy Act did not permit the Committee to request a curriculum vitae of any scientist, but many offered them voluntarily. The following information was usually obtained from each research unit: the number of staff with research doctorates; the scientific publication record of the unit, in peer reviewed journals and others; the statistical and computational resources of the unit; the procedures used for peer review; and a sense of the intellectual climate of the unit.

The Committee also examined the procedures used in conduct of "extramural" research through grants and contracts. Consultants were added as necessary to evaluate specific programs and special facilities such as animal housing and care. These and other aspects of quality assurance are described under the headings that follow.

1. Publication and Reporting of Research Results

Scientific investigators are part of a tradition which places great importance on scientific peer review of results prepared for publication in professional journals. As with other characteristics, there was high variability of attitudes and procedures among the different laboratories and divisions of laboratories. Some resembled university laboratories in their emphasis on scientific peer review of research plans and peer review of manuscripts before submission to high quality journals. In these cases publication was seen as an incentive for promotion and professional advancement. Publication in peer reviewed journals enhances the probability that a product of research will "stand up in court." These research units usually had strong interactions with local universities and promoted attendance at scientific meetings, development of symposia and workshops, and participation by IPAs.

At the other extreme were units that appeared to put no emphasis on publication in the scientific literature and who sensed that there was no incentive in EPA for such publication. Others recognized the desirability of such publication but felt so overwhelmed by other responsibilities that they could not find time to publish. Some felt that internal reports were all that the Agency expected.

The policy on review of manuscripts varied from in-house review only to submission of the document to up to five external reviewers. Some scientists not only met the formal requirements but also sent their manuscripts to one or two personal acquaintances whose opinions they particularly valued.

To ensure acceptability of research results, the studies must be reviewed by one's scientific peers and published in a reputable journal. Failure to so treat results of research investigations involves the risk that review will occur at a later date, with possible refutation of results and embarrassment to the Agency. Specific mechanisms must be established to require peer review of ORD results and to encourage prompt publication in peer reviewed journals.

Attendance at professional scientific meetings to present research results is not consistently encouraged.

It has been argued by some laboratory staff that peer review and publication are not necessary for mission-oriented research, the EPA focus. The Committee rejects this viewpoint; applied research, often with short-term goals, must be reviewed and published as surely as that related to more fundamental investigations. Applied research is the final product of years of basic research and should receive even greater review.

2. Quality Assurance in Grants and Contracts

Examinations of this important component of the health effects research program revealed serious problems, which affect in-house performance as well as the quality and relevance of extramural research. One aspect is wide variability in funding from year to year and the assignment of funds without any addition of personnel (this happens with the Energy-Environment "pass-through" appropriation, for example). Another serious problem is the uneven distribution of monitoring responsibility among scientists in a laboratory unit; some are overloaded to the extent they cannot possibly do a satisfactory job.

Both the old and new planning systems give authority to laboratory directors to obtain extramural services through award of contract or grant funds. Laboratory directors rely upon their managers to allocate resources under their jurisdiction to complete work unit tasks. Thus there is local or section management of contractors performing services for ORD. In depth examination of several of the laboratory, sub-unit extramural program procedures for contractor selection, monitoring and evaluation revealed good examples of contractor or grantee selection based on submissions and competitive selection. There were also examples of selection of weak or incompetent applicants, failure of laboratory staff to monitor performance, and almost a total absence of evaluation of the final submission and its relevance to the ORD program and EPA in general.

Some scientists see grants and contracts as a desirable extention of the scope of their personal efforts and enhancement of their contacts with the scientific community. Indeed, a healthy balance between intramural and extramural work can benefit both EPA and the universities. These kinds of relationships do not currently appear to be the norm.

Three kinds of arrangements are used for support of the extramural research program: contracts, grants, and cooperative agreements. Increasingly, contracts have also been used to provide operations and maintenance services directly supporting in-house efforts. The Committee did not systematically examine the quality of contract research and did not look at all of the cooperative agreements, a recent development which has been little used so far.

EPA has more specific requirements for the award of contracts than for grants. The Committee was told repeatedly that grants are being used increasingly, because processing them is easier and takes less time (three or four months, instead of six months to a year for a contract).

Examination of selected files indicated that the review procedures for grants were being abused in at least one

laboratory. There were examples of critical reviewers recommending that the work not be funded or stating that the proposed project was only marginally acceptable. Yet the project officer proceeded to rationalize the reviewer's comments and indicated alterations in the study protocol of the grant applicants which would overcome the objections of the reviewers. Because the proposed project review and the project officer's revisions were performed near the end of the Federal fiscal year, the funds were awarded without either further submissions or a modified submission by the applicant. In one example, inquiry revealed that one year later the project monitor still did not know if the grantee had modified the protocol, added additional personnel, etc., as was recommended by reviewers and as was rationalized by the project officer in justification of awarding the grant.

In other examples the Committee found that external reviews were not obtained before award of grants. (Some EPA staff informed the Committee that soliciting external reviews of contract proposals was illegal, except with permission of the applicants.)

Scientists were encountered who had difficulty keeping track of the number of awards they were assigned to monitor; they were not familiar with the details of extramural contract or grant work as it progressed. The quality of investigatory work external to EPA laboratories and supported by ORD funds was highly variable and of great concern, mainly because ORD oversight was usually lacking. It requires project monitoring effort to ensure that contractors or grantees perform responsive work on a timely basis. There is an efficient "mix" of one's own research and that of others that can be effectively monitored. Conversations with ORD laboratory staff suggested that monitoring one or two contracts or grants totalling perhaps $100-150,000 per year would be a stimulus to a senior ORD scientist. More extensive monitoring responsibility is a burden to the ORD scientist and, even more important, he/she cannot efficiently discharge the monitoring responsibilities. Some research units are so heavily committed to monitoring grants and contracts that no scientist in the unit has any time for his/her own research. The lesson is a clear one; Congress should not increase R&D funding without concomitantly increasing ORD staffing or without identifying alternative approaches.

A frequent complaint was that monitoring was handicapped by the absence of travel funds for the project officer to visit the institution where the research was being done.

Grant applications are of two types--solicited and unsolicited. The latter presumably represents the spontaneous interest of university scientists to do research on environmental problems in which EPA might be interested. The

common response to the Committee's inquiry was that unsolicited grant proposals have almost no chance of being funded, primarily because they are judged "not relevant." It seems clear that EPA scientists are using grants in lieu of contracts, that they monitor them like contracts, and that there is little opportunity for "investigator initiative."

The mechanisms for soliciting grant proposals vary from one unit to another. We found little evidence that EPA has found effective ways to interest university scientists in its problems on a sustained basis.

Another practice, employed to extend the time for longer-term research but with the potential for abuse, is the "front-end loading" of a newly awarded grant. In this practice the amount of the award may be as much as twice the amount of the first year's budget. The investigator can then request an extension for a second year without additional funds, an action routinely granted without a critical review of research progress. The Committee does recognize the need for assured funding of projects that may require more than one year to complete. However, if funds required for more than the first year's operation must be obligated, the project must be carefully monitored to assure that funds for the second year are required and appropriately used.

Another shortcoming of the present EPA system is the absence of a routine operational audit of the quality of extramural research. Individual scientists and laboratory directors told us that a contractor or grantee who performed poorly was not likely to obtain another grant or contract. This informal and spottily used system is not adequate to assure the high quality of extramural performance.

ORD's entire program to make extramural awards of funds under contracts, grants or cooperative agreements requires a thorough overhauling. Extensive standard operating procedures for awarding grants and contracts exist in the Agency; they are voluminous, difficult to comprehend, and are avoided by laboratory staff. It is necessary to establish simple, explicit procedures to be followed by laboratory directors and scientists throughout the life of an extramural award. At present, laboratory directors are expected to satisfactorily complete work unit tasks; extramural projects are their choice and responsibility. The Committee recognizes the need for extramural assistance, particularly if the trend continues to increase ORD dollars without increasing the number of positions for investigators, but the procedures for extramural programs must be placed on a more defensible basis throughout ORD.

3. Career Opportunities

The civil service system was examined as an influence on the quality of research programs and on career opportunities for EPA scientists. There were several examples of negative effects of the civil service system; for example, it does not permit the flexibility to hire new people or to move people as program orientation shifts. Consequently, there are cases in which excellent scientists are placed on projects where their expertise is not needed and where they have to be "re-tooled".

Although the Committee talked to people who had been promoted because of the quality of their research, more frequently promotion related to the assumption or increase of administrative responsibility. Many times a good scientist makes a poor administrator, but the scientist takes the administrative position for the higher salary, not because he or she has management skills. Talented researchers must be encouraged to continue as investigators. Mechanisms must be instituted to further their professional development and their allegiance to the Agency.

It appears that the policies and procedures for advancement do not encourage the emergence of either top scientific or managerial performance. The system does encourage job-hopping by bright people, particularly those in Program Offices. A promotion ladder based on scientific achievement rather than administrative responsibility would help to solve this problem. Many industrial research laboratories use dual ladders for advancement-- administrative and research. Senior research personnel are rewarded with remuneration and privileges comparable to those of a senior manager. ORD is experiencing difficulty in retaining research physicians, epidemiologists, and toxicologists, among others. At the time of this writing, the Human Inhalation Laboratory in Chapel Hill, N.C., a unique facility, is virtually without physicians to perform the research vital to scheduled regulations in the air media.

Administrative mechanisms should be developed to offer a challenging career ladder to these professionals if first rate health effects research is to be performed in ORD. The Committee recognizes that many of the reforms addressed elsewhere in this report will improve conditions for these professionals, but an explicit analysis of conditions and incentives related to a research career in ORD must be performed and improvements implemented where necessary.

4. Other Components of Quality Assurance

Performance evaluations of individuals and laboratories are often perfunctory. Many individual scientists were unclear about the criteria applied to their evaluations and advancement.

Evaluation of laboratories is not being done in terms of good laboratory practices, rewards and incentives, budget and resource allocations, and accountability.

Personal scientific integrity is difficult or impossible to determine in a study of this kind. To the extent that personal conversations, attitudes expressed, and measures taken to assure the quality of research, design, and analysis can be used to assess scientific integrity, the Committee was favorably impressed. If there were subtle biases in the interpretation of research results, they were not detected in this study.

There are periodic "program reviews" in which headquarters' staff members visit the laboratories. These are described by the laboratory scientists as superficial "show and tell" sessions. There is limited scientific feedback from headquarters' staff, and the only benefit to the laboratory is the stimulus to prepare material for presentation.

By contrast, it was noted that when NIH is involved in a jointly sponsored project, there is a visit by NIH staff members, who conduct an intensive critical analysis of the proposed research project. EPA staff who have thus been "nailed to the wall" to defend their projects say they would welcome this kind of evaluation of EPA projects.

There appears to be a general lack of understanding of the Science Advisory Board and its constituent committees by laboratory staff. In view of this, it was not surprising that the Science Advisory Board was criticized for its lack of scientific interaction, failures in communication, and lack of subsequent feedback.

5. Interagency Agreements

The Interagency Regulatory Liaison Group (IRLG) is a new activity which seems to be off to a promising start. Since it is a developing program, no attempt was made to evaluate it.

Other programs involving interagency agreements have had mixed success, at best. EPA has substantially supported the National Center for Toxicologic Research since its inception, with little evidence of any product benefiting EPA. Disappointment was also expressed about interagency agreements with Los Alamos and Oak Ridge National Laboratories and three of the National Institutes of Health.

A significant portion of EPA's health effects research is supported by interagency agreement for the special Energy-Environment appropriation. No attempt was made to examine this program in detail.

E. Other Relevant Topics

1. Long Range, or Core, Program Research

There are subjects for research which are important to several of the media programs. Examples are the properties of particle dispersions, be they in air or water, because of their relevance to collection of the disperse phase prior to effluent discharge, to particle deposition in the human respiratory tract and to particle retention or solubilization in the human gastrointestinal tract; epidemiological methodology because it is a major tool for relating exposures to pollutants to potential effects in the exposed population; and techniques of risk assessment and presentation of the implications prior to judging acceptability of risk. There should be a long term ORD investment in researchers and facilities to develop highly active and productive groups in those areas of research which are central to large segments of Agency regulatory activity. This investment is currently being augmented by initiation of extramural university centers. It is planned to shuttle ORD staff between their resident laboratories and the centers for "leaves of absence" during which they can pursue studies in core areas while upgrading their capabilities on a university campus. We applaud this plan, but also see the need for small, active core research groups in ORD laboratories. Allocation of a specific percentage, at least 10%, of the ORD budget for relevant research in core subject areas, but not on projects specifically traceable to immediate program needs (6 months-2 years), is a reasonable assignment of funds. There is no obstacle to this programming of funds under the present procedures for funds authorization. They are part of the funds assigned to research for the specific statutes, because results will be applicable to those statutes, as well as to others.

2. ORD/Congressional Staff Information Transfer

The relationship and relevance of ORD projects to regulatory needs is not always obvious, particularly to non-scientists. It is essential that members of Congress and their staffs understand the efforts of ORD. Such understanding does not develop accidentally. ORD should develop a plan to regularly inform interested members of Congress and their staffs of the results of ORD efforts and the manner in which they further the goals of statutes administered by the Agency. ORD's investment in what is essentially an educational program for legislators should involve ORD's most senior scientific staff. It is critical that this communication effort include laboratory personnel who are directly involved in the conduct of research. We note the 1978 and 1979 Research Outlook efforts by ORD, but believe efforts must go far beyond this and must incorporate personal communications, as well as transfer of printed information. The concepts of chronic disease, multiple etiologies of disease, host factors, and cumulative effects, to name only a few, are complex and crucial to understanding the underlying approaches to research in ORD.

VI. UTILIZATION OF ORD RESULTS

Different Program Offices utilize ORD research results to different extents. Senior program managers indicated that they did not look to ORD for results; rather, they sought capable laboratories and investigators related to their needs, be they within or outside the Agency. A Radiation Program manager indicated that ORD has little capability to assist them; ORD has no capabilities in the area of biological effects of noise. ORD appears to have little involvement with the Toxic Substances Office. The Water Program draws heavily on ORD at the present time, and recently ORD had a major involvement in the formulation of criteria documents for 65 water pollutants.

The input of research to the screening test and risk assessment process was clearly evident from the Drinking Water Research Program in Cincinnati and the Pesticide Programs at the Gulf Breeze and Wenatchee Laboratories. Their scientific standing is recognized. The respective leadership has maintained the kinds of communication necessary (with the help of pilot research committees) to keep the personnel in Washington knowledgeable and involved.

It is not surprising to find that the utilization of results from ORD projects is not carefully tracked when the joint planning of research by Program Offices and ORD is in its infancy with the pilot research committee program. Program managers elaborated on many needs not being met by ORD; there were few illustrations of ORD responsiveness to programs and subsequent incorporation of results into regulatory programs. On the other hand, ORD staff were often praised for their responses to requests for preliminary review of regulatory documents, consultation on imminent regulatory submissions to the courts and, in general, what can be characterized as technical support to the Program Offices. The Committee was not able to estimate the average percentage of ORD professional staff time devoted to technical support; it varied with individual research sections. It was clear that in some instances it represented a significant portion of some individuals' time. This technical support has on some occasions played a critical role in the Agency's formulation and defense of regulations.

The ORD function in the Agency is defensible mainly on the basis of program utilization of insights and results developed intramurally or extramurally under its auspices and guidance. The Committee found that ORD did not fully recognize or accept this criterion for judging its efficacy, had not developed mechanisms for efficient utilization of research results by Program Offices, and did not maintain records of results which had been incorporated into regulations.

VII. STATUS OF IMPLEMENTATION OF TWO SETS OF NATIONAL ACADEMY OF SCIENCES (NAS) RECOMMENDATIONS TO EPA

The analytical study of Research and Development in the Environmental Protection Agency conducted by the Environmental Research Assessment Committee (John M. Neuhold, Chairman), of the National Academy of Sciences, National Research Council, in 1974 and 1975 set forth a number of useful recommendations.*

Before that, a Review Committee on the Management of EPA's Research and Development Activities (Robert W. Berliner, Chairman) had developed recommendations submitted to the Agency on August 27, 1974. Our Committee (HERRG), therefore, in its collective judgment, has attempted to evaluate the extent to which former recommendations have or have not been implemented. This final exercise was undertaken at the end of our study when all visits had been completed. It was possible by this means to add a different, but closely related, viewpoint against which to compare our own observations of performance and changes during the past four years.

Although there has been significant improvement in selected aspects of EPA research planning and management, most notably the development of pilot research committees with representatives from across the Agency, the overall planning and management system is still unsatisfactory. Many of the reasons for inadequacies in the system in 1974 still exist today and will be enumerated in the following.

A. Recommendations from the Environmental Research Assessment Committee of 1975 **

(1) "EPA's research and development should concentrate primarily on support of the Agency's decision making and anticipation of future problems."

There are improvements arising from better communications between research workers in the laboratories and the Program Offices. The pilot research committees have helped establish communications and understanding.

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*Analytical Studies for the U.S. Environmental Protection Agency, Volume III, "Research and Development in the Environmental Protection Agency," Environmental Research Assessment Committee, Commission on Natural Resources, The National Research Council, National Academy of Sciences, Washington, D.C. 1977.

**Ibid. page 2.

(2) "EPA should supplement its primary research responsibilities with some fundamental research to help advance understanding in environmental sciences and technology."

Planning for fundamental or longer term research is still inadequate. However, to achieve the right kind of balance there first needs to be a close and direct relationship between researchers and program managers. Both must understand the research process and information needs of the regulatory process.

(3) "A new legislative mandate will be required if EPA is to conduct effective anticipatory and fundamental research."

The HERRG Committee does not agree that additional legislation is needed to fund and conduct "anticipatory and fundamental research."

(4) "We recommend that the Office of Science and Technology Policy (OSTP) develop a federal environmental research, development, and demonstration strategy that includes designation of the appropriate roles of all participating federal agencies and existing interagency coordinating committees, and delineation of the relationships between federal and nonfederal research and development. The OSTP should coordinate the implementation of the strategy through its mandated consultations with the Office of Management and Budget (OMB) about the scientific programs of federal agencies."

