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

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OFFICE OF
RESEARCH AND DEVELOPMENT

SUBJECT: Report on EPA's QA Program from the National Academy of Sciences

FROM: Stanley M. Blacker, Director Stan Blacker
Quality Assurance Management Staff (RD-680)

TO: See Below

At the request of the Agency's Senior management, the National Academy of Sciences undertook a multi-year study of the Agency's quality assurance program. The final report resulting from this study has now been issued. A copy is attached.

I believe this report presents a strong endorsement of the key elements of the Agency's strategy for assuring the quality of its data. For instance, the NAS panel singled out the concept of Data Quality Objectives (DQOs) for particular endorsement. However, the NAS panel also found some areas where the implementation of the QA program ought to be improved by shifts of emphasis (e.g., increased involvement and accountability of top management in determining needed quality) and some initiatives, e.g., development of guidance on common usage of QA terms such as "bias" and "completeness."

Also attached is a copy of a 3-page summary of the NAS Report. I urge you to read the entire report since it contains important statements about the Agency's QA program and valuable recommendations for its improvement. The summary was prepared to enable you to obtain a quick and accurate picture of the main substantive points of the report.

A workgroup comprised of QA Officers representing National Program Offices, Regional Offices, and ORD Laboratories prepared the summary in cooperation with QAMS. We used this approach to assure the summary's accuracy.

Addressees

Office Directors
Deputy Regional Administrators
ORD Laboratory Directors
Quality Assurance Officers
AA Quality Assurance Representatives
Office of Regional Operations
ESD Directors

Summary of the Report of the National Academy of Sciences on the EPA Quality Assurance Program

September 28, 1988

Introduction

In 1983, EPA asked for the assistance of the National Academy of Sciences (NAS) to assess the Agency's QA program and to provide recommendations on improving its effectiveness. The NAS panel, chaired by Dr. Stephen Berry of the University of Chicago, examined the QA activities of National Program Offices, Regional Offices, and the Office of Research and Development and worked with the Quality Assurance Management Staff (QAMS) over the next several years, issuing an interim report in 1985. The final report, submitted to EPA in August of 1988 confirms the fundamental strategy and principles of QA which EPA has adopted and provides recommendations for further improvement in the Agency's implementation of QA. In particular, the NAS panel endorses accelerated institutionalization of the DQO process and recommends holding management accountable for key portions of the QA program.

General Findings

The NAS panel believes that EPA can achieve an effective EPA Quality Assurance (QA) program if it specifies the fundamental elements of a QA program and if the responsibilities inherent in these fundamental elements are embraced throughout the Agency.

The Agency, through its Quality Assurance Management Staff (QAMS), has generally done an adequate job of specifying the elements essential to a successful QA program and has provided detailed guidance regarding QA principles to Agency groups involved with the generation and/or use of environmental data. Furthermore, QA responsibilities have been embraced whole-heartedly by many Agency groups and their managers. However, all components of the Agency's QA program are not yet fully implemented.

The NAS Panel report had major findings in 4 areas:

1. Accountability of management
2. The importance of specifying the adequacy of data
3. The need for technical guidance documents
4. The role of the QA Officer.

1. Accountability of Management.

The NAS panel recommended that EPA make explicit precisely where accountability rests for data quality. (p.11)[1]

The panel determined that the operation of an effective QA program has been hampered by the unclear placement of accountability for data quality within the Agency's structure. As a means of achieving better understanding and more involvement of program managers, specific individuals or offices must be accountable if the data supplied by or through their offices fail to meet the

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[1]Page numbers refer to the NAS report.

need. Only if that accountability is recognized and responded to, will that accountable person will have a viable QA program. (p.8)

The panel recognized more than a little cynicism from the regulatory and enforcement people concerning QA. These people said that it is wasteful to be concerned at all about data quality. As long as reasonable professional standards are maintained people are satisfied with simple QC. Unless there is accountability for collecting the right quality of data, no one is motivated to go beyond simple QC. (p.21). Furthermore, when accountability is not specified at a high enough level, EPA officials have little motivation to use funds for QA.

The panel found:

- No clear placement of accountability for data quality in EPA, (p.11)
- Top management accountability has not yet been established. (p.14)
- The role of QA is still not apparent in the administrative chart of EPA.