This recommendation has not been followed, per se. However, the Interagency Regulatory Liaison Group is seen as an excellent initiative which has the potential of reducing duplication and confusion among agencies. Better coordination of research efforts and better agreement on the methodologies applicable to hazard assessment are encouraged by this Committee.

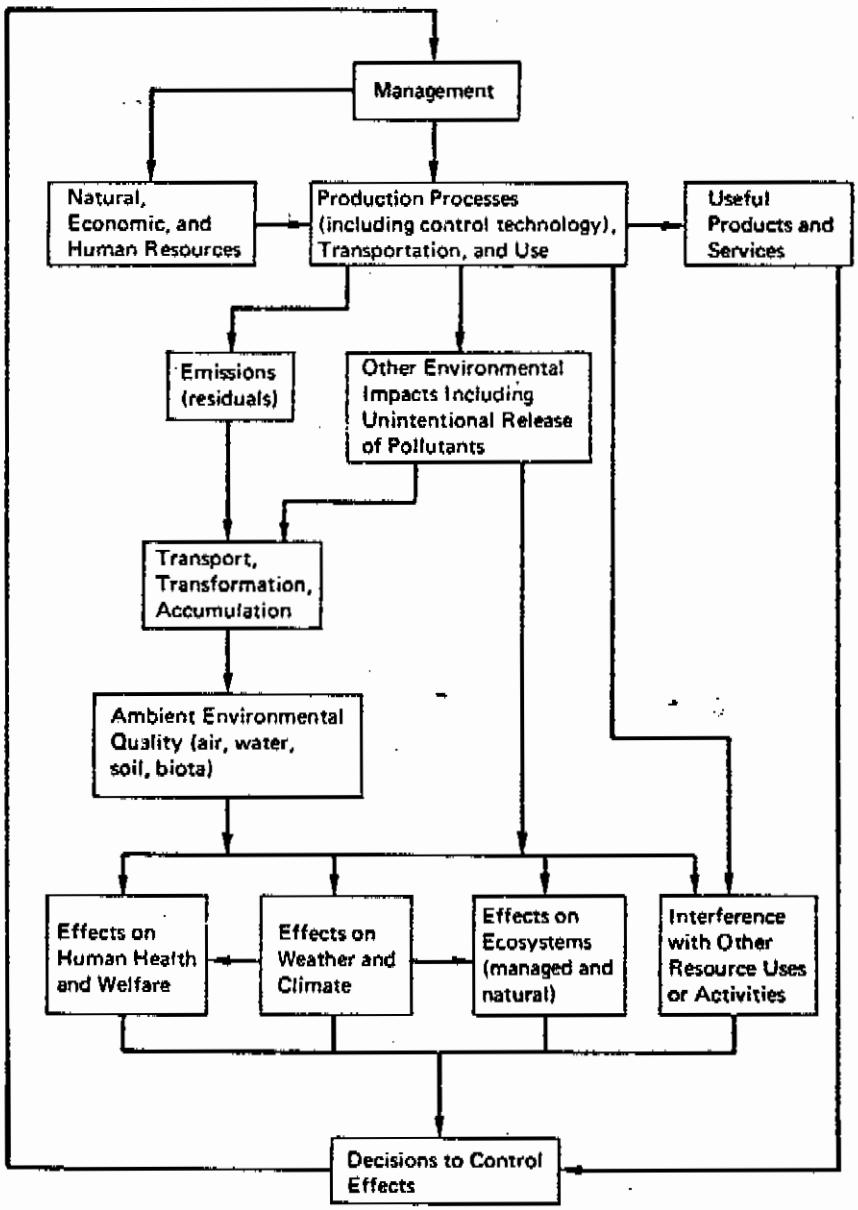
(5) "We recommend that the management of all research and development in EPA be centralized in the Office of Research and Development (OR&D)."

There seems to be progress in centralizing the management of R&D within ORD, but a number of Program Offices administer R&D contracts and grants directly. The Committee urges that this Academy recommendation be implemented to assure that proper oversight and scientific peer review be applied whenever research is conducted by the Agency.

(6) "EPA's research program needs to be better organized for balance and continuity, through planning developed around a logical conceptual framework of environmental protection..."

A number of areas within the present EPA research and development program are still not aligned within a logical conceptual framework of environmental protection and thus are not as effective as they could be. The conceptual framework proposed in the earlier NAS/NRC report (1977) still appears to offer a sound framework for the assessment of research needs, the planning and conduct of research, and the utilization of research results. The framework is shown below:

Framework for Environmental Protection



(7) "A central function of scientific support to decision making should be to provide integrated assessments of available scientific, technical, and economic data pertinent to pending decisions in forms suitable for use by Agency decision makers. We recommend that the importance of this function be recognized by giving it formal status and organization in OR&D."

The importance of integrated assessments continues to be recognized, and the Agency is moving toward establishing the formal organization required to make such assessments. When such an organization is fully operational, it should be of major assistance in providing information that is useful to the regulatory decision makers; but of equal importance is information that is crucial for the planning of a responsive research program. Carefully conducted assessments can identify gaps in research information or parameters that have the greatest influence on the effects of emissions. In the absence of such assessments there is a risk that research efforts may be directed to developing information that may have limited value in establishing or reassessing standards or in guiding their enforcement.

(8) "The research planning system now in use in OR&D, characterized as "top-down" in structure, should be retained for research in support of decision making. For anticipatory and fundamental research, however, we recommend a "bottom-up" scheme that relies on the scientific community to identify research needs."

Except for the pilot research committees, the planning process remains "top-down." Substantial improvements are needed to achieve involvement of those generating and using the data.

(9) "We recommend that block funding of extramural grants, contracts, and interagency agreements be considered as a mechanism to establish centers of excellence, federally funded contract research and development laboratories, and umbrella interagency agreements to supplement the intramural research and development program."

To date, block funding mechanisms have not been extensively used by ORD, although legislation has provided the opportunity for use of cooperative agreements that may very well match ORD needs. ORD has made preliminary plans for using such agreements and should proceed expeditiously to implement their use. Such agreements offer an opportunity for a complementary approach to the present system of grants and contracts for extramural performance.

(10) "All proposals and completed research should be subjected to review on their technical merits by scientific and technical peers."

Peer review of proposals and completed research was inconsistent and, in many cases, inadequate.

(11) "We recommend the use of a parallel grade advancement system, based on performance of research, that does not require researchers to assume administrative or managerial tasks to attain promotions."

There was little evidence of implementation of a parallel grade system. In some cases, individuals have accepted administrative or managerial assignments based on the perception that such assignments are critical to obtaining promotions.

B. Recommendations of the Review Committee on Management of EPA's Research and Development Activities *

The Review Committee report noted that the present (1974) "Office of Research and Development planning and management system fails to meet the needs of the Agency" and proceeded to identify two main categories of failure: (1) the nature of the system itself and (2) external constraints as perceived by the Office of Research and Development and communicated to the Review Committee.

1. The nature of the system itself.

a. "Planning is separated from responsibility for execution, leading to severe resentment among performing researchers. The assignment of responsibility for specific actions and decisions is difficult."

There is still an inadequate linkage between planning and responsibility for execution that is apparent, in varying degrees, at all levels of the organization below the Assistant Administrator for Research and Development. An individual researcher charged with responsibility for performing a task may have no input to the planning of that task.

b. "Priorities do not reflect the needs of regulatory offices and regional offices because of the 'vacuum cleaner' approach to soliciting ideas, and the system-induced barriers to using common sense in the selection process."

*Ibid. page 96.

There has been improvement in the establishment of priorities in selected areas, most notably those for which pilot research committees have been established, to yield a research program potentially more responsive to the needs of the Program Offices. In other areas, the research program is less clearly defined and priorities have not been established. Faced with necessarily limited resources, the responsible individuals have frequently elected to continue work in all areas at a reduced level of effort rather than electing to eliminate or defer the lowest priority projects. The result is a reduced potential for success in the highest priority areas because of lack of funds.

c. "Inadequate attention has been paid to the possibility for trade-offs, or modifications in budgeted costs, among various projects. This has aided in the development of a situation where there is only a series of discrete projects and no Agency program. This situation is further aggravated by the absence of long-term (3-5 year) planning."

Long-range planning within the Agency remains inadequate. The large portion of the planning within ORD is necessarily dependent upon the needs identified by the Program Offices. These long-term needs have often been inadequately stated, if at all, thereby handicapping the development of a responsive long-term research plan. It was originally anticipated that the pilot research committees would develop a strategic plan for their areas of responsibility. However, this was not done, in part because of the timing and pressure of the ZBB process which forced the pilot research committees to take a shorter-term outlook. An additional factor which should also be recognized is the reluctance of some individuals to engage in defining a strategic plan until they are certain that managers are serious about the effort.

d. " The complexity of the system makes it counter-productive. The large amount of paperwork and excessive bureaucratic review is a wasteful consumption of time and energy. The needs of the Agency are complex; however, this does not change--but rather heightens--the need for a simple and understandable planning and reporting system clearly directed by the Assistant Administrator and in which field personnel have a real participatory input."

The planning and management system is still extremely complex, involves a large amount of paperwork, and is often a waste of valuable time and energy. An inadequate amount of authority has been delegated downward to the laboratory directors and lower echelons of the Agency. In those cases where authority has been delegated, there appear to be excessive requirements for keeping all upper levels of the Agency informed. One example is the use of the highly structured quarterly "Project Status Reports," which include detail at the task level (tasks ranging in expenditures of less than $10,000 to over $200,000 per year); the volume of material developed at the laboratory scientist's level is passed successively to the Division Director, the Accomplishment Plan Manager, and the Office of Health and Ecological Effects and its various staff units.

e. "Accountability is made impossible by the parallel but separate management systems--some for housekeeping and the others for program content--and by the hopelessly complex Program Area Manager-Program Element Director-Program Assessment Group-Strategies system which obfuscates management responsibility."

The chain of accountability is extremely difficult to trace from the laboratory scientist (either in-house or engaged as a contractor or grantee) to the Assistant Administrator for Research and Development. The "chain of command" is excessive with numerous intermediate steps that serve only to delay or, in some cases, reprocess information without serving any clear management functions to enhance research productivity, efficiency, or responsiveness. Indeed, in many areas the number of information reprocessors and/or relayers makes it difficult to identify the laboratory scientist.

f. "Excessive requirements for detail at all planning levels lead to an oversized headquarters staff and to the stifling of innovation in the laboratory."

The level of detail required at all levels and the transfer of materials with limited informational or management value continues to contribute to the maintenance of an overly large Washington staff. In what appears to be a contradiction, the Washington staff is understaffed in relation to the amount of material being transferred and processed. Unfortunately, much of this effort is misdirected. Because of the attempts to maintain detailed accountability of even extremely small projects, the innovative responsibilities of the laboratory scientists continue to be unfulfilled.

g. "The existing management structure does not allow for the corrective feedback and flexibility which are essential to any successful research and development program."

Because the "chain of command" is so long and the communication pathways are jammed with trivia, corrective feedback does not occur at the level required for effective management. The rigid system of accountability to the laboratory directors diminishes the flexibility needed for operation of a responsive and innovative research program.

h. "A long-term program designed to meet stated goals is missing and this is vital for any scientific venture."

The ORD program has few clearly stated long-term strategies, specific to each Program Office, with easily identifiable objectives and goals. In the absence of long-term objectives and goals, the Agency's research and development resources seem excessively preoccupied with meeting short-term goals, some of which are restatements of goals not previously attained.

i. "A false sense of control is generated by the highly structured mechanism for planning."

The highly structured planning and control system, which generates considerable activity, has promoted the feeling that something is happening that is of a positive nature. The widespread lack of clearly stated and agreed upon long-term objectives and goals, however, makes it difficult to determine whether the movement is positive, negative, or random in nature.

j. "Relationships between the headquarters and field are strained at best; a state of frustration in the field staff is apparent."

Considerable frustration is apparent in many of the organizational units below the Assistant Administrator's office. In many cases, the individuals have resigned themselves to tolerating a work environment that is constantly changing, but rarely for the better.

2. External constraints as perceived by the Office of Research and Development.

a. "Enabling legislation is noncoherent and mandates a set of unbalanced and uncoordinated research objectives and timetables."

The enabling legislation for the Agency has been and continues to be viewed as noncoherent, mandating a set of unbalanced and uncoordinated research objectives and timetables. Since the enabling legislation has not and may not be changed in the near future, ORD has no real choice but to accept the situation that exists and strive to adjust its planning and operations accordingly.

b. "The lack of an integrated approach to environmental pollution control in the Agency as a whole makes an integrated research and development program very difficult to form."

Although some individuals view the Agency as not having an integrated approach to environmental pollution control, some progress has been made, and the use of approaches such as the pilot research committees offers the opportunity for developing an integrated research program with long-range objectives and goals as recommended in 1974.

c. "Civil Service rules, parochial political pressures, and human nature combine as barriers to the simplification, assembly into 'critical masses,' and logical organization of the research units which were inherited by EPA when it was created."

Civil service rules, parochial political pressures, and human nature continue to be barriers to simplification, assembly into "critical masses," and logical organization of the research units. Of perhaps equal importance has been the failure to recognize that in the absence of a clearly recognizable research and development strategies specific for the Program Offices, the constraints of civil service rules, the influence of political pressures, and human nature will have substantial adverse impacts on the research program. An identifiable strategy with well thought out objectives and goals will go a long way toward minimizing the impact of factors that can push a reaction-oriented program, with ill-defined objectives and goals, off course. As addressed elsewhere in this report, civil service rules do adversely impact the research program, and suggestions for change are offered. However, in the absence of changes in the rules, the situation must be accepted and plans developed within the constraints of the rules. Parochial political pressures have been, and probably will continue to be, brought to bear. However, it should be recognized that the Agency has strong political supporters, who can counter parochialism if they know that the Agency has a research program that is scientifically and managerially sound and programatically responsible with a plan for the future. Without question human nature may at times offer constraints, but, if properly directed, can also provide forward momentum.

d. "A level budget (except for the energy 'roller coaster' of FY 74,75,76) prevents transitions which would be possible in a steady growth situation. An internal 'roller coaster' budget appears to be particularly disruptive to individual projects."

The level budgets of fiscal years 1974, 1975, and 1976 were given as the reason for the failure of the ORD planning and management progression. The level budget was said to prevent transitions that would be possible in a steady growth situation. Recent budgets have shown an increase; however, transitions do not appear to have occurred any more smoothly. A concern raised even more frequently than the shortage of funds is the restriction on the number of full-time employees. Although the impacts of the restriction are real, little has been or is likely to be accomplished by merely accepting the OMB mandated personnel ceilings until they can be changed. Until changes are made, it would seem prudent to exercise greater care in the use of available personnel and to have a strategic plan for addition of personnel when vacancies do occur. Such a strategy for the management of personnel resources is an essential part of the total Agency research and development plan and is the only way the personnel resources (as to number of individuals with specific types and levels of disciplinary training) can be matched to the long-term needs of the Agency.

The 1974 letter report of the NAS/NRC Review Committee listed four major recommendations.* The recommendations have been implemented to varying degrees and, even where not fully implemented, still seem appropriate. Because they are still germane, each is reviewed below.

1. "The Environmental Research Objective Statement-Research Objective Achievement Plan-Program Area Manager-Program Element Direction-Program Assessment Group-system should be abolished. Responsibility for carrying out a program designed to meet the goals of the Office of Research and Development should be delegated directly to the National Environmental Research Center directors. Resources of manpower and money should be allocated directly to each National Environmental Research Center."

*Ibid. page 98.

-- The planning and management system referred to has been largely abolished. It has not been replaced by a system that is understandable to all parties involved; thus vestiges of the old system remain. The five Pilot Research Committees cover a portion of the ORD program and partially meet the planning function requirement. The National Environmental Research Centers and related field stations in existence in 1974 have since been separated into 15 individual laboratories, which report through four deputy assistant administrators to the Assistant Administrator for Research and Development. Although allocations of resources are made directly to the individual laboratories, there appear to be numerous strings attached which severely restrict the authority of the laboratory directors.

2. "The line reporting within the Office of Research and Development should be from the National Environmental Research Center directors to the Assistant Administrator. The Assistant Administrator should have a small staff to perform only staff functions and not to serve as a filter or layer through which the National Environmental Research Center directors report. This should develop into a simple pyramidal management system through which all direction, supervision, and evaluation is accomplished. This would, in effect, eliminate all layers or parallel management plans and result in a clear chain of authority from the individual researchers to the Assistant Administrator for Research and Development. The pyramid should decentralize quickly from Washington Headquarters to major field units. The Headquarter's staff should be trimmed appropriately and those necessary for "Washington liaison" activities clearly labeled. We did not have sufficient time to evaluate the role and position of the Washington Environmental Research Center. Such an evaluation should be made.

   "Because of the recent formation of the Agency by coalescence of disparate portions of other agencies, a particular need for intra-agency communication exists. To this end, a planned continuing rotation of field personnel into and back from a small Headquarters staff unit and between other units should be carried out. Short term, non-government talent should also be worked into this rotation system."

--The Washington staff of ORD is still quite large with a relatively large number of individuals serving in special staff roles and on numerous ad hoc committees. Clear chains of authority do not exist between individual researchers and the Assistant Administrator for Research and Development; rather there are numerous filters through which information exchange must take place. Despite the largeness of the Washington staff, many appear overwhelmed by their work load, while others apparently fill slots for which there are no longer meaningful work assignments. Approximately 90% of the work load seems to be carried by one-half of the staff.

Communication between Program Offices and the Office of Research and Development has been virtually non-existent in some areas. The five recently organized pilot research committees appear to have helped improve intra-agency communication and offer considerable promise for further improvement.

Rotation of field personnel into and back from headquarters has occurred to a limited extent, but more exchanges are needed. A limited number of short-term, nongovernment individuals have rotated through the system, however more exchanges of this type are also needed.

3. "The function of the Assistant Administrator for Research and Development should be to assemble, analyze, and clearly define Agency research and development needs and objectives with the participation of the other Assistant Administrators and the National Environmental Research Center directors as the mechanism to develop goals, programs, and priorities. He should allocate objectives and the resources for their accomplishment to the National Environmental Research Centers. Once allocation is decided upon, the performer of the research or development should be linked directly to the user of the projected output for information exchange.

   "A performance evaluation should be set up to include continued inputs from users, and outside visiting committees reporting at a high level should be regularly employed. The system of visiting committees employed by the National Bureau of Standards should be studied for applicability.

   "A plan for a 3-5 year period to be revised at least annually should be developed."

--The Assistant Administrator for Research and Development has not systematically assembled, analyzed or clearly defined research and development needs and objectives. "The Research Outlook: 1978-1983", which has been published, and "The Research Outlook: 1979-1984", currently nearing completion, are perhaps the most definitive statements of research and development needs and objectives. However, neither document is an adequate statement of near-term, mid-term or long-term plans and objectives. Participatory discussions have apparently occurred with laboratories. Until initiation of the pilot research committees, most planning activities were carried out in headquarters with only limited and late stage input from the laboratories. With the advent of the pilot research committees, laboratory and Program Office input to near-term research planning has occurred in those research areas for which committees have been developed. This has had a positive impact on planning; however, in most cases where the laboratory director was not involved in the committee's activities, it has minimized the role of the laboratory director in the planning process. For a majority of the research programs, the laboratory directors and staff have been involved primarily in near-term planning and then most frequently at late stages of the budget cycle. In many cases the input has been fragmentary and spurious, i.e., "What would you and your people like to do next year?"

Resource allocations (personnel and finances) are in a continuous state of flux. As expected in relation to the Federal budget system, changes are made up to the beginning of the current fiscal year, but frequently continue on throughout the year. The major certainty appears to be that change will take place. The laboratory directors apparently are given little authority for shifting resources within program areas and even less authority for shifting resources between program areas. This lack of flexibility, with continuous management from headquarters, appears to have had a negative impact on the productivity of the programs. EPA scientists, in many cases, are confronted with changes in program direction and level of effort with very short notice. Extramural projects have, in many cases, been treated as the most flexible portion of the system. Contracts that have been expanded or shifted in direction on very short notice have served to alienate substantial portions of the research community. Precipitous actions, discontinuation of programs, or shifting of program direction raises legitimate questions concerning the adequacy of Agency research and development planning. Precipitous increases of funds, although having associated moments of elation, are usually followed by a recognition that the time and personnel resources available do not allow careful selection of new contractors, resulting in projects that are less successful than they should be.

4. "Not only the changing nature of environmental problems but also the exigencies of the economy, suggest that it would be inadvisable to build up a large permanent staff. Rather, maintaining the necessary competence to monitor grant and contract work as needed would appear to be a prudent course.

"A careful review of the contract and grant procedures should be undertaken."

--The Agency has not given adequate attention to developing a strategy for the implementation of its research program, i.e., balance among intramural research, contracts, grants and interagency agreements. Although the mandated ceiling on numbers of personnel is recognized, the Agency has not made adequate plans for living within that ceiling. To circumvent the personnel ceiling, contracted personnel are used on site at many laboratories to perform maintenance operations, thereby extending the work force. There are numerous individuals who are faced with a multitude of competing responsibilities: performing hands-on research; supervising technicians who directly assist them; preparing orders and monitoring the efforts of on-site contract personnel; soliciting and reviewing research grants and proposals; monitoring research being performed by contractors and grantees, either by personal visit or review of innumerable reports expected of the contractors and grantees; and participating in the preparation and review of criteria documents and related material. In some instances, there are experienced scientists and managers available who do an excellent job of balancing and meeting these competing demands. In a few instances, individuals, who have been unwilling to accept the demands placed on them, have retreated into their corners to do "their thing," i.e., perform specific research in line with their interests, and are content to let the system go on its own merry way. Although this has solved their immediate problem, it has increased the workload and demand placed on their colleagues. In many cases, the demands are excessive in relation to the experience and training of the staff member, and one or more of the aspects of the job are performed poorly.

The impact on both intramural and extramural research is apparent. The impact on the intramural program is discernible by the fact that many EPA scientists do not publish because they have performed relatively little research. A review of how selected grants and contracts were initiated and monitored suggests that, in some cases, the individuals involved did not have adequate experience or time to perform their assignments. A related and contributing factor has been the development of an "unwritten" set of procedures for promoting the use of grants rather than contracts because of the more cumbersome nature of the contract award process.

In summary, a careful review of contract and grant procedures is as much needed now as it was at the time of the NAS/NRC report. A key aspect of such a review should be the development of a strategy dealing with how much research can be appropriately performed in the Agency and how extramural work can best be performed.

VIII. COMMUNITY HEALTH AND ENVIRONMENTAL SURVEILLANCE SYSTEM (CHESS): AN INVESTIGATIVE REPORT

A. Background of the CHESS Program

The Community Health and Environmental Surveillance System (CHESS) was initiated about 1970 and involved collection of data during the period 1970 to 1975. This research and surveillance program was designed to investigate the relationship, if any, between air pollution and health in human populations (up to a few thousand persons), studied at single contacts or followed for short periods of time (up to two years), for characterization of health status. These observations were coordinated with observations on air pollution in the environments of the study populations. The populations and areas included for study were selected to represent pairs or larger sets of contrasting exposures, for example, a "clean" and a "dirty" town or a series of several communities with a known or suspected substantial range of air pollution conditions. Most populations consisted of persons not previously known to have any special health problems, although some studies within CHESS were directed at groups defined by disease conditions, for example, known asthma patients.

The program operated from 1970 to 1975 and resulted in a major publication in May 1974 (Health Consequences of Sulfur Oxide: A Report from CHESS, 1970-1971). That publication included analysis and interpretation of the first two data collection years. Other smaller papers and presentations involved these and some later years' data. The major review in 1974 implicated sulfates, sulfuric acid, and sulfur dioxide as causing health effects, chiefly respiratory tract disease or disturbance of pulmonary function, at or near levels of these pollutants commonly considered "safe." That report was extensively reviewed by a number of individuals and groups and received both praise and criticism. In part because of some of the criticism, CHESS, in its original form, was discontinued. It was recommended, however that additional substantial efforts be made to optimally use the collected data beyond those uses reported in 1974. Special features to be considered in further work were to include: (1) analysis of extensive data collected from 1973 to 1975 and not included in the 1974 report; (2) improvements of statistical data and analytic techniques; (3) assessment of validity of coded data and of extent of coding errors or other correctable problems in the data set; (4) increased objectivity in interpretation of findings; and (5) assessment of confidence range of estimates of pollution.

B. Findings of the Subgroup

During the site visit in September 1978, the status of the CHESS program was reviewed and a summary follows. The mechanism for continuing work on CHESS is a contract from the Environmental Protection Agency to the University of North Carolina, Chapel Hill, principal investigator Dr. Carl Shy. This contract work is closely followed by members of the epidemiology division and the statistics unit of the Health Effects Research Laboratory, Environmental Protection Agency. Dr. Shy was formerly extensively involved with the CHESS project as a member of the epidemiology unit; he is now a member of the faculty, University of North Carolina. The plan is to review all of the CHESS data collected for 1970 to 1975. The contract to the University was let in September 1977.

To date there has been a major effort to validate the CHESS data sets. This was projected to require two years but is now expected to be completed about eight months ahead of schedule because special priority was given to the validation project. This has been accomplished in spite of a budget deletion of the funds planned for this purpose, thereby making it necessary to discontinue other work to meet this mandated task. The validation project is designed to identify discordances between manually recorded original data and tape recordings on exposure (pollution), outcome (health measures), and control demographic and confounding variables. It is being done very effectively under the direction of Mr. Gerald Nehls, Director of the Data Management Unit in the Health Effects Research Laboratory. It must be noted that any validation of these old data is now limited to validation of the previous coding and automating and not to any review of the correctness of initial observations of symptoms and other health effects.

A standing committee has been created, reporting to Dr. Shy and supported under the research contract, to review all planned publications of the CHESS data. The committee presently consists of Dr. Warren Winkelstein (University of California), Dr. James Grizzle (University of North Carolina), and Dr. Michael Lebowitz (University of Arizona). This committee has just been funded, and its effectiveness cannot yet be judged. The membership seems appropriate, and the plan for a standing procedure for outside review is a useful move in response to criticism regarding objectivity of reporting.

A report of a current analysis of a portion of the CHESS data from the Southeast region (Charlotte, North Carolina and Birmingham, Alabama) was presented to the site group by Ms. Shi-Ping Lan. The analysis and presentation indicated a high degree of statistical competence and good collaboration among Dr. Shy, Ms. Lan, and Dr. Hasselblad of the Health Effects Research Laboratory. The material presented will presumably be in a form for publication soon. A principal feature of the new analysis is more adequate use of the symptoms data from the health survey, employing a 5-level symptom scale rather than the dichotomy used in earlier analyses.

The information that can optimally be obtained from this Southeastern study is limited, however, because any possible effect of air pollution on the measured health indices is lower by factors of 10 to 100 than effects of smoking or job exposure. Even though a pollution (intercity) association is found, it remains possible that this association is not causal but is due to a variable related to the stronger effects of smoking or job exposure or to other confounding variables for which no observations are available.

While the acronym CHESS is understood to apply to the 1970 to 1975 group of studies, certain new work in progress follows the general outline of that program. The study most clearly conforming to that design is in four Utah communities, in which 1976 observations are being compared with former 1970 CHESS observations of chronic respiratory disease and of acute lower respiratory tract disease, as related to increasing SO_2 pollution in the region.

A substantial change in the operation of CHESS and related studies has been made in the past three years with a change in emphasis from in-house research to research grants and contracts. This appears to be a result, in part, of the extensive criticism of the previous CHESS program and is reflected in the entire activity of the Epidemiology Division. Only four professional researchers from a previous epidemiology staff of 15 remain in that division. Three new, young junior investigators have recently joined the division. The reduced staff is essentially completely occupied with their duties as project officers on contracts and grants. The result of this change from intramural to extramural with regard to CHESS appears not to be obstructive and may offer certain advantages.

C. Steps Taken by EPA to Meet Brown Committee Recommendations

Public Law 95-155, passed by the 95th Congress, mandated a review of and a report on "the findings and recommendations of the report to the House Committee on Science and Technology entitled 'The Environmental Protection Agency's Research Program with Primary Emphasis on the Community Health and Environmental Surveillance System (CHESS): An Investigative Report.'" It was further specified that special attention be focused on "procedural safeguards required to preserve scientific integrity of such research and to insure the reporting and use of such research in subsequent recommendations."

Although Chairman Brown emphasized the desirability of a positive attitude in the letter of transmittal of the Committee Report, the document impressed some members of the subgroup as often being hypercritical and demanding an approximation to perfection that is not obtainable in studies of human populations. The EPA has published a response to the recommendations of the Investigative Committee in the EPA Research Outlook of March 1978. The report of this subgroup will address only those recommendations that deal with on-going activities related to CHESS or other epidemiological and biostatistical work at HERL/RTP. Recommendations will be identified by the numbers used in the Investigative Report and in the Agency's response.

3(a): EPA should publish an announcement regarding the limitations of the CHESS Monograph.

3(c): EPA should publish an addendum to the CHESS Monograph including most of the Investigative Report.

Subgroup findings: It is believed that the EPA response covers these recommendations satisfactorily, although it is difficult to see how the response can be delivered to all holders of the CHESS Monograph. Most scientists, however, will be aware of the limitations of the data in this Monograph.

4(a): Legislation should be reexamined regarding unrealistic procedures and schedules.

Subgroup findings: The legislative mandate for a study of air pollution and its effects on the Gulf Coast (Houston) area appears to require an unreasonably rapid approach to a very complex problem. The epidemiology group expressed an interest in investigating this situation in a systematic, planned fashion. They doubted that the mandated crash approach would be maximally productive but stated their intent to obtain as much valid data as possible. It is not known to what extent this legislative mandate was reexamined. No evidence was found at this level to indicate that reexamination was effective in producing any important changes. Current procedures referred to in the Agency's response in the EPA Research Outlook do not appear to be adequate to solve problems caused by unrealistic legislative mandates.

4(d): EPA should advise Congress if budgetary restrictions will impact completion of major projects.

Subgroup findings: Budget restrictions forced the statistical unit at HERL to discontinue other work to "clean" the data tapes for continued CHESS analyses. The response of the Administration and of Congress to this restriction is not known. While it did not affect CHESS, it must have had an adverse effect on other programs.

5: OMB should be asked to develop procedures for prompt review of questionnaires.

Subgroup findings: The Population Studies Division has found OMB responsive to their need for quick approval of questionnaires. The subgroup supports the EPA position that its questionnaires for volunteers in research projects should not require submission to OMB.

6(a): CHESS data analyses should be carried out only on data with high validity potential.

Subgroup findings: Dr. Shy's group at the University of North Carolina and the epidemiologists and statisticians at HERL have reviewed the CHESS data and have decided which data sets warrant analysis for publication.

6(b): EPA should publish research in refereed journals in a timely fashion.

6(c): EPA should not publish large projects solely in monograph form.

6(d): EPA should not initiate projects for policy consideration unless they can be completed in a realistic time frame.

Subgroup findings: Staff indicated their desire to see results published in scientific peer reviewed journals but emphasized their lack of time to do or report their research or the findings of contractors. It is reasonable to assume, however, that most grant recipients and contractors will publish their findings in appropriate journals. It should be noted, however, that a document entitled "CHESS Bibliography, December 1, 1977" lists, for the period 1/75 to 12/77, only one journal article, seven government publications, and ten EPA in-house publications, plus three more in-house publications that are undated but whose authors or titles suggest that they belong in this time period. For 1977, the bibliography lists only one government publication, which must have been planned well in advance of the Brown Committee report.

It seems unlikely that the EPA responses to this recommendation can be properly assessed until the epidemiologic staff is increased to a size more commensurate with its duties.

7(a): EPA should strengthen the CHAMP aerometric and quality control programs.

7(b): EPA should shorten the time between data acquisition and quality assurance analysis of data.

7(c): EPA should stop employing development stage instruments before qualification testing.

7(d): EPA should not use laboratory models of instruments in the field until they have been field checked and operating personnel trained.

7(e): EPA should reevaluate the opening of the CHAMP operations contract to competition.

Subgroup findings: CHAMP is no longer at HERL. We were informed that it no longer exists as an identifiable unit separate from other monitoring activities.

7(f): EPA research and monitoring personnel should closely coordinate regarding chemical species.

Subgroup findings: Coordination of CHAMP with health effects personnel is now potentially more difficult because of the transfer of the responsibilities of CHAMP to another laboratory. It is still too early to tell whether the transfer will help by strengthening this type of monitoring activity or will hinder the accomplishment of the Agency's mission by impeding coordination.

10(a): An interdisciplinary task force should draw up an integrated air epidemiology exposure assessment program plan for EPA.

Subgroup findings: There is a desire for an advisory group not only to meet this recommendation for assessing health effects of air pollution but also to provide consultation for other epidemiologic studies, both intra- and extramural.

10(c): EPA should have epidemiological questionnaires and panel selection criteria approved by peer groups.

Subgroup findings: Aside from a comparison of self-administered versus interviewer-administered questionnaires, the work related to this recommendation is limited to the information that can be gathered from the extensive analyses of CHESS data being carried out by Dr. Shy. The panel data are not scheduled for analysis.

Planning for a second round of CHESS or for investigation of air pollution "episodes" was not mentioned. It is difficult to see how very much can be done along this line with the limited staff. It seems reasonable to delay planning for a second round of CHESS until the current analyses are completed.

APPENDIX A

APPENDIX A

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

JUL 12 1978

THE ADMINISTRATOR

TO: Dr. Emil M. Mrak
Chairman
Executive Committee, Science Advisory Board

THRU: Dr. Richard M. Dowd RMD

SUBJECT: Charge to the Science Advisory Board's Health Effects Research Review Group

The Authorization Act of 1978 for Research and Development, PL 95-155, requires that a special evaluation report on the Agency's health effects research efforts be prepared by the Science Advisory Board (SAB). The Act specifically outlines what is expected to be included in the report regarding your assessment of our health effects research programs, and the procedures for the conduct, review, reporting and use of such research.

To delineate the Congress's charge more sharply, I urge the Study Group to define health effects research to include all planned activities, collection and analyses of data done within the Agency for the purpose of adding to the scientific basis for understanding the effects of environmental factors on human health. This definition would include those activities within the Agency which may be used to assess human risk, and which support standard setting and regulatory decisions, and any activity which gathers new knowledge about human health, or improves our understanding of human health either directly or which can be used to extrapolate to human health impacts. I am happy to hear that Dr. James Whittenberger and Dr. Roger McClellan will chair and co-chair this review group.

I can assure you that your assessment of the Agency's activities within the scope of this definition will be appreciated and that you will have our full cooperation in this endeavor.

Douglas M. Costle

Public Law 95-155
95th Congress

An Act

To authorize appropriations for activities of the Environmental Protection Agency, and for other purposes.

Nov. 8, 1977
[H.R. 5101]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Environmental Research, Development, and Demonstration Authorization Act of 1978".

Environmental Research, Development, and Demonstration Authorization Act of 1978.

SEC. 2. (a) There are authorized to be appropriated to the Environmental Protection Agency for environmental research, development, and demonstration activities for fiscal year 1978—

(1) $92,500,000 for water quality activities authorized under the Federal Water Pollution Control Act of which— 33 USC 1251 note.

(A) $25,200,000 is for the Health and Ecological Effects program;

(B) $9,300,000 is for the Industrial Processes program;

(C) $6,069,000 is for the Monitoring and Technical Support program;

(D) $22,300,000 is for the Public Sector Activities program; and

(E) $29,631,000 is for the Energy program.

(2) $10,800,000 for activities authorized under the Federal Insecticide, Fungicide, and Rodenticide Act, in the Health and Ecological Effects program. 7 USC 136 note.

(3) $16,000,000 for water supply activities authorized under the Safe Drinking Water Act, in the Public Sector program. 42 USC 300f note.