2. Data Quality Goals

The initial specification of the quality of data needed to support Agency decisions and programs is an especially important QA element because the highest attainable quality may be quite unrelated to the quality that makes data adequate for a purpose. EPA must be careful to use its resources efficiently and not purchase data quality in excess of what it needs (above items from p.9)

The process which translates the needs of Agency decision makers into the specifications for data quality which scientists and technicians can implement in their data collection is not trivial and the responsible Agency managers need to be involved directly. The key element is two-way communication between data users and data generators. (p.18)

Communication Between the Agency's Data Users and Data Suppliers. The NAS panel found that QAMS, through its DQO initiative, has proposed a means to achieve the communication link needed between data users and data suppliers. The DQO process is seen as the mechanism for incorporating data into decision making in a reasonable, effective, and efficient manner. EPA's Deputy Administrator issued memos in May 1984 and Nov 1986 on DQO institutionalization within EPA. The NAS panel found that DQO institutionalization is happening more slowly than the NAS panel considers reasonable. (p.20)

The NAS panel recommends that the Agency use the DQO process to control the scope for data gathering and that DQOs be developed

in a cooperative participatory way with QAMS taking a strong initiative in all aspects of the DQO process. (p.22). This activist role should be explicitly stated by the Administrator as one of QAMSs responsibilities. (p.19) The panel also suggested that development of DQOs for broad areas of data use (e.g., regulation of nonradioactive dumps for toxic waste or enforcement of point-source emission regulations) would assure reasonable coverage of Agency data collection while avoiding the danger of trying to do too many, case-specific DQOs.

3. Technical Guidance Documents

The NAS panel also found a need for Agency-wide standardization of common practices for data measurement, treatment, and management. The panel recommended that QAMS initiate and guide the development of technical guidance documents for measurements and data practices that have Agency-wide application.

4. The Role of the QA Officer.

In general, the NAS panel calls for an empowerment of the Agency's QAOs. The QAO "protects" the accountable Agency manager from the embarrassment of making wrong decisions because of inadequate data and accordingly needs enhanced stature and authority within the organization. (p.12).

Other Recommendations

The NAS panel also recommended that EPA:

- Develop and implement mechanisms for assessing the reliability of data to be archived and disseminated in one of the many Agency data banks and for including notations of this assessed reliability in the archived data. Currently, a multitude of data generated by EPA is stored in computer data banks without any indication of its quality. (p.29)

- Allocate resources to what is most needed, not necessarily to what people know best how to do. (p.24)

- Reestablish QA training programs. (p.14)

- Establish standing panels of experts to advise about data collection in crisis situations. (p.16)

- Use the SAB to monitor QC and EPA's progress in meeting these recommendations. (p.16)

Final Report on Quality Assurance to the Environmental Protection Agency

FINAL REPORT
ON QUALITY ASSURANCE
TO THE
ENVIRONMENTAL PROTECTION AGENCY

Panel on Quality of Environmental Data
Numerical Data Advisory Board
Commission on Physical Sciences, Mathematics, and Resources
National Research Council

NATIONAL ACADEMY PRESS
Washington, D.C. 1988

NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

The National Academy of Sciences is a private, nonprofit, self-perpetuating society of distinguished scholars engaged in scientific and engineering research, dedicated to the furtherance of science and technology and to their use for the general welfare. Upon the authority of the charter granted to it by the Congress in 1863, the Academy has a mandate that requires it to advise the federal government on scientific and technical matters. Dr. Frank Press is president of the National Academy of Sciences.

The National Academy of Engineering was established in 1964, under the charter of the National Academy of Sciences, as a parallel organization of outstanding engineers. It is autonomous in its administration and in the selection of its members, sharing with the National Academy of Sciences the responsibility for advising the federal government. The National Academy of Engineering also sponsors engineering programs aimed at meeting national needs, encourages education and research, and recognizes the superior achievements of engineers. Dr. Robert M. White is president of the National Academy of Engineering.

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Available from:

Numerical Data Advisory Board
2101 Constitution Avenue, N.W.
Washington, D.C. 20418

Printed in the United States of America

PANEL ON QUALITY OF ENVIRONMENTAL DATA

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PREFACE

In April 1983, the Environmental Protection Agency (EPA) asked the National Research Council (NRC) to review the agency's control of the quality of its scientific data, and particularly its Quality Assurance (QA) program. The NRC called upon its Numerical Data Advisory Board (NDAB) to carry out the task. To conduct the requested assistance and review, the NDAB established a panel of six scientists to work with EPA, under the guidance of the NDAB, for three years, to (1) engage in discussions and briefings to help the EPA establish a sound QA program, (2) review methods, methodology, and selected key EPA QA documents, and (3) present its findings and recommendations. The final report is to be distributed as an advisory document that EPA could use to strengthen its programs, particularly those involving numerical scientific data.