(4) $8,200,000 for toxic substance control activities authorized under the Toxic Substances Control Act, in the Health and Ecological Effects program. 15 USC 2601 note.

(5) $830,000 for radiation activities authorized under the Public Health Act, in the Health and Ecological Effects program. 42 USC 201 note.

(6) $35,000,000 for air quality activities authorized under the Clean Air Act, which shall be in addition to funds previously authorized in the Clean Air Act Amendments of 1977 (Public Law 95-95), so that the total amount authorized for such activities in fiscal year 1978 is $155,000,000, of which— 42 USC 1857 note. *Ante*, p. 685.

(A) $36,000,000 is for the Health and Ecological Effects program;

(B) $11,000,000 is for the Monitoring and Technical Support program;

(C) $7,000,000 is for the Industrial Processes program; and

(D) $101,000,000 is for the Energy program.

(7) $31,273,000 for interdisciplinary activities, of which—

(A) $9,230,000 is for the Health and Ecological Effects program;

(B) $6,066,000 is for the Industrial Processes program;

(C) $1,599,000 is for the Public Sector Activities program; and

(D) $14,378,000 is for the Monitoring and Technical Support program.

29-139 O - 77 (170)

(b) In addition to any other sums authorized by this section or by other provisions of law—

(1) there are authorized to be appropriated to the Administrator of the Environmental Protection Agency for fiscal year 1978, $10,000,000 for long-term research and development in accordance with section 6 of this Act;

(2) there are authorized to be appropriated to the Administrator, for fiscal year 1978, $2,000,000 for training of health scientists needed for environmental research and development in fields where there are national shortages of trained personnel; and

(3) there are authorized to be appropriated to the Administrator, for fiscal year 1978, $3,000,000 to implement the study authorized in section 103(d) of the Clean Air Act Amendments of 1977 (Public Law 95-95).

Ante, p. 687.

Appropriation authorization.

(c) There is authorized to be appropriated to the Administrator $19,000,000 for fiscal year 1978 for program management and support related to environmental research and development.

Transfer of funds, restriction.

(d) No funds may be transferred from any particular category listed in subsection (a) or (b) to any other category or categories listed in either such subsection if the total of the funds so transferred from that particular category would exceed 10 per centum thereof, and no funds may be transferred to any particular category listed in subsection (a) or (b) from any other category or categories listed in either such subsection if the total of the funds so transferred to that particular category would exceed 10 per centum thereof, unless—

(1) a period of thirty legislative days has passed after the Administrator of the Environmental Protection Agency or his designee has transmitted to the Speaker of the House of Representatives and to the President of the Senate a written report containing a full and complete statement concerning the nature of the transfer and the reason therefor, or

(2) each committee of the House of Representatives and the Senate having jurisdiction over the subject matter involved, before the expiration of such period, has transmitted to the Administrator written notice to the effect that such committee has no objection to the proposed action.

SEC. 3. Appropriations made pursuant to the authority provided in section 2 of this Act shall remain available for obligation for expenditure, or for obligation and expenditure, for such period or periods as may be specified in the Acts making such appropriations.

Budget projections. 42 USC 4361a. 42 USC 4361.

SEC. 4. The Administrator of the Environmental Protection Agency, in each annual revision of the five-year plan transmitted to the Congress under section 5 of Public Law 94-475, shall include budget projections for a "no-growth" budget, for a "moderate-growth" budget, and for a "high-growth" budget. In addition, each such annual revision shall include a detailed explanation of the relationship of each budget projection to the existing laws which authorize the Administration's environmental research, development, and demonstration programs.

Public sector agencies, grants. 42 USC 300j-3a.

SEC. 5. (a) The Administrator of the Environmental Protection Agency shall offer grants to public sector agencies for the purposes of—

(1) assisting in the development and demonstration (including construction) of any project which will demonstrate a new or improved method, approach, or technology for providing a dependably safe supply of drinking water to the public; and

(2) assisting in the development and demonstration (including construction) of any project which will investigate and demonstrate health and conservation implications involved in the reclamation, recycling, and reuse of wastewaters for drinking and the processes and methods for the preparation of safe and acceptable drinking water.

(b) Grants made by the Administrator under this section shall be subject to the following limitations: Grants, limitations.

(1) Grants under this section shall not exceed 66⅔ per centum of the total cost of construction of any facility and 75 per centum of any other costs, as determined by the Administrator.

(2) Grants under this section shall not be made for any project involving the construction or modification of any facilities for any public water system in a State unless such project has been approved by the State agency charged with the responsibility for safety of drinking water (or if there is no such agency in a State, by the State health authority).

(3) Grants under this section shall not be made for any project unless the Administrator determines, after consultation, that such project will serve a useful purpose relating to the development and demonstration of new or improved techniques, methods, or technologies for the provision of safe water to the public for drinking.

(c) There are authorized to be appropriated for the purposes of this section $25,000,000 for fiscal year 1978.

SEC. 6. (a) The Administrator of the Environmental Protection Agency shall establish a separately identified program to conduct continuing and long-term environmental research and development. Unless otherwise specified by law, at least 15 per centum of any funds appropriated to the Administrator for environmental research and development under section 2(a) of this Act or under any other Act shall be allocated for long-term environmental research and development under this section. Research and development program. 42 USC 4363.

(b) The Administrator, after consultation with the Science Advisory Board, shall submit to the President and the Congress a report concerning the desirability and feasibility of establishing a national environmental laboratory, or a system of such laboratories, to assume or supplement the long-term environmental research functions created by subsection (a) of this section. Such report shall be submitted on or before March 31, 1978, and shall include findings and recommendations concerning— Report to President and Congress. Contents.

(1) specific types of research to be carried out by such laboratory or laboratories;

(2) the coordination and integration of research to be conducted by such laboratory or laboratories with research conducted by existing Federal or other research facilities;

(3) methods for assuring continuing long-range funding for such laboratory or laboratories; and

(4) other administrative or legislative actions necessary to facilitate the establishment of such laboratory or laboratories.

SEC. 7. (a) The Administrator of the Environmental Protection Agency shall assure that the expenditure of any funds appropriated pursuant to this Act or any other provision of law for environmental research and development related to regulatory program activities shall be coordinated with and reflect the research needs and priorities 42 USC 4364.

of the program offices, as well as the overall research needs and priorities of the Agency, including those defined in the five-year research plan.

Program offices.

(b) For purposes of subsection (a), the appropriate program offices are—

(1) the Office of Air and Waste Management, for air quality activities;

(2) the Office of Water and Hazardous Materials, for water quality activities and water supply activities;

(3) the Office of Pesticides, for environmental effects of pesticides;

(4) the Office of Solid Waste, for solid waste activities;

(5) the Office of Toxic Substances, for toxic substance activities;

(6) the Office of Radiation Programs, for radiation activities; and

(7) the Office of Noise Abatement and Control, for noise activities.

Report to President and Congress.

(c) The Administrator shall submit to the President and the Congress a report concerning the most appropriate means of assuring, on a continuing basis, that the research efforts of the Agency reflect the needs and priorities of the regulatory program offices, while maintaining a high level of scientific quality. Such report shall be submitted on or before March 31, 1978.

Science Advisory Board. Establishment. 42 USC 4365.

SEC. 8. (a) The Administrator of the Environmental Protection Agency shall establish a Science Advisory Board which shall provide such scientific advice as the Administrator requests.

Membership.

(b) Such Board shall be composed of at least nine members, one of whom shall be designated Chairman, and shall meet at such times and places as may be designated by the Chairman of the Board in consultation with the Administrator. Each member of the Board shall be qualified by education, training, and experience to evaluate scientific and technical information on matters referred to the Board under this section.

(c) In addition to providing scientific advice when requested by the Administrator under subsection (a), the Board shall review and comment on the Administration's five-year plan for environmental research, development, and demonstration provided for by section 5 of Public Law 94-475 and on each annual revision thereof. Such review and comment shall be transmitted to the Congress by the Administrator, together with his comments thereon, at the time of the transmission to the Congress of the annual revision involved.

42 USC 4361.

Report to Administrator, President, and Congress.

(d) The Board shall conduct a review of and submit a report to the Administrator, the President, and the Congress, not later than October 1, 1978, concerning—

(1) the health effects research authorized by this Act and other laws;

(2) the procedures generally used in the conduct of such research;

(3) the internal and external reporting of the results of such research;

(4) the review procedures for such research and results;

(5) the procedures by which such results are used in internal and external recommendations on policy, regulations, and legislation; and

(6) the findings and recommendations of the report to the House Committee on Science and Technology entitled "The

Environmental Protection Agency's Research Program with primary emphasis on the Community Health and Environmental Surveillance System (CHESS): An Investigative Report".

The review shall focus special attention on the procedural safeguards required to preserve the scientific integrity of such research and to insure reporting and use of the results of such research in subsequent recommendations. The report shall include specific recommendations on the results of the review to ensure scientific integrity throughout the Agency's health effects research, review, reporting, and recommendation process.

(e)(1) The Administrator, at the time any proposed criteria document, standard, limitation, or regulation under the Clean Air Act, the Federal Water Pollution Control Act, the Resource, Conservation and Recovery Act of 1976, the Noise Control Act, the Toxic Substances Control Act, or the Safe Drinking Water Act, or under any other authority of the Administrator, is provided to any other Federal agency for formal review and comment, shall make available to the Board such proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information in the possession of the Environmental Protection Agency on which the proposed action is based. 42 USC 1857 note. 33 USC 1251 note. 42 USC 6901 note. 42 USC 4901 note. 15 USC 2601 note. 42 USC 300f note.

(2) The Board may make available to the Administrator, within the time specified by the Administrator, its advice and comments on the adequacy of the scientific and technical basis of the proposed criteria document, standard, limitation, or regulation, together with any pertinent information in the Board's possession.

(f) In preparing such advice and comments, the Board shall avail itself of the technical and scientific capabilities of any Federal agency, including the Environmental Protection Agency and any national environmental laboratories.

(g) The Board is authorized to constitute such member committees and investigative panels as the Administrator and the Board find necessary to carry out this section. Each such member committee or investigative panel shall be chaired by a member of the Board. Member committees and investigative panels.

(h)(1) Upon the recommendation of the Board, the Administrator shall appoint a secretary, and such other employees as deemed necessary to exercise and fulfill the Board's powers and responsibilities. The compensation of all employees appointed under this paragraph shall be fixed in accordance with chapter 51 and subchapter III of chapter 53 of title 5 of the United States Code. Secretary, appointment. 5 USC 5101, 5331.

(2) Members of the Board may be compensated at a rate to be fixed by the President but not in excess of the maximum rate of pay for grade GS-18, as provided in the General Schedule under section 5332 of title 5 of the United States Code. 5 USC 5332 note

(i) In carrying out the functions assigned by this section, the Board shall consult and coordinate its activities with the Scientific Advisory Panel established by the Administrator pursuant to section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. 7 USC 136w.

SEC. 9. (a) The Administrator of the Environmental Protection Agency, in consultation and cooperation with the heads of other Federal agencies, shall take such actions on a continuing basis as may be necessary or appropriate— 42 USC 4366.

(1) to identify environmental research, development, and demonstration activities, within and outside the Federal Govern-

ment, which may need to be more effectively coordinated in order to minimize unnecessary duplication of programs, projects, and research facilities;

(2) to determine the steps which might be taken under existing law, by him and by the heads of such other agencies, to accomplish or promote such coordination, and to provide for or encourage the taking of such steps; and

(3) to determine the additional legislative actions which would be needed to assure such coordination to the maximum extent possible.

Report. 42 USC 4361.

The Administrator shall include in each annual revision of the five-year plan provided for by section 5 of Public Law 94-475 a full and complete report on the actions taken and determinations made during the preceding year under this subsection, and may submit interim reports on such actions and determinations at such other times as he deems appropriate.

(b) The Administrator of the Environmental Protection Agency shall coordinate environmental research, development, and demonstration programs of such Agency with the heads of other Federal agencies in order to minimize unnecessary duplication of programs, projects, and research facilities.

(c)(1) In order to promote the coordination of environmental research and development activities, and to assure that the action taken and methods used (under subsection (a) and otherwise) to bring about such coordination will be as effective as possible for that purpose, the Council on Environmental Quality in consultation with the Office of Science and Technology Policy shall promptly undertake and carry out a joint study of all aspects of the coordination of environmental research and development. The Chairman of the Council shall prepare a report on the results of such study, together with such recommendations (including legislative recommendations) as he deems appropriate, and shall submit such report to the President and the Congress not later than May 31, 1978.

Report to President and Congress. Legislative recommendations.

(2) Not later than September 30, 1978, the President shall report to the Congress on steps he has taken to implement the recommendations included in the report under paragraph (1), including any recommendations he may have for legislation.

Presidential report to Congress.

42 USC 4361b.

SEC. 10. The Administrator of the Environmental Protection Agency shall implement the recommendations of the report prepared for the House Committee on Science and Technology entitled "The Environmental Protection Agency Research Program with primary emphasis on the Community Health and Environmental Surveillance System (CHESS): An Investigative Report", unless for any specific recommendation he determines (1) that such recommendation has been implemented, (2) that implementation of such recommendation would not enhance the quality of the research, or (3) that implementation of such recommendation will require funding which is not available. Where such funding is not available, the Administrator shall request the required authorization or appropriation for such implementation. The Administrator shall report the status of such implementation in each annual revision of the five-year plan transmitted to the Congress under section 5 of Public Law 94-475.

Personnel positions, increase.

SEC. 11. The Administrator of the Environmental Protection Agency shall increase the number of personnel positions in the Health and Ecological Effects program to 862 positions for fiscal year 1978.

Annual statement, filing. 42 USC 4367.

SEC. 12. (a) Each officer or employee of the Environmental Protection Agency who—

(1) performs any function or duty under this Act; and

(2) has any known financial interest in any person who applies for or receives grants, contracts, or other forms of financial assistance under this Act,

shall, beginning on February 1, 1978, annually file with the Administrator a written statement concerning all such interests held by such officer or employee during the preceding calendar year. Such statement shall be available to the public.

(b) The Administrator shall—

(1) act within ninety days after the date of enactment of this Act—

(A) to define the term "known financial interest" for purposes of subsection (a) of this section; and

(B) to establish the methods by which the requirement to file written statements specified in subsection (a) of this section will be monitored and enforced, including appropriate provision for the filing by such officers and employees of such statements and the review by the Administrator of such statements; and

Report to Congress.

(2) report to the Congress on June 1 of each calendar year with respect to such disclosures and the actions taken in regard thereto during the preceding calendar year.

(c) In the rules prescribed under subsection (b) of this section, the Administrator may identify specific positions of a nonpolicymaking nature within the Administration and provide that officers or employees occupying such positions shall be exempt from the requirements of this section.

Violation, penalty.

(d) Any officer or employee who is subject to, and knowingly violates, this section, shall be fined not more than $2,500 or imprisoned not more than one year, or both.

Paperwork minimization, encouragement.

SEC. 13. It is the national policy that to the maximum extent possible the procedures utilized for implementation of this Act shall encourage the drastic minimization of paperwork.

Approved November 8, 1977.

LEGISLATIVE HISTORY:

HOUSE REPORTS: No. 95-157 (Comm. on Science and Technology) and No. 95-722 (Comm. of Conference).

SENATE REPORT No. 95-188 accompanying S. 1417 (Comm. on Environment and Public Works).

CONGRESSIONAL RECORD, Vol. 123 (1977):

Apr. 19, considered and passed House.

May 27, considered and passed Senate, amended, in lieu of S. 1417.

Oct. 20, Senate agreed to conference report.

Oct. 25, House agreed to conference report.