The panel's study is now concluded, and this is the report of its findings and recommendations. An interim report was prepared in early 1985 to give the EPA information and advice on several particularly urgent problems at the midpoint of the study. The agency responded to that report in a very positive way; this report in part discusses the issues covered in the interim report and how the EPA is currently dealing with them. In addition, this report discusses several issues that were not discussed in the interim report. There are still some significant unresolved problems, and there are some very positive steps that could be taken toward solving some of the biggest, most refractory, and long-standing problems. Our overall outlook is hopeful, and we wish the EPA success in the establishment and maintenance of an exemplary Quality Assurance program.

We wish to thank the EPA for opening its operation to us and particularly to thank Stanley Blacker and Thomas Stanley for their assistance and candid insight into the problems of the agency.

R. S. Berry
Chairman
Panel on Quality of
Environmental Data

CONTENTS

1. EXECUTIVE SUMMARY AND KEY RECOMMENDATIONS

The primary issues associated with establishing and maintaining an effective quality assurance program in the Environmental Protection Agency fall conveniently into two categories: the specification and acceptance throughout the Agency of a few key concepts, and the recognition and acceptance, again throughout the Agency, of the responsibilities following inevitably from the basic concepts.

This summary first defines the key concepts, starting with the very notion of quality assurance itself, and then integrates the implementation of that concept into the existing institutional structure of EPA by defining precisely the components of this structure.

Then, with the conceptual structure in hand, this summary lays out the responsibilities that fall on each of the individuals and offices--and here, the panel emphasizes that this includes data users as much as data suppliers--if EPA is to have effective quality assurance and, more important, the underlying substantive provision of data of known and acceptable quality.

Key recommendations then follow.

Key concepts required for an effective QA system

1. Quality assurance (QA) is the guarantee that the quality of a product is actually what is claimed by the supplier, as achieved by the practice of quality control (QC). The purpose of QA is to assure the supplier as well as possible that the needs of the user will be met, or at least that the user will know the quality of the product. For EPA's data, this means that the user--meaning the person responsible for assessments or legislation or regulation or compliance monitoring--can be assured that the quality of the data on which the criteria are based is indeed that for which he or she has asked, or is, at the very least, that specified by the supplier. Quality assurance, being a guarantee, is a means for an accountable individual or office to protect the integrity of that individual or office.

2. A quality assurance officer (QAO) reports directly to the person who requires the protection of quality assurance. The QAO should be independent of those whose data are being quality assured and should have no other conflict-of-interest positions. The QAO should be technically highly trained, and have competence in statistics. The QA officer should have some authority over the suppliers of the product. This authority should be exercised in a mode of friendly guidance as much as possible, which can in many cases be done because one presumes that the supplier and the QA officer have a common goal.

3. Data quality objectives (DQOs) are an interactive management

tool used to interpret data needs of the data-using administrator/regulator to the data supplier, in a manner the supplier can translate into objectives for quality assurance and appropriate levels of quali control. These devices, intended to allow data suppliers to improve the services they provide to data users, are now seen more as harassment than as aids. It should be a responsibility of the Quality Assurance Management Staff to change and improve this situation and see that the DQO system becomes effective.

4. The Quality Assurance Management Staff (QAMS) is an important office that must be defined on the administrative chart. QAMS needs to be at a high enough level and staffed by recognized technical experts so that it has the influence and respect required to help ensure that quality assurance is correctly carried out in all parts of the Agency and to facilitate the work of the QAO and the preparation of the DQOs.

Key responsibilities for an effective QA system

1. At every level, responsibilities of all parties must be clearly defined. If QA is to be useful or effective, an office must be held accountable for the quality of the product. Accountability for data quality should be assigned by EPA if it wishes to use QA to assure the quality of its data.

2. Data users (administrators, regulators), by the nature of their responsibilities, are accountable for their decisions, including those depending on environmental data. They therefore need the assistance of a quality assurance program through which they can find the way to communicate their needs to EPA's suppliers of data. This includes assessments of sites, situations, and effects as well as laboratory data. Data users need to collaborate interactively and draw on the assistance of the relevant QAO and QAMS people in DQO development.

3. The QAO is responsible for four items: (a) assuring, by suitable checks, the accountable person or office supplying data that the quality of data meets the needs of the user so far as possible and that the user in any case knows the quality of the data; (b) carrying out the interactive development of the DQO, by data user and provider, which specifies a scheme appropriate to the required data and data quality (when possible, DQOs should be prepared for classes of similar data situations, to eliminate unnecessary and costly repetition); (c) monitoring site observation plans and their execution; and (d) overseeing and assisting the field scientists in their responsibilities (next item).

4. The field, or "bench" scientists are responsible for (a) the technical conduct of the measurement, including quality control (QC) and "good laboratory practices"; (b) participation in development of the DQO, indicating what is technically feasible for a given level or size of project; and (c) participating in Agency-wide development of documents defining common practices. Skills must be commensurate with these tasks.

5. The Quality Assurance Management Staff (QAMS) should have the responsibility for the QA infrastructure, oversight, and active interaction with all parties. The visibility and powers of this office need to be elevated in EPA (currently QAMS does not appear on the administrative chart). The panel believes QAMS's responsibilities include (a) scientific and technical support to the QAOs; (b) coordination of Agency-wide development and ultimately, preparing and disseminating documents for common practices; (c) establishment of crisis panels for data, composed of outside voluntary experts; and (d) conducting ongoing quality assurance educational and assistance programs aimed at all three parties: data users, data suppliers and QAOs, and management staff. QAMS should employ technically qualified personnel whose competence includes statistics.

6. The Science Advisory Board (SAB) is responsible for scientific and technical overview and backup for QAMS. SAB's own expertise should include quality control, quality assurance, and data handling.

At the EPA, some elements of these concepts and assignments exist, others are being developed, and still others are lacking and must be put in place, for reasons described in the remainder of this report.

Key recommendations

The following are the key recommendations of the panel, beyond those dealing with the concepts and responsibilities just mentioned.

o Specific accountability for data quality should be established, in the sense that the holders of particular positions take on responsibility that the quality of data supplied by or through their offices is indeed as claimed. Note that this is not a recommendation to make individuals responsible for maintaining particular levels of data quality.

o Levels of data quality should be expressed as goals set by the needs of the users, which will sometimes but not always be possible to achieve; when suppliers cannot assure that they can provide data of the quality the users want, they should make the users fully aware of the situation.

o Through efforts by QAMS and higher administrative levels, a degree of communication between data-using and data-supplying arms of the Agency should be established, so that data suppliers understand what constitutes "adequate" quality of data, as needed by the data users, and can respond to the needs in a cooperative manner.

o Effort and funds for data should be allocated in a manner assuring (a) that the needs of the user are met through achieving adequate quality of the data and (b) that efforts yield what is most needed, not necessarily what people know best how to do.

- Educational efforts should be reestablished within EPA regarding quality control and quality assurance, particularly to train new QA officers.

- A document or documents should be developed that set standards, guidelines, and common practices for data measurement, treatment, and management, for Agency-wide use. Setting of standards on common practices should be done on an ongoing basis involving scientists both from within and outside EPA and should incorporate, as much as possible, conventions already established by international agreement, or, lacking that, those with national acceptance.

- Standing panels of experts should be established who can be called upon to advise about data collection in crisis situations.

- The Science Advisory Board should be used to monitor quality control within the Agency and to follow the progress of the Agency toward meeting the recommendations of this report.

2. INTRODUCTION

CHARGE TO THE PANEL AND ITS REALIZATION

The charge given by the Environmental Protection Agency to the Panel on Quality of Environmental Data was to assist and advise the EPA Quality Assurance program so that this program would provide integrity and quality assurance of EPA's scientific data adequate to fulfill the EPA's intended scientific and regulatory purposes. After discussion with the EPA staff, this was interpreted to mean that the panel should:

1. Examine the structural and institutional situation of the QA program to see whether these fit the needs of the Agency and the program.
2. Examine the specification of objectives of the QA program itself, to evaluate how well the objectives fit with the Agency's mission.
3. Examine the budgeting, staffing, and documentation for the EPA QA program, to estimate how well those help the program and the Agency achieve their goals.
4. Examine how the substantive operations of QA programs function in the regional offices, the Environmental Monitoring Systems Laboratories (EMSLs), and the support laboratories.
5. Examine the relation between the maintenance of professional quality control in the Agency and the operation of the QA program.