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APPENDIX B

Appendix B

COMMITTEE MEMBERS AND CONSULTANTS

1. Subcommittee Core Members

Chairman: Dr. James L. Whittenberger
Professor of Physiology
School of Public Health
Harvard University

Co-chairman: Dr. Roger O. McClellan
Director of Inhalation Toxicology
Research Institute
Lovelace Foundation

Members: Dr. Peter Bloomfield
Associate Professor
Department of Statistics
Princeton University

Dr. George W. Comstock
Professor of Epidemiology
Johns Hopkins Training Center

Dr. Morton Corn
Professor of Industrial Health and
Air Engineering
Graduate School of Public Health
University of Pittsburgh

Dr. Julius E. Johnson
Consultant
Dow Chemical Company

Dr. Wendell Kilgore
Professor of Toxicology
Department of Environmental
Toxicology
University of California at Davis

Dr. Robert A. Neal
Director, Center in Toxicology
Department of Biochemistry
Vanderbilt Medical School

Dr. Gerard A. Rohlich
Professor of Environmental
Engineering, Department of Civil
Engineering, University of Texas

SAB Staff Officer: Dr. Frode Ulvedal
Supervisory Toxicologist
Office of Research and Development
Environmental Protection Agency

2. Consultants

Dr. Edwin Lennette, Biomedical Labs, California State Department of Health
expertise: microbiology, virology

Dr. Jeanne Manson, Kettering Laboratory
University of Cincinnati
expertise: reproduction,teratology

Dr. Sol M. Michaelson, Professor of Radiation Biology and Biophysics, University of Rochester
expertise: non-ionizing radiation

Dr. Steven M. Horvath, Director, Institute of Environmental Stress, University of California
expertise: pulmonary physiology, inhalation toxicology

Dr. George Hutchinson, Professor of Epidemiology, Harvard School of Public Health
expertise: epidemiology, microbiology

Dr. James G. Fox, Director, Laboratory of Animal Medicine, Massachusetts Institute of Technology
expertise: laboratory animal care and facilities

Dr. Jennifer L. Kelsey, Associate Professor of Epidemiology, Department of Epidemiology and Public Health, Yale University School of Medicine
expertise: epidemiology of chronic disease

Dr. Ralph C. Buncher, University of Cincinnati Medical Center
expertise: epidemiology

APPENDIX C

APPENDIX C

MEETING AND TRAVEL SCHEDULE FOR HERRG

DATE	LOCATION	PARTICIPANTS
21 June 78	Preliminary meeting, with Dr. Hueter, HERL/RTP	Dr. Whittenberger Dr. Ulvedal
13-14 July 78	Public meeting, Washington, D.C.	HERRG
20-21 July 78	Environmental Research Lab Duluth, Minn.	Dr. McClellan Dr. Kilgore Dr. Ulvedal
23 Aug. 78	Office of Water & Waste Management Washington, D.C.	Dr. Rohlich Dr. Neal Dr. Johnson Dr. Ulvedal
25 Aug 78	Office of Toxic Substances Washington, D.C.	Dr. Neal Dr. Kilgore Dr. Johnson Dr. Ulvedal
25-27 Sept. 78	Health Effects Research Lab Research Triangle Park, N.C.	HERRG and Dr. Manson Dr. Michaelson Dr. Horvath Dr. Hutchinson Dr. Fox Dr. Kelsey Dr. Ulvedal
28 Sept. 78	Preliminary Mtg. with Dr. Garner HERL/Cincinnati	Dr. McClellan Dr. Ulvedal
5-6 Oct. 78	Environmental Research Lab Gulf Breeze, Fla.	Dr. Whittenberger Dr. Kilgore Dr. Ulvedal
16-18 Oct. 78	Health Effects Research Lab Cincinnati, Ohio	HERRG and Dr. Lennette Dr. Hutchinson Dr. Fox Dr. Buncher
19 Oct. 1978	Health Effects Research Lab. Field Station Wenatchee, Wash.	Dr. McClellan Dr. Johnson Dr. Kilgore Dr. Ulvedal

DATE	LOCATION	PARTICIPANTS
24 Oct. 78	Office of Air, Noise, & Radiation	Dr. Whittenberger Dr. Corn Dr. Bloomfield Dr. Ulvedal
26 Oct. 78	Environmental Research Lab. Narragansett, R.I.	Dr. Whittenberger Dr. Lennette Dr. Ulvedal
27 Oct. 78	Health Effects Research Lab Field Station W. Kingston, R.I.	Dr. Whittenberger Dr. Lennette Dr. Ulvedal
30 Oct. 78	Office of Planning and Management Washington, D.C.	Dr. McClellan Dr. Ulvedal
8 Nov. 78	Region I Boston, Mass.	Dr. Whittenberger Dr. Ulvedal
9 Nov. 78	Environmental Monitoring & Support Laboratory, Las Vegas, Nev.	Dr. McClellan Dr. Ulvedal
13-14 Nov. 78	Public Meeting Washington, D.C.	HERRG
13 Nov. 78	Office of Planning and Management Washington, D.C.	Dr. Corn Dr. McClellan Dr. Johnson Dr. Bloomfield
13 Nov. 78	Office of Research and Development Washington, D.C.	Dr. Whittenberger Dr. Kilgore Dr. Neal

APPENDIX D

APPENDIX D

PRINCIPAL EPA PERSONNEL PROVIDING INFORMATION TO HERRG

* Interviewed
\+ Provided written information

Office of the Administrator

Douglas M. Costle*+
Administrator

Dr. Richard Dowd*
Science Policy Advisor to the Administrator
Staff Director, Science Advisory Board

Dr. Toby Clark*+
Special Assistant to the Administrator

Regional Offices

William R. Adams, Jr.*
Regional Administrator, Region I

Dr. Richard Keppler*
Director, ORD, Region I

Office of General Counsel

James C. Nelson*+
Attorney Advisor

John W. Lyon*
Attorney

Edward Gray*
Deputy Associate General Counsel for Program Support

Office of Legislation

Marianne Thatcher*
Congressional Liaison Specialist

Alice White+
Legislative Reference Specialist

Office of International Activities

Jack E. Thompson+
Director, International Organizations and Western Hemisphere Division

Office of International Activities (Continued)

Thomas Lepine+
Chief, Scientific Activities Overseas Branch

Office of Planning and Management

Roy N. Gamse*
Deputy Assistant Administrator for Planning and Evaluation

Frans J. Kok*
Director, Economic Analysis Division

Marian Mlay*
Director, Program Evaluation Division

Matthew Pilzys*
Associate Deputy Assistant Administrator for Resource Management

Raymond A Pugh*+
Director, Budget Operations Division

Donald Hambric+
Chief, Cost Review and Policy Branch
Contract Management Division (CMD)

Vincent Jay+
Chief, Interagency Agreements Branch, CMD

Carlene Foushee+
Grants Specialist, Grants Division

Office of Water and Waste Management

Thomas C. Jorling*
Assistant Administrator for Water and Waste Management

Allen Cywin*+
Senior Science Advisor

Swep T. Davis*
Deputy Assistant Administrator for Water Planning and Standards

Albert J. Erickson*
Associate Deputy Assistant Administrator for Water Planning and Standards

John T. Rhett*
Deputy Assistant Administrator for Water Program Operations

Henry L. Longest*
Associate Deputy Administrator for Water Program Operations

Office of Water and Waste Management (Continued)

Kenneth Mackenthun*
Director, Criteria and Standards Division

Gary N. Dietrich*
Direcotr, Office of Program and Management Operations

Victor J. Kimm*
Deputy Assistant Administrator for Drinking Water

John P. Lehman*
Director, Hazardous Waste Management Division

Joseph Cotruvo*+
Director, Criteria and Standards Division
Office of Drinking Water

Shelly Williamson*+
Epidemiologist

Office of Air, Noise and Radiation

David G. Hawkins*
Assistant Administrator for Air, Noise and Radiation

Rudolph M. Marrazzo*
Science Assistant to the Deputy Assistant Administrator for Noise Abatement and Control

William A. Mills*
Director, Radiation Criteria and Standards Division
Acting Deputy Assistant Administrator for Radiation Programs

Walter C. Barber, Jr.*
Deputy Assistant Administrator for Air Quality Planning and Standards

John O'Connor*+
Strategies and Air Standards Division

Joseph Padgett*
Director, Strategies and Standards Division

Michael P. Walsh*
Deputy Assistant Administrator for Mobile Source Air Pollution Control

Stan Blacker*
Special Assistant to DAA for Mobile Source Air Pollution Control

Office of Toxic Substances

Steven D. Jellinek*
Assistant Administrator for Toxic Substances

Warren R. Muir*
Deputy Assistant Administrator for Testing and Evaluation

John DeKaney*
Deputy Assistant Administrator for Chemical Control

Edwin L. Johnson*
Deputy Assistant Administrator for Pesticide Programs

James M. Conlon*
Associate Deputy Assistant Administrator for Pesticide Programs

William S. Murray*+
Director, Technical Services Division

Jack Griffith*
Chief, Human Effects Monitoring Branch, Technical Services Division

Don Barnes+
Special Assistant to the Assistant Administrator for Toxic Substances

Norbert Page*
Director, Health Review Division

James R. Beall*
Toxicologist, Health Review Division

David Gould*
Toxicologist, Health Review Division

David Anderson*
Biochemist, Health Review Division

Carl Morris*
Pharmacologist, Health Review Division

Office of Research and Development

Stephen J. Gage*+
Assistant Administrator for Research and Development

Sam Rondberg*+
Director, Office of Planning and Review

Dennis Tirpak+
Special Assistant to AA for Research and Development

Office of Research and Development (Cont.)

Randall W. Shobe+
Director, Technical Information Division

Robert W. Lane*+
Special Assistant to AA for Research and Development

Delbert Barth*
Deputy Assistant Administrator for Health & Ecological Effects

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APPENDIX E

Federal Register

THURSDAY, NOVEMBER 30, 1978
PART II

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGULATORY AGENDA

[6560-01-M]

ENVIRONMENTAL PROTECTION AGENCY

[FRL 983-5]

AGENDA OF REGULATIONS

AGENCY: Environmental Protection Agency.

ACTION: Agenda of Regulations.

SUMMARY: Four times a year the Agency publishes a summary of the significant regulatory actions under development to help assure that interested parties have an early opportunity to participate in shaping our regulations. We call the summary our Agenda of Regulations.

FOR FURTHER INFORMATION CONTACT: For information about any particular item on the Agenda contact the individual identified as the contact person for that item. For general information about public participation in the regulatory process contact:

Chris Kirtz, (PM-223), Standards and Regulations Evaluation Division, Environmental Protection Agency, 401 M Street, SW Washington, D.C. 20460.

SUPPLEMENTARY INFORMATION: On March 23, 1978, President Carter signed Executive Order 12044, *Improving Government Regulations*, which directed all executive agencies to adopt procedures to improve existing and future regulations. One procedure which the Order required all agencies to adopt was the publication twice a year of a list of significant regulations which are under development or review. The Order also directed that the Agenda provide the following information about the potential regulations:

- A brief description
- A citation of its statutory authority
- Its status
- The name and phone number of a knowledgeable official
- Whether we will prepare a regulatory analysis due to the regulation's potentially major economic consequences
- Whether the listed item is an existing regulation which we are reevaluating

The Order also directed that the Agenda provide the status of all items listed on the previous Agenda.

EPA's previous Regulatory Agenda was published April 6, 1978.

COVERAGE

We have tried to list all significant actions which are going through the Agency's formal regulation development process, but we may have inadvertently omitted a few. Appearance or nonappearance in the Agenda carries with it no legal significance.

Executive Order 12044 gave general guidelines on determining what regulations were significant and which, therefore, should be included on the Agenda. It directed each agency to develop specific criteria for identifying significant regulations. We will describe our criteria for determining significant regulations in our final report responding to the Executive Order. I will be signing this report soon, and you will be able to obtain copies of it from Philip Schwartz (PM-223), Washington, D.C., 20460.

The Agency's formal process of regulation development starts when an Assistance Administrator sends a notice form to the Administrator and other senior management. This form notifies all EPA offices that a regulation is about to be prepared and allows these offices to plan their participation.

Different events might trigger the start of the Agency's formal regulation development process. The most common event is the passage of new legislation. Other common triggers include new scientific studies; advances in technology; petitions for rulemaking sent in from outside EPA; judicial documents such as court orders and consent agreements; and simply, operating experience with a particular regulation which may suggest ways that we can improve it.

EXPLANATION OF INFORMATION IN THE AGENDA

The Agenda lists prospective regulatory actions authorized by the following laws:

- the Clean Air Act (CAA)
- the Motor Vehicle Information and Cost Savings Act (MVICSA)
- the Safe Drinking Water Act (SDWA)
- the Noise Control Act (NCA)
- the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
- the Atomic Energy Act (AEA)
- the Public Health Service Act (PHSA)
- the Resource Conservation and Recovery Act (RCRA)
- the Toxic Substances Control Act (TSCA)
- the Federal Water Pollution Control Act as amended by the Clean Water Act (CWA)

The first column of the Agenda provides the following information about each regulation:

- A citation from the Code of Federal Regulations
- A short title
- A citation of statutory authority
- A description, including whether the item is an existing regulation which we are reevaluating

If the regulation may have economic consequences large enough to require a regulatory analysis, an asterisk (*) appears at the beginning of the entry.

The second column lists the date we proposed a regulation in the FEDERAL REGISTER or the month in which we expect to propose it.

The third column lists the date we published a final regulation or the month in which we expect to publish the final regulation.

The fourth column provides the name, address, and phone number of whom to contact for each regulation.

DOUGLAS M. COSTLE,
Administrator.

NOVEMBER 20, 1978.