MEANS OF ADDRESSING THE CHARGE

The panel took its primary responsibility to be improving the assurance of the quality of scientific data and the functioning of the QA program of the EPA. With this view, it operated with the realization that only some of the panel's goals would be accomplished by written reports. Others were achieved by the running constructive dialogue between the panel and the EPA staff and the review of relevant documents in various stages of development. Throughout this report, the panel will refer to matters that were handled through such dialogue and point out how the EPA's ways of dealing with these matters have evolved.

The panel carried out a series of meetings with various groups within the EPA during its three-year study. The calendar of these meetings is in Appendix A; it shows how the panel tried to see a wide range of EPA's component parts in action, and to talk with as many as possible of the key actors involved in the maintenance and assurance of data quality. These included staff in the Washington headquarters at many levels, from deputy administrator to staff scientist; people in regional offices and laboratories, in Environmental Monitoring Systems

Laboratories (EMSLs), and in support laboratories; and staff in regulation and enforcement. Most of the panel's regular contacts with EPA were made through the Quality Assurance Management Staff (QAMS) of the Washington office. Many meetings were held with the full panel and the selected EPA staff; several meetings consisted of one, two, or three panel members with EPA staff in a particular office, in such instances usually in EPA offices away from Washington, D.C. The panel also read a fairly large number of written reports, primarily internal EPA documents, ranging from documents on guidelines and common practices to documents on audits and documents involving DQOs.

The interaction between the panel and the EPA involved frequent discussions with QAMS, the preparation and distribution of the interim report, two briefings with the deputy administrator and several senior staff members particularly to discuss the interim report, and collaboration on this final report. A final briefing for EPA on this report is anticipated.

WHAT THE REPORT AIMS TO ACCOMPLISH

This report is intended primarily as advice to the Environmental Protection Agency, including

- the administrator and deputy administrator;
- the assistant administrator for research and development;
- the Office of Acid Deposition, Environmental Monitoring and Quality Assurance;
- the Quality Assurance Management Staff;
- all the regional administrators and their staffs;
- all EPA staff members charged with responsibility for data quality, including the assistant administrators for water, air, and hazardous waste;
- the assistant administrator for enforcement and compliance monitoring and the Enforcement Offices under that administrator; and
- the Office of Standards and Regulations and the Science Advisory Board.

These are the primary generators and users of scientific data, the people who are directly responsible for the quality of data and those who depend on that quality in order to carry out their missions.

Secondarily, the report may be useful to others concerned with knowing the reliability of data generated or used by the EPA. This community may include, among others, committees of the Congress and their staffs, government agencies concerned with the effective functioning of the EPA, and other scientific, medical, and engineering communities and institutions, such as the Center for Disease Control.

The report attempts to examine how the quality of scientific data generated or used by the EPA is maintained and, more particularly, assured to the primary users of those data, especially the people within the EPA using the data for regulatory, enforcement, or scientific purposes. The panel hopes that this report outlines the issues and problems of maintaining and assuring data quality, the ways

the EPA has already made progress toward solving those problems, and some ways in which the panel believes that the EPA should go further, in many cases with little or no extra expenditure, to improve its QA program and aspects of its operation that rest on scientific data.

Some of the suggestions involve nothing more than a little redistribution of responsibilities by asking data users to articulate their needs more effectively to data generators. Some involve redistribution of efforts from areas where skills are high and answers can be found easily toward areas where answers are badly needed, even at very approximate levels, but where finding those answers is relatively difficult.

This report is intended as a stimulus for EPA to find new approaches toward ensuring data quality, to enable it to move toward its goals more effectively.