MAJOR EPA REGULATIONS UNDER CONSIDERATION

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE CLEAN AIR ACT			
We are developing the following seven items under the authority of secs. 108 and 109 of the CAA which direct the Administrator to establish national Ambient Air Quality Standards (NAAQS). To write a NAAQS for any pollutant, we first prepare a criteria document which contains the latest scientific knowledge on the kind and extent of public health and welfare problems caused by the presence of the pollutant in the air. If we revise the criteria document, we may find it necessary to also change the NAAQS. A National Primary Ambient Air Quality Standard defines the Maximum amount of an air pollutant which the Administrator of EPA determines is compatible with an adequate margin of safety to protect the public health. A National Secondary Ambient Air Quality Standard defines levels of air quality which the Administrator judges necessary to protect the public welfare from any known or anticipated adverse effects of a pollutant.			
40 CFR 50 **Review of NAAQS for Photochemical Oxidants*, CAA 108. The proposed regulation would change the existing primary, health-based standard to 0.10 ppm for a 1-hour average from the existing 0.08 ppm standard. The secondary, welfare-based standard would remain at 0.08 ppm for 1-hour average. The pollutant we control would be changed from photochemical oxidants to ozone, which is the principal measurable ingredient in photochemical oxidants.	June 22, 1978	December 1978	Joe Padgett (MD-12), Environmental Protection Agency, Research Triangle Park, N.C. 27711, 919-541-5204, FTS 8-629-5204.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
	THE CLEAN AIR ACT		
40 CFR 50 **NAAQS for Lead.* CAA 108. EPA proposed an ambient lead standard of 1.5 micrograms per cubic meter averaged over 30 days. Public reaction has been mixed. Federal agencies and public interest groups support the proposal. Industry argues that: (1) the health data and analyses do not support the standard, (2) large parts of the secondary lead and foundry industries are *Technically* unable to comply, and (3) plant closures for economic and technical reasons will result from enforcement of the standard.	Dec. 14, 1977	Oct. 5, 1978	Do.
40 CFR 50 **Review of NAAQS for Carbon Monoxide.* CAA 108. The health basis for control of this pollutant will we reviewed. This requires preparation of an updated criteria document and analysis of whether or not NAAQS should be revised.	September 1979	February 1980	Do.
40 CFR 50 **Review of NAAQS for Sulfur Oxides.* CAA 108. A review of the health basis for control of this pollutant will require preparation of an updated criteria document and analysis of whether or not NAAQS should be revised.	May 1980	December 1980	Do.
40 CFR 50 **Review of Long Term NAAQS for Nitrogen Dioxide* CAA 108. The NAAQS for nitrogen dioxide is undergoing review. ORD will complete a revised criteria document by January 1979. Under the CAA amendments, the criteria and the decision to revise the standard must address both the long-term effects of NO2, and effects associated with other nitrogen species in the air, particularly nitrates, and nitric acid aerosol.	January 1979	June 1979	Do.
40 CFR 50 **Review of NAAQS for Particulates.* CAA 108. A review of the health basis for control of this pollutant will require preparation of an updated criteria document and analysis of whether or not NAAQS should be revised.	May 1980	December 1980	Do.
40 CFR 50 **Development of Short Term NAAQS for Nitrogen Dioxide.* CAA 109. The Clean Air Act Amendments of 1977 require proposal and promulgation of a 1-3 hour standard for NO2 unless EPA finds that such a standard is not necessary to protect the public health.	January 1979	June 1979	Do.
We are developing performance standards to control emissions from the following industries under sec. 111(b) of the CAA. This section requires that the Administrator develop New Source Performance Standards (NSPS) for stationary sources which significantly contribute to air pollution. The NSPS are based on the best system of continuous emission reduction which has been adequately demonstrated. The standards would apply to both new sources and existing sources which are modified after approval of the regulation.			
40 CFR 60 **NSPS—Fossil Fuel Steam Generators (Revision).* CAA 111. Revised standards are being proposed for utility boilers for control of SO2, NOx and particulates. The revised NSPS will apply to any fossil-fueled utility boiler with a heat input of 250 million Btu/hour or greater. The NSPS will require a percent removal of sulfur dioxide and will include an emission ceiling and an emission floor.	Sept. 19, 1978	March 1979	Don Goodwin (MD-13), Environmental Protection Agency, Research Triangle Park, N.C. 27711, 919-541-5271, FTS 8-629-5271.
40 CFR 60 *NSPS—Petroleum Liquid Storage Vessels.* CAA 111. This is a revision of 1974 NSPS. The revised standard will propose the use of double seals rather than single seals on floating roofs. The standard, as currently being developed, will essentially eliminate one of two types of seals currently in use.	May 18, 1978	....do	Do.
40 CFR 60 *NSPS—Glass Manufacturing.* CAA 111. This regulation will address the problem of emissions from new glass manufacturing furnaces. The Governor of New Jersey requested that EPA develop national standards.	February 1979	December 1979	Do.
40 CFR 60 *NSPS—Internal Combustion Engines.* CAA 111. These regulations will require the application of best demonstrated control technology to control emissions from stationary internal combustion engines. It will also require States to act under sec. 111(d) to regulate these compounds from existing sources.	December 1978	....do	Do.
40 CFR 60 *NSPS—Sulfur Recovery in Natural Gas Fields.* CAA 111. This regulation will control emissions of total reduced sulfur compounds.	July 1979	May 1980	Do.
40 CFR 60 *NSPS—Non-Metallic Minerals.* CAA 111. Particulate emissions from quarrying operations and related facilities will be controlled.	January 1979	December 1979	Do.
40 CFR 60 *NSPS—Organic Solvent Metal Cleaning.* CAA 111. This rule will control evaporative emissions from metal cleaning and degreasing operations.	March 1979	January 1980	Do.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE CLEAN AIR ACT			
40 CFR 60 *NSPS—Surface Coating Operations for Auto Assembly Plants.* CAA 111. Evaporative emissions from coating operations in the auto and light truck industry will be controlled.	February 1979	do	Do.
40 CFR 60 *NSPS—Synthetic Organic Chemical manufacturing.* CAA 111. Selection of a degree of control of emission from manufacture of over 100 major organic chemicals is to be made. A series of standards will be proposed.	March 1979	do	Do.
40 CFR 60 *NSPS—Can Coating.* CAA 111. This regulation will establish emission standards for volatile organic emissions from can coating operations.	November 1979	September 1980	Do.
40 CFR 60 *NSPS—Pressure Sensitive Tapes and Labels Coating.* CAA 111. This regulation will establish emission standards for volatile organic emissions from pressure sensitive tapes and label operations.	January 1980	November 1980	Do.
40 CFR 60 *NSPS—Metal Furniture Surface Coating.* CAA 111. This regulation will establish emission standards for volatile organic emissions from metal furniture operations.	December 1978	December 1979	Do.
40 CFR 60 *NSPS—Lead Battery Manufacturing.* CAA 111. This regulation will establish emission standards for lead and sulfuric acid mist emissions from lead battery manufacturing facilities. The action on H2S04 will key the requirement that States regulate existing sources under sec. 111(d).	April 1979	February 1980	Do.
40 CFR 60 *NSPS—Gas Turbines.* CAA 111. This regulation will establish limitations on oxide of nitrogen emissions from stationary gas turbines.	Oct. 3, 1977	February 1979	Do.
40 CFR 60 *NSPS—Industrial Boilers.* CAA 111. This regulation will control the emissions of particulates, NOx and SO2.	October 1980	August 1981	Do.
40 CFR 60 *NSPS—Phosphate Rock.* CAA 111. This regulation will control the emission of particulates.	May 1979	March 1980	Do.
40 CFR 60 *Aluminum Plant Flouride Control—Existing Plants.* CAA 111(d). These are guidelines for State control of flouride emissions from existing aluminum plants.	January 1979	November 1979	Do.
40 CFR 60 *Guidelines for Existing Kraft Pulp Mills.* CAA 111(d). These are guidelines to control sulfur (odors) from existing Kraft pulp mills will allow States flexibility in establishing controls.	Feb. 23, 1978	January 1979	Do.
40 CFR 60 *List of New Source Performance Standards.* CAA 111(f). The 1977 Clean Air Act requires the Administrator to list the categories of major stationary sources that are not already controlled by NSPS. He must then issue standards for these categories within 4 years.	Aug. 31, 1978	May 1979	Do.
We are developing emission standards for hazardous air pollutants under sec. 112 of the CAA. This section requires that the Administrator develop National Emission Standards for Hazardous Air Pollutants (NESHAPS) for emissions which cause or contribute to air pollution which results in an increase in mortality, or an increase in serious or incapacitating illness. The standards would apply to both new sources and existing sources.			
40 CFR 61 *NESHAPS. Asbestos-Iron Ore Beneficiation.* CAA 112. This regulation would establish limits on asbestos emissions from iron ore beneficiation facilities.	September 1979	July 1980	Don Goodwin (MD-13), Environmental Protection Agency, Research Triangle Park, N.C. 27711, 919-541-5271, FTS 8-629-5271.
40 CFR 61 *NESHAPS: Vinyl Chloride Amendments.* CAA 112. The proposed regulations have called for increased control of existing sources, stringent control of new sources, and a zero emission goal.	June 7,1977	Indeterminate	Do.
40 CFR 61 *NESHAPS: Handling and Storage.* CAA 112. This regulation would control the handling and storage of benzene and benzene-rich liquids.	August 1979	June 1980	Do.
40 CFR 61 *NESHAPS. Gasoline Distribution Systems.* CAA 112. This regulation would control benzene emissions from major marketing sources such as bulk terminals, bulk plants, and service stations	Indeterminate	Indeterminate	Do.
40CFR 61 *NESHAPS—Refinery Sources.* CAA 112. This regulation would control the emission of benzene from point sources as well as from fugitive sources (pumps, valves, etc.) and waste disposal.	September 1979	November 1980	Do.
40 CFR 61 *NESHAPS—Maleic Anhydride.* CAA 112. This regulation would control the emission of benzene in the manufacture of maleic anhydride.	January 1979	November 1979	Do.
40 CFR 61 *NESHAPS—Ethyl Benzene.* CAA 112. This regulation would control the emission of benzene in the manufacture of ethyl benzene.	March 1979	January 1980	Do.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE CLEAN AIR ACT			
40 CFR 61 *NESHAPS—Styrene.* CAA 112. This regulation would control the emission of benzene in the manufacture of styrene.	June 1979	April 1980	Do.
40 CFR 61 *NESHAPS: Asbestos Released from Crushed Stone.* CAA 112. Use of crushed serpentine rock for roadway surfacing may release significant quantities of asbestos. A monitoring program is under way and results indicate standards will be proposed.	May 1980	March 1981	Do.
40 CFR 61 *NESHAPS: Coke Oven Emission-Charging Operations.* CAA 112. The regulation would define coke oven emissions as a hazardous air pollutant. Charging operations would be regulated first. Regulations on top side leaks would follow.	December 1978	September 1979	Do.
40 CFR 61 *NESHAPS: Arsenic.* CAA 112. A health risk assessment is being conducted. If it is determined that arsenic emissions (primarily from copper smelters) are a hazardous air pollutant, then emission standards would be proposed.	December 1979		Joe Padgett (MD 12). Environmental Protection Agency, Research Triangle Park, N.C. 27711 919-541-5204, FTS 8-629-5204.
40 CFR 57 *Primary Nonferrous Smelter Orders.* CAA 119. These regulations will establish the substantive requirements of initial primary nonferrous smelter orders (NSO's) and the procedures to be used in issuing them. NSO's will allow certain copper, lead, and zinc smelters to delay compliance with the requirements for constant control of sulfur dioxide emissions and let them use tall stacks and supplementary control systems to meet ambient standards.	December 1978	April 1979	Judith Larsen (EN-341). Environmental Protection Agency, Washington, D.C. 20460, 202-755-2583.
40 CFR 56 *Noncompliance Penalties.* CAA 120. EPA is required to establish a penalty program to start collecting money from polluters after mid-1979 in an amount equal to the money the polluter saves by failing to obey the law.	....do	Undetermined	Bob Homiak (EN-341). Environmental Protection Agency, Washington, D.C. 20460, 202-755-2542.
40 CFR 51 *Tall Stack Regulation.* CAA 123. The regulations will specify what height stacks may be given credit for dispersion under State implementation plans.	November 1978	April 1979	Dick Rhoads (MD-15). Environmental Protection Agency, Research Triangle Park, N.C. 27711, 919-541-5251, FTS 8-629-5251.
40 CFR 51.240 *Regulations Providing for State/Local Consultation.* CAA 121. The regulations will ask the States to provide a satisfactory process of consultation with local governments, elected officials, and Federal land managers. The regulations will also require the States to choose a lead planning organization to coordinate the State Implementation Plan revisions for oxidants (smog) and carbon monoxide.	May 18, 1978	December 1978	John Hidinger (AW-445). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0481.
1979 Listing of Radioactive Pollutants. CAA 122. Determine whether radioactive pollutants shall be classified as 108, 111, or 112 pollutants or none of these categories.	August 1980	Undetermined	William A. Mills (AW-460). Environmental Protection Agency, Washington, D.C. 20460, 703-557-0704.
40 CFR 51 *Emission Offset Policy Regulations.* CAA 129. These regulations address the issue of whether and to what extent the national ambient air quality standards established under CAA restrict or prohibit growth of major new or expanded air pollution sources. These proposed revisions reflect the public comments (including four public hearings on the December 21 ruling and the changes required by CAA Amendments of 1977).	Dec. 21, 1976	November 1978	Kent Berry (MD-11). Environmental Protection Agency, Research Triangle Park, N.C. 27711, 919-541-5343, FTS 8-629-5343.
40 CFR 51 and 52 *Prevention of Significant Deterioration (PSD).* Set II. CAA 166. These regulations will insure that areas which are in compliance with hydrocarbon, carbon monoxide, photochemical oxidant, and nitrogen oxide standards will remain in compliance.	December 1979	October 1980	Dick Rhoads (MD-15). Environmental Protection Agency, Research Triangle Park, N.C. 27711, 919-541-5251, FTS 8-629-5251.
Visibility Protection. CAA 167(a). EPA is required to prepare a report to Congress and guidelines which require SIP's to address visibility problems.	October 1979	August 1980	Joe Padgett. Environmental Protection Agency, Research Triangle Park, N.C. 27711, 919-541-5204, FTS 8-629-5204.
40 CFR 85 *Requirements to Build Demonstration Cars Meeting 0.4 Gram/Mile NOx Standard.* CAA 202. All manufacturers with a least a 0.5 pct share of the U.S. passenger car market will have to build research vehicles which meet the 0.4 grams nitrogen dioxide per mile research objective. This regulation will be published in interim-final form.	December 1978	July 1979	Karl Hellman. Emission Control Technology Division, Environmental Protection Agency, 2565 Plymouth Rd., Ann Arbor, Mich. 48105, 313-668-4246.
40 CFR 86 *Light-Duty Diesel Particulate Standards.* CAA 202. EPA is required to set particulate standards for mobile sources starting in 1981. The regulation will contain 1981 standards and more stringent standards for 1983 and later model years.	....do	July 1979	Merrill Korth. Emission Control Technology Division, Environmental Protection Agency, 2565 Plymouth Rd., Ann Arbor, Mich. 48105, 313-668-4299.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE CLEAN AIR ACT			
40 CFR 86 *Heavy Duty Diesel Particulate Standards.* CAA 202. Although required by CAA for 1981 models, there is no test procedure available that can be used as the basis for a standard. A 1983 model year is targeted.	December 1980	August 1980	Do.
40 CFR 86 *Test Procedures for Measuring Heavy Duty Evaporative Emissions.* CAA 202(a). The Clean Air Act requires that a test procedure be promulgated which will require measurement of evaporative emission from the vehicles as a whole. EPA will promulgate test procedure and standards.	December 1978	August 1980	Mike Leiferman, Environmental Protection Agency, Ann Arbor, Mich. 48105. 313-668-4271.
40 CFR 86 *Heavy-Duty Evaporative Emission Standards.* CAA 202(a). Standards will apply to heavy-duty gasoline vehicles and will control emissions due to evaporation of gasoline beginning in model year 1981.	January 1979	August 1980	Do.
40 CFR 86 *Light-Duty Truck Emission Standards (Up to 8500 lbs. Gross Vehicle Weight Rating—GVWR).* CAA 202(a). CAA requires standards for 6,000-8,500 lb trucks that represent a 90 percent reduction in HC and CO from baseline for 1983. Standards are expected to be equivalent in stringency to 1981 passenger car standards and are expected 1 year ahead of CAA deadline, i.e. 1982 model year. The same standards will also be applied to trucks under 6,000 lb GVWR.	....do	August 1979	William Houtmann, Environmental Protection Agency, Ann Arbor, Mich. 48105, 313-668-4272.
40 CFR 86 *HC and CO Emission Standards for Heavy Duty Vehicles (Over 8,500 Pounds).* CAA 202(a)(3). The CAA requires EPA to establish emission standards for engines for heavy-duty vehicles over 8,500 pounds. Standards for HC and CO are a 90 percent reduction from baseline emissions for 1983 model year. EPA is in the process of developing a new test procedure for measuring exhaust emissions and measurements of baseline emissions.	December 1978	December 1979	Chet France, Environmental Protection Agency, Ann Arbor, Mich. 48105. 313-668-4338.
40 CFR 86 *NOx Emission Standard for Heavy Duty Vehicles (Over 8,500 Pounds).* CAA 202(a)(3). The CAA requires EPA to establish emission standards for heavy-duty vehicles (over 6,000 lbs. GVWR). A 75 percent reduction for NOx beginning with 1985 model year. EPA is in the process of developing a new test procedure for measuring exhaust emissions and must then measure baseline emissions.	December 1979	September 1980	Do.
Fill Pipe Standards. CAA 202(a)(5). At such time as phase II vapor recovery regulations are promulgated, EPA is required to set standards for vehicle refueling orifices and associated parts of the fuel system to provide effective connection between the fill pipe and vapor recovery refueling nozzles. The effective model is to be determined on the basis of lead time required for design and production of the required systems. The type of fill pipe needed depends of whether phase II or on-board HC control is selected by EPA.	September 1979	June 1980	Ernie Rosenberg (AW-455), Environmental Protection Agency, Washington, D.C. 20460. 202-755-0596.
On-Board Hydrocarbon Technology. CAA 202(a)(6). Under this section EPA is required to determine whether onboard HC controls are feasible and more desirable than Phase II: Vapor Recovery, taking into consideration such factors as fuel economy, costs, administrative burdens, equitable distribution of costs and safety. If found feasible and desirable, onboard HC control standards are to be set by EPA, with such lead time as is needed for implementation. In issuing such regulations, EPA is required to consult with the Department of Transportation regarding the safety of the controls.	September 1979	June 1980	Paul Stolpman (AW-443), Environmental Protection Agency, Washington, D.C. 20460. 202-426-2484.
40 CFR 86 *Interim High Altitude Requirements.* CAA 202(a), (f). The regulations will set requirements ,or car to meet the standards at high altitude for 1981-83.	December 1978	August 1979	William Houtmann, Environmental Protection Agency, Ann Arbor, Mich. 48105. 313-668-4272.
40 CFR 85 *Importation of Motor Vehicles and Motor Vehicle Engines.* CAA 203. The regulation attempts to improve the effectiveness and administration of EPA's program to prevent importation of vehicles and engines which fail to conform to Federal emission standards.	December 1978	July 1979	Tom Preston (EN-340), Environmental Protection Agency, Washington, D.C. 20460. 202-755-0944.
40 CFR 86 *Regulations Defining Certificate of Conformity.* CAA 206(a). The regulations will identify the components and specifications that are a required part of motor vehicle certification: the parameters of allowable deviation of parts; and the specifications for the certification tests.	Dec. 23, 1974	March 1979	Do.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE CLEAN AIR ACT			
40 CFR 86 *Selective Enforcement Auditing of Motorcycles.* CAA 206(b). The regulation will establish a program for testing motorcycles at the assembly line to assure compliance with emission standards.	Holding		Frank Slaveter (EN-338). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0596.