3. TERMS OF REFERENCE: CONCEPTS OF QA AND QC

DEFINITIONS OF QA AND QC

Quality control (QC) is the maintenance and statement of the quality of a product, specifically that it meets or exceeds some minimum standard based on known, testable criteria. Quality control in science is a professional obligation that is usually assumed to be deeply ingrained in the training of aspiring scientists. Science as we know it cannot function unless its products are so reliable that each new piece of explicit work can be built on the preceding results. The products of science are data, insight, and understanding. Quality control regarding insight and understanding usually means maintaining the validity of the logic in the steps of an inference. It is the control of the quality of scientific data that demands special skills and attention, in this case to the degree that an outside advisory study was requested by EPA. Establishing the inherent uncertainties of the procedures and seeing that the procedures are properly carried out are typical central components of quality control. In carrying out a scientific task, one is expected to take the responsibility to establish quality control over the data, including maintaining surveillance over that quality.

Quality assurance (QA) is the guarantee that the quality of a product is actually what is claimed on the basis of the quality control applied in creating that product. Quality assurance is not synonymous with quality control. Quality assurance is meant to protect against failures of quality control. The need for quality assurance is predicated on the notion that some person or office is accountable if the quality of the product fails to meet the standards claimed for it and therefore that whoever is accountable has a strong interest in seeing that the claims of quality are valid.

In the context of scientific data, the logic behind a quality assurance program is this:

1. A body of scientific data is put to use by somebody who depends on the data meeting or exceeding a specific level of quality in order to achieve a particular objective.
2. If the intended use fails because the data do not meet the standard of quality claimed for them by the supplier, then the supplier of the data--some particular person or office--can be held accountable for that failure.
3. The accountable person or office therefore has a strong vested interest not only in providing data as economically as possible, but also in seeing that the standards of adequate quality are actually met; an institutionalized quality assurance program is therefore created to serve that purpose.
4. The balance between achieving adequate quality and economy leads

to a design of the data-gathering effort commensurate with the user's needs; that is, quality assurance assures that an assay is neither underdesigned nor overdesigned.

SPECIFYING "ADEQUACY" OF DATA QUALITY

Scientific data serve many functions in the Environmental Protection Agency. They play roles in the proposal and drafting of the laws and regulations, in the enforcement of laws and regulations, in scientific research on environmental matters, and in guiding the thinking in fields such as environmental medicine. In each of these uses, scientific data may or may not be of a quality that is adequate for the use. It is important for EPA to maintain the quality of its data at a level that will make the data valid for those uses. It is also important for EPA to recognize that the highest attainable quality may be quite unrelated to the quality that makes data adequate for a purpose. Sometimes, the highest attainable quality may fall below the standard considered adequate for a particular purpose. In this case, either the methods of getting the data must be improved or the expectations for data quality must be lowered. Sometimes the highest attainable quality may far exceed in quality and cost the quality adequate for particular uses. In this situation, EPA must be careful to use its resources efficiently and not purchase data quality far in excess of what it needs.

The adequacy of the quality of a product for its task can only be judged by the users of the product. The suppliers should know what quality can be achieved, respond to the users' needs in terms of quality, and avoid unnecessary high costs associated with making the quality far higher than is needed. This maxim, translated explicitly into the EPA situation, means that the users of EPA's scientific data must specify as best they can what quality of data is adequate for their purposes. Then the suppliers can tune their quality control procedures to meet these needs, and those accountable for data quality can see that their quality assurance support is maintaining the correspondence between claims and performance at the selected level.

In the past, it was apparently never considered within EPA (or at least, so the panel's findings showed) that the users of data should convey to their suppliers what the quality of the data should be.* The discussions between the panel and the EPA seemed to have helped to stimulate the Agency to establish procedures for articulating what constitutes "adequate" quality of data for particular users (e.g., those drafting or enforcing laws and regulations). The panel discusses this issue in detail in Chapters 5 and 6. Here, it simply comments

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*In the late 1970s, before the existence of the Quality Assurance Management Staff (QAMS), a call was issued for specification of data use and quality, but this recommendation was never fulfilled. This may have been part of the motivation to establish a QA program.

that an awareness of this issue is growing within EPA and that active steps are being taken to implement a system to attain data quality that meets intended use at the program level.

4. INSTITUTIONAL ISSUES

ACCOUNTABILITY AND ORGANIZATIONAL STRUCTURE IN EPA

Some of EPA's functions depend on the knowledge and reliability of the quality of scientific and technical data. Without dwelling unnecessarily on specific instances, the panel can say that the Agency has, on occasion, functioned badly because of failures in the maintenance of data quality; such occasions were important stimuli for the creation of this panel. In discussions with the highest levels of the EPA staff, it was said to panel members that there were probably no clear placements of accountability for data quality. It may be possible in principle for the Agency to function without such specification, provided the QC procedures are virtually impeccable. However, in most situations, an extreme being field sampling in crises, it is necessary to specifically place accountability to see that the needed quality of data is achieved. This in turn becomes the justification for the existence of a QA program.