40 CFR 86 *Selective Enforcement Auditing of Heavy Duty Engines and Vehicles.* CAA 206(b). The regulation will establish a program for testing heavy duty engines and vehicles at the assembly line to assure compliance with emission standards.	December 1978	February 1979	Do.
40 CFR 86 *Engine Parameter Adjustment Regulations.* CAA 206(b). This regulation will limit the adjustment parameters of emissions-related controls on vehicles to ensure that after the vehicles pass certification tests, they are not readjusted in the field by dealerships or service stations to improve their driveability at the cost of increased emissions.	Oct. 21, 1977	November 1978	Ron Kruse. Environmental Protection Agency, Ann Arbor, Mich. 48105, 313-668-4317.
40 CFR 86 *1984 High Altitude Standards.* CAA 206(f). These regulations will require all vehicles to meet standards at all altitudes beginning with 1984 models.	May 1981	May 1982	Ernie Rosenberg (AW-455). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0596.
40 CFR 86 *Penalties for Noncomplying Heavy-Duty Engines and Vehicles.* CAA 206(g). This regulation would allow heavy-duty engine or vehicle manufacturers to sell vehicles or engines exceeding the standards if they pay a noncompliance penalty. They still would not be sold, however, if they exceed an upper limit.	December 1978	February 1979	Frank Slaveter (EN-338). Environmental Protection Agency, Washington, D.C. 20460, 202-755-1572.
40 CFR 86 *Emission Control Warranty.* CAA 207(a)(1). The regulations activate a manufacturer's warranty that becomes enforceable if the vehicle exceeds emission standards as a result of defects present at the time of sale.	December 1978	June 1979	Rick Friedman (EN-340). Environmental Protection Agency, Washington, D.C. 20460, 202-426-4690.
40 CFR 86 *Aftermarket Parts Certification.* CAA 207(a)(2). The regulation establishes guidelines so aftermarket parts manufacturers can certify that their parts do not degrade emissions.	January 1979	August 1979	David Feldman (EN-340). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0297.
40 CFR 86 *Short Test for Emission Warranties.* CAA 207(b). The regulation establishes procedures for tests of emissions from light duty trucks and light duty vehicles to be performed in conjunction with inspection/maintenance programs.	May 25, 1977	January 1979	Dick Nash. Environmental Protection Agency, Ann Arbor, Mich. 48105, 313-668-4412.
40 CFR 85 *Emission Control (Performance) Warranty.* CAA 207(b)(2). This regulation specifies performance warranty requirements based on short-cycled emissions test for in-use vehicles. It was proposed in May 1977 and is now being reproposed to take the Clean Air Act Amendments into account.	November 1978	April 1979	David Feldman (EN-340). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0297.
40 CFR 79.6 *Fuels and Fuel Additives Protocols for Testing.* CAA 211. The protocols will help determine effects of fuels and fuel additives on public health and emission control devices.	January 1979	May 1979	Matt Bills (RD-680). Environmental Protection Agency, Washington, D.C. 20460, 202-426-4452.
40 CFR 86 *High Altitude Performance Adjustments.* CAA 215. EPA is required to set procedures by which manufacturers must have adjustments to their cars for high altitude operation approved.	February 1979	February 1980	Ernie Rosenberg (AW-455). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0596.
40 CFR 86 *Turbine Aircraft Gaseous Emissions Retrofit and Modification of 1973 Standards.* CAA 231. This regulation will propose, and for some classes of aircraft, repropose emission standards for large aircraft to reduce HC, NOx, and CO.	Mar. 24, 1978	September 1979	William Houtmann. Environmental Protection Agency, Ann Arbor, Mich. 48105, 313-668-4272.
40 CFR 56 *Regional Consistency.* CAA 301. EPA is required to provide for consistent implementation of the Clean Air Act by the various EPA Regional Offices.	January 1979	Undetermined	Darryl Tyler (MD-13). Environmental Protection Agency, Research Triangle Park, N.C. 27711, 919-541-5351, FTS 8-629-5425.
40 CFR 51, 52, 53, 58, and 60 *Monitoring Regulations.* CAA 319. These regulations will revise the requirements for State and local air pollution monitoring for purposes of State implementation plans and for reporting air quality data to EPA.	Aug. 7, 1978	January 1979	Robert Neligan (MD-14). Environmental Protection Agency, Research Triangle Park, N.C. 27711, 919-541-5447, FTS 8-629-5447.
THE MOTOR VEHICLE INFORMATION AND COST SAVINGS ACT (MVICSA)			
40 CFR 85 *Testing Retrofit Devices for Fuel Economy Performance.* MVICSA 511. The regulation provides for EPA evaluation of claims by a manufacturer that it has produced a fuel economy retrofit device.	Aug. 10, 1977	December 1978	Ernie Rosenberg (AW-455). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0596.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE CLEAN WATER ACT (Federal Water Pollution Control Act as amended by the Clean Water Act Amendments of 1977)			
40 CFR 35(F) *State Management Assistance.* CWA 101(b)/205. States may use up to 2 percent of their title II allotment or $400,000 whichever is greater, to finance the administration of sec. 201, 203, 208, 212, 402, and 404 programs.	Apr. 25, 1978, interim final	Sept. 27, 1978	Joe Easley (WH-547). Environmental Protection Agency, Washington, D.C. 20460, 202-426-4445.
7 CFR 634 *Agricultural Cost Sharing.* CWA 208(j).). The Department of Agriculture will provide grants covering up to 50 percent of costs to install best management practices for water quality management. The program will be imple-by the USDA. The regulations will be promulgated by USDA with EPA concurrence.	June 22, 1978	To be determined	Joe Krivak (WH-585) Environmental Protection Agency, Washington, D.C. 20460, 202-755-7000.
40 CFR 35 *Water Quality Management Regulations.* CWA 106, 208, 303(e). These regulations revise and update the water quality management regulations previously issued under 40 CFR 130 and 131.	Sept. 12, 1978	January 1979	Linda Eichmiller (WH-554). Environmental Protection Agency, Washington, D.C. 20460, 202-755-6965.
40 CFR 35.15 *State 208 Regulatory Programs for Dredge and Fill Materials.* CWA 208(b)(4). These regulations will authorize States to establish regulatory programs for the discharge of dredge and fill material to supplement State 404 permit programs.	January 1979	July 1979	Joe Krivak. Environmental Protection Agency, Washington, D.C. 20460, 202-755-7000.
40 CFR 233 *Modification of Secondary Treatment Requirements for Marine Dischargers.* CWA 301(h). The 1977 amendments of the Clean water Act allow EPA to modify the treatment requirements for existing ocean dischargers from Publicly Own Treatment Works (POTW's) in regard to the required degree of removal of Biological Oxygen Demand (BOD), Total Suspended Solids (TSS), and pH. Applicants are required to meet eight specific 301(h) criteria in addition to any other applicable criteria of the Act. The receipt of modification would not relieve a POTW from compliance with performance standards which EPA will later publish to reflect Best Practicable Wastewater Treatment Technology (BPWTT). This rule establishes the criteria which EPA will apply and the procedures it will follow in its evaluation of application for a modification.	Apr. 25, 1978	December 1978	Tom O'Farrell (WH-551). Environmental Protection Agency, Washington, D.C. 20460, 202-426-8976.
40 CFR 124 *Extension of Pollution Control Deadlines for Publicly Owned Treatment Works and Other Point Sources Planning to Discharge to Those Publicly Own Treatment Works.* CWA 301(j). This regulation establishes criteria which EPA and NPDES States will use in reviewing requests for 301(i) extensions from the July 1, 1977, treatment requirements.	May 16, 1978, interim final	Will be incorporated into NPDES program regulations 40 CFR 122 to 125.	Ed Kramer (EN-336). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0750.
40 CFR 125 *Requirements for Application for 301 (c) and (g) Variances.* CWA 301(j)(1)(B). These regulations require dischargers desiring 301 (c) and (g) variances to file initial applications by Sept. 25, 1978, or 270 days after promulgation of BAT limitations whichever is later.	Sept. 13, 1978, interim final	January 1979, will be incorporated into NPDES program regulations 40 CFR 122 to 125.	Scott Siesinger (EN-336). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0750.
Effluent guidelines representing best available treatment technology, new source performance standards, and pretreatment standards are being developed for the following industries to comply with the Act and a court order mandating control of certain toxic substances in industrial effluents. CWA 301, 304, 306, and 307.			
40 CFR 420 *Iron and Steel Manufacturing*	November 1979	May 1980	Ernst Hall (WH-552). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2576.
40 CFR 435 *Petroleum Refining*	March 1979	October 1979	Robert Dellinger (WH-552). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2497.
40 CFR 429 *Timber Products Processing*	May 1979	December 1979	John Riley (WH-552). Environmental Potection Agency, Washington, D.C. 20460, 202-426-5554.
40 CFR 423 *Steam Electric Power Plants*	do	do	John Lum (WH-552). Environmental Protection Agency, Washington, D.C. 20460 202-426-4617
40 CFR 425 *Leather Tanning and Finishing*	January 1979	August 1979	William Sonnett (WH-552). Environmental Protection Agency, Washington, D.C. 20460 202-426-2440.
40 CFR 421 *Nonferrous Metals Manufacturing*	August 1979	March 1980	Patricia Williams (WH-552). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2586.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE CLEAN WATER ACT			
40 CFR 46 *Paint and Ink Formulation*	September 1979	April 1980	Richard Gigger (WH-552), Environmental Protection Agency, Washington, D.C. 20460, 202-426-2583.
40 CFR 448 *Printing and Publishing Services*	November 1979	June 1980	Do.
40 CFR 440 *Ore Mining and Dressing*	....do	July 1980	Gail Coad (WH-586), Environmental Protection Agency, Washington, D.C. 20460, 202-426-2503.
40 CFR 434 *Coal Mining*	December 1979	June 1980	William Telliard (WH-586), Environmental Protection Agency, Washington, D.C. 20460, 202-426-2726.
40 CFR 414 *Organic Chemicals Manufacturing*	January 1980	August 1980	Paul Parenthold (WH-552), Environmental Protection Agency, Washington, D.C. 20460, 202-426-2497.
40 CFR 415 *Inorganic Chemicals Manufacturing*	September 1979	April 1980	Walter Hunt (WH-552), Environmental Protection Agency, Washington, D.C. 20460, 202-426-2724.
40 CFR 410 *Textile Mills*	May 1979	December 1979	James Gallup (WH-552), Environmental Protection Agency, Washington, D.C. 20460, 202-426-2554.
40 CFR 416 *Plastics and Synthetic Material*	January 1980	August 1980	Paul Fahrenthold (WH-552), Environmental Protection Agency, Washington, D.C. 20460, 202-426-2497.
40 CFR 430 *Pulp and Paper*	February 1980	....do	Bob Dellinger (WH-552), Environmental Protection Agency, Washington, D.C. 20460, 202-426-2554.
40 CFR 428 *Rubber Processing*	June 1979	January 1980	Do.
40 CFR 417 *Soap and Detergents Manufacturing*	July 1980	July 1981	Sammy Ng (WH-586), Environmental Protection Agency, Washington, D.C. 20460, 202-426-2503.
40 CFR 444 *Auto and Other Laundries*	December 1979	July 1980	Richard Gigger (WH-552), Environmental Protection Agency, Washington, D.C. 20460, 202-426-2583.
40 CFR 456 *Miscellaneous Chemicals—Adhesives and Sealants.*	February 1980	August 1980	Elwood Forsht (WH-552), Environmental Protection Agency, Washington, D.C. 20460, 202-426-2707.
40 CFR 457 *Miscellaneous Chemicals—Explosives Manufacturing.*	December 1979	July 1980	Elwood Martin (WH-552), Environmental Protection Agency, Washington, D.C. 20460, 202-426-2440.
40 CFR 454 *Miscellaneous Chemicals—Gum and Wood.*	August 1979	March 1980	Richard Williams (WH-552), Environmental Protection Agency, Washington, D.C. 20460, 202-426-2555.
40 CFR 455 *Miscellaneous Chemicals—Pesticides*	March 1980	October 1980	George Jett (WH-552), Environmental Protection Agency, Washington, D.C. 20460, 202-426-2497.
40 CFR 439 *Miscellaneous Chemicals—Pharmaceuticals.*	December 1979	July 1980	Joe Vitalis (WH-552), Environmental Protection Agency, Washington, D.C. 20460, 202-426-2497.
40 CFR 413 *Electroplating*	March 1980	October 1980	Maurice Owens (WH-586), Environmental Protection Agency, Washington, D.C. 20460, 202-755-1331.
40 CFR 459 *Machinery and Mechanical Products—Photographic Equipment and Supplies.*	February 1980	August 1980	Ernst Hall (WH-552), Environmental Protection Agency, Washington, D.C. 20460, 202-426-2576.
40 CFR 433 *Machinery and Mechanical Products—Mechanical Products.*	August 1980	March 1981	Do.
40 CFR 469 *Machinery and Mechanical Products—Electrical and Electronic Components.*	March 1980	October 1980	Do.
40 CFR 464 *Machinery and Mechanical Products—Foundry Operations.*	October 1979	May 1980	Do.
40 CFR 468 *Machinery and Mechanical Products—Copper and Copper Alloy Products.*	April 1980	November 1980	Do.
40 CFR 461 *Machinery and Mechanical Products—Battery Manufacturing.*	March 1980	October 1980	Do.
40 CFR 465 *Machinery and Mechanical Products—Coil Coating.*	August 1979	March 1980	Do.
40 CFR 463 *Machinery and Mechanical Products—Plastics Processing.*	October 1980	May 1981	Do.
40 CFR 466 *Machinery and Mechanical Products—Porcelain Enamel.*	October 1979	May 1980	Ernst Hall (WH 552), Environmental Protection Agency, Washington, D.C. 20460, 202 426-2576.
40 CFR 467 *Machinery and Mechanical Products—Aluminum Forming.*	March 1980	October 1980	Do.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE CLEAN WATER ACT			
40 CFR 124 and 125 *Veto Modification.* CWA 301(b)(a), 304(1), 307(a), 402(b), 501(a). This regulation revises existing regulations to conform to the requirements in the NRDC versus Train Consent Decree June 8, 1976 and to clarify the procedures under which EPA will exercise its power to object to (veto) State issued NPDES permits.	Jan. 6, 1978	May 23, 1978	Ed Kramer (EN-336). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0750.
40 CFR 125 *Substantive Criteria for 301(c) and (g) Variances from BAT Requirements.* CWA 301 (c) and (g). This criteria will establish information necessary for assessment of economic and environmental variance requests.	January 1979	Will be incorporated into NPDES program regulations 40 CFR 122 to 125.	Do.
40 CFR 130.17 *"Revision of Water Quality Standards Regulation (Part 130.17).* CWA 303. This regulation will amend the existing regulation covering State Water Quality Standards to establish requirements regarding States adopting standards for toxic pollutants when EPA has issued national ambient water quality criteria for those pollutants. One effect of this amendment will be that dischargers (both municipal and industrial) may have to install treatment technology beyond that required by Best Available Wastewater Treatment Technology (BPWTT) or Best Available Technology (BAT) guidelines.	March 1979	March 1980	Ken Mackenthun (WH-585). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0100.
40 CFR *Quality Criteria for Water; Volume II.* CWA 304(a). Ambient water quality criteria will be established for 65 pollutants.	(29 pollutants) March 1979 (36 pollutants) July 1979	September 1979 December 1979	Do.
40 CFR 400 to 469 *Secondary Industry Review.* CWA 304(b). This regulation will provide for promulgated of Best Practicable Conventional Pollutant Control Technology (BTC) for certain subcategories of the "secondary industries" industries not covered by the NRDC Settlement Agreement. For other subcategories, Best Available Technology (BAT) limits will be suspended. The methodology that will be used for BCT for secondary industries will also be applied to BCT for primary industries at the time that BAT regulations are established	Aug. 23, 1978	April 1979	Dave Fege (WH-586). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2617.
40 CFR 125 *Criteria and Standards for Imposing Best Management Practices for Ancillary Industrial Activities.* CWA 304(e). This regulation will indicate how "best management practices" for on-site industrial activities may be imposed in NPDES permits to prevent release of toxic and hazardous pollutants to surface waters.	Sept. 1, 1978	Will be incorporated into NPDES program regulations 40 CFR 122 to 125.	Ed Kramer (EN-336). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0750.
General Pretreatment Regulations for Existing and New Sources of Pollution. CWA 307(b)(1). This regulation establishes requirements and procedures for a general pretreatment program including development of State and local programs.		June 26, 1978	Steve Heare (WH-586). Environmental Protection Agency, Washington, D.C. 20460, 202-755-6883.
40 CFR 117 *Revision of Hazardous Substances Discharge Regulations.* CWA 311. As a result of amendments of sec. 311, pts. 117 and 119 will be withdrawn and pt. 118 revised, principally to clarify which dischargers will be subject to the provisions of sec. 311.	November 1978	December 1978	Colburn T. Cherney (A-131). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0760.
40 CFR *Oil Spill Liability.* CWA 311(q). This rule will establish maximum limits of liability for fixed non-transportation related facilities which may face cleanup liabilities under sec. 311.	September 1979	June 1980	Joseph Lewis (WH-535). Environmental Protection Agency, Washington, D.C. 20460, 202-245-0581.
40 CFR 140 *Marine Sanitation Devices.* CWA 312. These rules will establish secondary treatment or equivalent for ships navigating the Great Lakes.			Jonathan Anson (WH-585). Environmental Protection Agency, Washington, D.C. 20460, 202-245-3036.
40 CFR 140 *Drinking Water Intake Zone Exemptions.* CWA 312. These regulations, which will establish guidance for State no-discharge prohibitions for drinking water intake zones, are a part of the Marine Sanitation Devices regulations.			Do.
40 CFR 35 *Clean Lakes.* CWA 314. These rules will establish procedures for administering grants to the States for the purpose of restoring lakes.	December 1978	February 1979	Robert Johnson (WH-585). Environmental Protection Agency, Washington, D.C. 20460, 202-472-3430.
40 CFR 151 *Hazardous Substances Pollution Prevention for Facilities Subject to Permitting Requirements.* CWA 402. This proposed regulation sets forth requirements for Spill Prevention Control and Countermeasure Plans for nontransportation related facilities which handle hazardous substances and are subject to NPDES permits.	Sept. 1, 1978	February 1979	Thomas J. Charlton (WH-548). Environmental Protection Agency, Washington, D.C. 20460, 202-245-3045.
40 CFR *NPDES Program.* CWA 402. This regulation revises, updates, clarifies, and reorganizes existing NPDES regulations.	Aug. 21, 1978	January 1979	Ed Kramer (EN-336). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0750.
40 CFR 124 *Veto Modification.* CWA 402. These regulations will establish the use of short-term permits as the preferred mechanism for assuring compliance with NRDC Consent Decree.	May 23, 1978		Do.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE CLEAN WATER ACT (Federal Water Pollution Control Act as amended by the Clean Water Act Amendments of 1977)			
40 CFR 231 *Ocean Discharge Criteria.* CWA 403(c). These guidelines pertain to discharges to the ocean. They are based on prevention of environmental degradation of waters of the territorial seas, the contiguous zone, and the oceans. Both industrial and municipal dischargers would have to meet these criteria.	April 1979	December 1979	Tom O'Farrell (WH-551). Environmental Protection Agency, Washington, D.C. 20460, 202-426-8976.
40 CFR 230 *Guidelines to Protect the Aquatic Environment, Including Wetlands, From the Discharge of Dredged or Fill Material.* CWA 404(b)(1). These guidelines must be considered in the issuance of individual and general permits, in the preparation of Environmental Impact Statements (EIS's) for Federal activities specifically authorized by the Congress, and in preparation of Best Management Practices (BMP's) under the State 208(b)(4)(B) program. Failure to comply with these guidelines justifies denial of permit applications and return of State permit programs to the Corps of Engineers. Sept. 5, 1975, interim-final guidelines are being revised and expanded by this effort.	January 1979	July 1979	John Crowder (WH-585). Environmental Protection Agency, Washington, D.C. 20460, 202-472-3400.
40 CFR 123 *Procedural Regulations Concerning State Qualifications for Assuming the Section 404 Permit Program.* CWA 404(g). Certain requirements that must be met for States to assume permitting authority under sec. 404(g) such as codification of State laws and certifications by the State attorney general are similar to NPDES requirements. Therefore, the appropriate parts of sec. 404(g) have been included in the proposed revision of existing regulations for NPDES in pt. 123.	Oct. 21, 1978	December 1978	Office of Water Enforcement. Environmental Protection Agency, Washington, D.C. 20460, 202-755-0440.
40 CFR 127 *Procedural Regulations for Exercising the 404(c) Veto.* CWA 404(c). These regulations will establish the procedures for preventing the discharge of dredged or fill material into a defined area of the waters of the United States.	January 1979	July 1979	John Crowder, Environmental Protection Agency, Washington, D.C. 20460, 202-472-3400.
40 CFR 126 *Substantive Regulations Concerning State Implementation of Section 404 Permit Program.* CWA 404(g), (h). States may propose for approval by the Administrator of EPA a sec. 404 program in lieu of the Federal for permitting the discharge of dredge or fill material in certain waters of the United States. These regulations described the components of a State permit program that will be minimally acceptable to the Administrator.	January 1979	July 1979	Do.
40 CFR 258 *Sewage Sludge Disposal.* CWA 405 and RCRA 4004. These regulations are to assure that municipal sludge is managed in a manner that will protect public health and the environment and that valuable resources are conserved through beneficial utilization where practicable.	July 1979	August 1980	Bruce Weddle (WH-564). Environmental Protection Agency, Washington, D.C. 20460, 202-755-9120.
THE SAFE DRINKING WATER ACT			
40 CFR 141 **Control of Organic Chemical Contaminants in Drinking Water.* SDWA 1412. The first part of this regulation sets a maximum contaminant levels for trihalomethanes and the second part establishes a required treatment techniques for synthetic organic chemicals.	Feb. 9, 1978	January 1979	Joe Cotruvo (WH-550). Environmental Protection Agency, Washington, D.C. 20460, 202-472-5016.
40 CFR 141 *Technical Amendments to the National Interim-Primary Drinking Water Regulations.* SDWA 1412. These regulations will be adjustments to the previously published National Interim-Primary Drinking Water regulations.	December 1978	April 1979	Do.
40 CFR 143 *National Secondary Drinking Water.* SDWA 1412(C). These regulations will be nonenforceable guidelines on esthetic drinking water quality.	Mar. 31, 1977	February 1979	Frank Bell (WH-550). Environmental Protection Agency, Washington, D.C. 20460, 202-472-6820.
40 CFR 146 *Underground Water Source Protection Program Grants.* SDWA 1443(b). This regulation would set forth requirements for underground injection control grants.	Aug. 31, 1976	Oct. 12, 1978	Tom Belk (WH-550). Environmental Protection Agency, Washington, D.C. 20460, 202-426-3934.
40 CFR 146 *Underground Water Source Protection Program.* SDWA 1421(a). These regulations are intended to protect groundwater drinking supplies from contamination caused by improper underground injection of fluids. The vast majority of injection practices occurs in the oil and gas industry. States can apply for primary enforcement authority if they meet the minimum criteria specified in the regulations. The regulations can require a permit program to ensure that a case-by-case determination is made.	January 1979 (reproposal)	May 1979	Do.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE NOISE CONTROL ACT			
40 CFR 205 *Light Duty Motor Vehicles.* NCA 5. This action will result in a decision regarding whether or not light duty vehicles are or are not a major noise source. If they are found to be, then resulting noise emission and/or noise labeling standards will be prepared.	Work plan under development		William Roper (AW-490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7747.
40 CFR 205 *Buses.* NCA 5/6. This regulation will set noise emission standards for new inter-State, inner-city, and schoolbuses.	Sept. 12, 1977	June 1979	Do.
40 CFR 204 *Truckmounted Solid Waste Compactor.* NCA 5/6. The regulations sets noise emission standards for solid waste compactors.	Aug. 26, 1977	June 1979	Kenneth Feith (AW-490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-2710.
CFR 206, 207 *Lawnmowers.* NCA 5/6. The regulation sets noise emission standards for new lawnmowers.	October 1979	October 1980	Henry Thomas (AW-490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7743.
40 CFR 204 *Pavement Breakers and Rock Drills.* NCA 5/6. The regulation sets noise emission standards for new pavement breakers and rock drills.	June 1979	June 1980	Kenneth Feith (AW-490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-2710.
40 CFR 204 *Truck Transported Refrigeration Units.* NCA 5/6. The regulation sets noise emission standards for new truck transport refrigeration units.	Developmental work halted pending analysis of regulatory alternatives.		Do.
40 CFR 204 *Wheel and Crawler Tractors.* NCA 5/6. The regulation sets a noise emission standard for new wheel and crawler tractors.	July 11, 1977	June 1979	Henry Thomas (AW-490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7743.
40 CFR 205 *Motorcycles.* NCA 5/6. This regulation sets noise emission standards for motorcycles and replacement exhaust systems.	Feb. 15, 1978	October 1979	William Roper (AW-490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7747.
40 CFR 211 *Labeling: Hearing Protectors.* NCA 8. The regulation requires the labeling of hearing protectors.	June 22, 1977	January 1979	Henry Thomas (AW-490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7743.
40 CFR 211 *Labeling: General.* NCA 8. The regulation establishes general labeling provisions.	....do	....do	Do.
40 CFR 210 *Administrative Hearing Procedures.* NCA 11. These procedures will apply to hearings for the issuance of remedial orders under sec. 11(d) of the Act. As mandated, these are adjudicatory hearings under the Administrative Procedure Act, 5 U.S.C. 554.	Aug. 3, 1978	December 1978	Jim Kerr (EN-387). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7410.
40 CFR 203 *Low Noise Emission Products.* NCA 15. This regulation allows a determination of when a product is a low noise emission product and whether it is suitable for special consideration in Federal purchasing.	May 27, 1977	May 1979	Henry Thomas (AW-490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7743.
40 CFR 205 *Interstate Rail Carriers.* NCA 17. This regulation sets noise emission standards for railroad "facilities." EPA has prepared this regulation as a result of a successful lawsuit brought by the Association of American Railroads which said EPA's regulations setting noise emission standards for locomotives and cars failed to address the related problem of noise from facilities such as railroad yards. The Court ordered EPA to adopt final regulations controlling railroad facilities—everything in addition to the cars and locomotives.	December 1978	February 1979	William Roper (AW-490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7747.
40 CFR 201 *Special Local Conditions.* NCA 17(c)2/18(c)2. The regulation establishes procedures permitting adoption by a State or otherwise preempted State and local rail and motor carrier noise regulations when necessitated by special local conditions..	Nov. 29, 1976		Henry Thomas (AW-490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7743.
40 CFR 202 *Interstate Motor Carrier.* NCA 18. This action will update the noise emission standards for interstate motor carriers to reflect increased knowledge about available noise abatement technology.	Work plan under development		William Roper (AW-490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7747.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT			
40 CFR 162 *Pesticide Registration Guidelines:* *Introduction.* FIFRA 3. This subpart B (will become A) includes the general purposes of all of the guidelines, degree of flexibility in requirements and in interim data usage, definition of terms used throughout the guidelines, and requirements for retention of data and test samples at laboratories.	July 10, 1978	April 1979	Bill Preston (TS-769). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7351.
Experimental Use Permits. FIFRA 3. This subpart A (will become subpart C) specifies the data that must be submitted in support of an application for an experimental use permit.			Do.
Chemistry Requirements. FIFRA 3. This subpart D covers data submission requirements relating to chemistry of pesticide products' active ingredients and their formulation components and manufacturing impurities. (Chemical study requirements dealing with environmental fate of pesticides may be included here or be moved to a new subpart.).	July 10, 1978	April 1979	Do.
Hazard Evaluation: Wildlife and Aquatic Organisms. FIFRA 3. This subpart E outlines the data submission requirements for studies of pesticide effects on birds, wild mammals, fish, and other aquatic animals.	...do	May 1979	Do.
Hazard Evaluation; Humans and Domestic Animals. FIFRA 3. This subpart F delineates the data submission requirements for studies of pesticide effects in laboratory animals involving oral, dermal, and inhalation uptake routes, acute, subchronic, anbd chronic exposures, and including local or systemic injury and maladies such as oncogenic, teratogenic, mutagenic, and neurotoxic effects.	Aug. 22, 1978	June 1979	Do.
Product Performance. FIFRA 3. This subpart G specifies the data submission requirements that registrants must submit to demonstrate that the prospective pesticide product will control the pests or control undesired growth or behavior as specified in label claims.	December 1978	August 1979	Do.
Label Development. FIFRA 3. This subpart H describes all essential parts of a pesticide product label, how labeling and label statements must comply with the Act, and how claims and directions must correspond to evidence presented or on hand in data on efficacy and safety.	March 1979	October 1979	Do.
40 CFR 162 *Pesticide Use Restrictions.* FIFRA 3. This regulation will classify pesticide uses for restricted use..	December 1978	January 1979	Walt Waldrop (TS-770). Environmental Protection Agency, Washington, D.C. 0460, 202-755-7014.
Conditional Registration Regulation. FIFRA 3(c)(7) (A) and (B). This interim/final regulation would establish procedures for conditional registration of pesticide products which are identical or substantially similar to those currently registered or new uses of existing pesticide products.		February 1979	Bob Rose (TS-767). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2510.
Conditional Registration Regulation. FIFRA 3(c)(7)(C). This regulation provides for the conditional registration of new chemicals when certain data are missing.	July 1979		Do.
40 CFR 162.9, 173 *Registration Data Compensation.* FIFRA 3(C)(1)(D). These rules provide for compensation when one pesticide registrant relies on test data generated by another registrant.	June 21, 1977	February 1979	Ed Gray (A-132). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0846.
40 CFR 172 *State Experimental Use Permits.* FIFRA (5)f. The regulation defines the scope of State jurisdiction to allow experimental uses of pesticides.	Sept. 30, 1975, interim final		Phil Gray (TS-770). Environmental Protection Agency, Washington, D.C. 20460, 202-755-7014.
40 CFR 165 *Storage and Disposal Practices (Prohibition).* FIFRA 19. These rules will prohibit dangerous or environmentally unsound pesticide storage practices.	Oct. 15, 1974	Will not be issued	John Lehman (WH-565). Environmental Protection Agency, Washington, D.C. 20460, 202-755-9185.
40 CFR 162 *State Registration to Meet Special Local Needs.* FIFRA 24(c). This part defines the scope of State jurisdiction over the registration of pesticides.	Sept. 3, 1975	March 1979	Phil Gray (TS-770). Environmental Protection Agency, Washington, D.C. 20460, 202-755-7014.
40 CFR 162.16 *Pesticide Special Packaging Regulations.* FIFRA 25. The rule prescribes when and what form of child-proof packaging is required.	Feb. 16, 1977	December 1978	Maureen Grimmer (TS-766). Environmental Protection Agency, Washington, D.C. 20460, 202-755-8030.
40 CFR 162 *Exemption of New Human Drugs.* FIFRA 25(c)(2). This part would exempt from FIFRA pesticides that are also new drugs regulated by FDA.	Oct. 13, 1978	...do	Dave Brandewein (TS-766). Environmental Protection Agency, Washington, D.C. 20460, 202-755-8037.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE ATOMIC ENERGY ACT			
Protective Action Guidelines for Nuclear Emergencies. AEA 274(i). This is a guidance for emergency response plans in the event of a nuclear accident, i.e. effluent release from a nuclear reactor.	September 1979	February 1980	Jim Hardin (AW-460) Environmental Protection Agency, Washington, D.C. 20460, 703-557-8610.
Guidance for Occupational Radiation Exposure. AEA 274(h). This guidance will update existing (1960) radiation occupational exposure limits for workers at Federal facilities and those facilities inspected by Federal agencies.	January 1979	June 1979	Luis Garcia (AW-460), Environmental Protection Agency, Washington, D.C. 20460, 703-557-8224.
Transuranic Elements. AEA 274(h). This guidance to Federal agencies establishes dose rate limits for persons exposed to transuranium elements in the general environment. The final guidance is to be signed by the President.	Nov. 3, 1977	January 1979	Gordon Burley (AW-460), Environmental Protection Agency, Washington, D.C. 20460, 703-557-8610.
Environmental Standards for High-Level Radioactive Wastes. AEA 274(h). The regulation will set standards for release of radioactivity to the environment as a result of storage of waste isotopes.	January 1979	July 1979	Jim Martin (AW-460), Environmental Protection Agency, Washington, D.C. 20460, 703-557-8927.
Environmental Criteria for Radioactive Wastes. AEA 274(h). The criteria are general guidance as to what constitutes radioactive waste and factors to be considered in evaluating disposal modes and sites.	November 1978	April 1979	Harry Pettengill (AW-460). Environmental Protection Agency, Washington, D.C. 20460, 703-557-8927.
Florida Phosphate Tailings. PHSA 301. A 1975 commitment to the Governor of Florida by the Administrator requries EPA to establish guidelines as to what to do (1) about existing houses on uranius "contaminated" land; (2) about new construction on such land.	January 1979	July 1979	Joe Fitzgerald (AW0460). Environmental Protection Agency, Washington, D.C. 20460, 703-557-8224.
THE RESOURCE CONSERVATION AND RECOVERY ACT			
40 CFR 241 *Guidelines for Solid Waste Management Landspreading Practices.* RCRA 1008(a). These are nonregulatory technical guidelines on landscaping practices for the beneficial use of solid waste as soil conditioner and plant nutrient.			Bruce Weddle (WH-564). Environmental Protection Agency, Washington, D.C. 20460, 202-755-9120.
40 CFR 250 *Hazardous Waste Criteria—Identification and Listing.* RCRA 3001. These regulations define those wastes that will be controlled under the nationwide hazardous waste management program. Criteria are provided for identifying characteristics of hazardous waste and for listing hazardous waste. The selected characteristics are: ignitability, corrosiveness, reactivity, and toxicity. Testing procedures are included for determination of whether a waste meets the described characteristics. The regulation also lists certain hazardous wastes or processes which are presumed to generate hazardous wastes. Also, means are provided for demonstration of noninclusion in the subtitle C system.	January 1979	January 1980	Alan Corson (WH-565), Environmental Protection Agency, Washington, D.C. 20460, 202-755-9187.
40 CFR 250 *"Standards for Generators of Hazardous Wastes.* RCRA 3002. This regulation establishes national standards for generators of hazardous wastes, covering such items as record-keeping, containerization and labeling, waste identification, and reporting. This regulation also contains provisions for a hazardous waste manifest system.	.....do	.....do	Harry Trask (WH-565). Environmental Protection Agency, Washington, D.C. 20460, 202-755-9187.
40 CFR 250 *Standards for Transporters of Hazardous Wastes.* RCRA 3003. These national standards make transporters of hazardous wastes responsible for shipping only properly labeled containers and only to permitted facilities.	Apr. 28, 1978	.....do	Do.
40 CFR 250 *"Standards for Hazardous Waste Treatment, Storage and Disposal Facilities."* RCRA 3004. The standards establish technical performance standards for hazardous waste management facilities, relative to operating practices, location, and design. The contain provisions for protection of surface water, ground water, and air quality.	January 1979	.....do	John Schaum (WH-565). Environmental Protection Agency, Washington, D.C. 20460, 202-755-9200.
40 CFR 250 *Permit Regulations for Hazardous Waste Treatment, Storage, and Disposal Facilities.* RCRA 3005. This regulation establishes a permit program to assure uniform control by States (or EPA) over hazardous waste management facilities.	.....do	.....do	Sam Morekas (WH-564). Environmental Protection Agency, Washington, D.C. 20460, 202-755-9120.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE RESOURCE CONSERVATION AND RECOVERY ACT			
40 CFR 250 *Guidelines for State Hazardous Waste Programs.* RCRA 3006. These guidelines are to assist States in the development of their own hazardous waste regulatory programs. The guidelines also specify minimum requirements States must meet in order to be authorized by EPA to implement their hazardous waste programs.	Feb. 1, 1978	January 1979	Dan Derkics (WH-565), Environmental Protection Agency, Washington, D.C. 20460, 202-755-9190.
40 CFR 250 *Notification System for Hazardous Waste Generators, Transporters, Storers, Treaters, and Disposers.* RCRA 3010. The regulation describes the one-time notification requirement for generators, transporters, treaters, storers, and disposers of hazardous waste, which will bring them to the attention of the persons administering RCRA's hazardous waste program.	July 11, 1978	August 1979	Timothy Fields (WH-565), Environmental Protection Agency, Washington, D.C. 20460, 202-755-9206.
40 CFR 256 *Guidelines for State Solid Waste Programs.* RCRA 4002(b). These guidelines are to assist States in the development and implementation of solid waste management programs.	Aug. 28, 1978	June 1979	George Garland (WH-565), Environmental Protection Agency, 202-755-9125.
40 CFR 257 *Criteria for Classification of Solid Waste and Disposal Facilities.* RCRA 4004(a). These criteria provide a basis against which solid waste land disposal facilities can be evaluated in order to determine probability of adverse effects on health or the environment.	Feb. 6, 1978	July 1979	Kenneth Shuster (WH-564), Environmental Protection Agency, Washington, D.C. 20460, 202-755-9116.
Guidelines for Federal Procurement Practices. RCRA 6002(e). These guidelines will assist Federal agencies to comply with the RCRA's requirement that procured materials be composed of the highest percentage of recovered materials practicable:			Stephen Lingle (WH-563), Environmental Protection Agency, Washington, D.C. 20460, 202-755-9140.
Utilization of Fly Ash and Slag	April 1979	July 1979	
Use of Recycled Paper in Paper Products	June 1979	September 1979	
Use of Waste in Construction Products	July 1979	October 1979	
THE TOXIC SUBSTANCE CONTROL ACT			
40 CFR 740 to— **Testing of Chemical Substances and Mixtures.* TSCA 4. These regulations require testing of chemical substances that may present an unreasonable risk to human health or the environment, or are produced in substantial quantities but are not supported by adequate test data. EPA is preparing two testing regulations: on cogenicity testing and environmental fate testing.	December 1978	Mar. 1979, 749	Norbert Page (TS-792), Environmental Protection Agency, Washington, D.C. 20460, 202-755-6841.
40 CFR 720 *Premanufacture Notification.* TSCA 5. This regulation will establish the procedure whereby a company will notify EPA of its intent to manufacture a new chemical. The regulation will prescribe the required premanufacture notification form, describe the procedure for EPA review, and contain testing guidelines.	December 1978	April 1979	Blake Biles (TS-794), Environmental Protection Agency, Washington, D.C. 20460, 202-755-5482.
40 CFR 761 *PCB's Manufacture and Distribution.* TSCA 6. This regulation bans the manufacturing and distribution of PCBs and products containing PCBs.	June 7, 1978	January 1979	Peter Principe (TS-794), Environmental Protection Agency, Washington, D.C. 20460, 202-755-0920.
Control of Polybrominated Biphenyls. TSCA 6. The regulation would control the use of polybrominated biphenyls.	January 1979	July 1979	Lucy Sibold (TS-794), Environmental Protection Agency, Washington, D.C. 20460, 202-755-8983.
Chlorofluorocarbon Emissions. TSCA 6. This regulation would apply to nonaerosol uses of chlorofluorocarbons.	To be determined		Ferial Bishop (TS-794), Environmental Protection Agency, Washington, D.C. 20460, 202-755-8963.
40 CFR 730 *Reporting on Substances Recommended for Testing.* TSCA 8(d). The regulation requires reporting of existing health and safety studies for chemical categories as recommended for testing.	May 1979	December 1979	Ed Brooks (TS-793), Environmental Protection Agency, Washington, D.C. 20460, 202-755-0932.
40 CFR 720 *Records of Adverse Reaction.* TSCA 8(c). The regulation requires industry to keep records of allegations of significant adverse health and environmental reactions to its chemical products.	March 1979	October 1979	Do.
40 CFR *Procedures for Export Notification.* TSCA 12(b). These rules tell exporters how and when to submit export notifications.	December 1978	May 1979	Do.
40 CFR 22 *Consolidated Rules of Practice Governing the Assessment of Civil Penalties.* TSCA 16. These rules would be promulgated under the authority of FIFRA 14, RCRA 3008, Marine Protection Research and Sanctuaries Act (MPRSA) 105, CAA 211, and TSCA 16.	Aug. 4, 1978, interim final	October 1979	Terrell Hunt (EN-342), Environmental Protection Agency, Washington, D.C. 20460, 202-755-0970.

[FR Doc. 78-33253 Filed 11-29-78; 8:45 am]

★ U. S. GOVERNMENT PRINTING OFFICE : 1979 620-007/3761