The panel recommends that the EPA make explicit precisely where the accountability rests for data quality. No one person or office could carry the accountability for the quality of all the data supplied by EPA. However, each kind of data must be associated with some responsible office--laboratory data with the appropriate EMSL, regional field data with the appropriate regional office, and so forth. It is useful to make this specification not only because it focuses a responsibility that was heretofore diffused, but also because it has direct implications for the institutional structure of the QA program, as we shall now see.

The administrative structure of EPA largely separates the responsibility for supplying data from the responsibilities of using the data to carry out the Agency's mission. Presumably, when accountability for data quality is designated, it will fall on those who administer the programs that supply data. Anyone in a position designated as accountable for scientific data has direct interest in having the protection of a QA program--perhaps only a single individual who reports directly to the accountable person. When accountability was not specified at a high enough level in the decision process, EPA officials had little motivation to use funds under their control for quality assurance. As a consequence, quality assurance was often left to people ill-trained to carry out its critical demands, or to people whose other responsibilities conflicted with their QA duties. Thus, quality assurance was often unable to function well enough to achieve its goals. Only if there are people both capable of establishing the programs and motivated by their responsibilities to see that they function, can a QA program perform its job.

CHARACTERISTICS NECESSARY FOR A QA PROGRAM TO FUNCTION

In any situation, a QA program must have certain characteristics if it is to function:

1. Independence.
2. Technical competence and the capacity to assist.
3. Clearly understood authority.
4. Vigorous management.

It is vital that a person responsible for quality assurance be independent of the people whose performance he or she is overseeing. A QA officer must be a staff representative, free to report to the person that officer is protecting. Second, a QA officer must be technically competent to evaluate the work of those he or she oversees and must have the confidence of those people, to the extent that the QA officer should be a resource to assist the bench scientists in the control and maintenance of the quality of their product. Third, the authority of the QA officer must be clear enough that the person to whom the QA officer reports can get accurate information and that the QA officer can act to maintain or restore adequate quality of the product. Fourth, the QA program must be treated as an active, ongoing monitoring program requiring vigilance and cooperation among the data user, the data generator, and the QA officer.

Within the EPA, these general terms translate into specifics in this way:

Quality assurance officers must report to and be members of staffs of the accountable individuals they protect. They must not be on the payrolls of the people they oversee. This is necessary to maintain the independence that QA demands. The QA officers must have the scientific and mathematical competence to assist the people they oversee and evaluate their work, to help them carry out their normal professional responsibilities for quality control. Furthermore, the central management of the EPA's quality assurance program, the Quality Assurance Management Staff (QAMS), should be technically competent to provide training and assistance to the QA officers in the field on such general issues as statistical problems and to see that QA officers get any needed assistance on specific scientific problems. The interaction of QA officers and QAMS with data suppliers needs to be one of friendly support carried out in a constructive yet authoritative relationship. The Science Advisory Board has a responsibility to provide scientific expertise and oversight to assist QAMS and the QA officers on these matters.

The necessary authority involves more than mandated power, but maintaining that authority does require a clear designation of responsibility and reporting in the organizational chart. Each accountable person should have the authority to place responsibility for maintaining quality assurance on a QA officer. Beyond that, the QA officer should have the support of a set of Agency-wide documents describing rules, norms, standards, and definitions regarding technical terms such as precision, bias, limits of detection, and other scientific terms and concepts that demand uniform treatment throughout the Agency. Otherwise, data use and interpretation will be riddled with errors. This is discussed further in Chapter 8. Furthermore the QA officers must be

empowered to carry out on-site observations and audits as they see necessary.

Vigorous management of the QA program requires organizational ability, particularly in its formative stage. After the program is established, it must, above all, have technical strength. Each particular scientific area needs leadership that stays aware of the current progress in that area. All the QA officers must possess skills in the statistical treatment of data or must have access to staff with such skills, statistics being the single topic that pervades all of data quality control and assurance. This implies that QAMS needs at least one person who is widely recognized for his or her expertise in statistics and who interacts with the professional statistical community.

An aspect of vigor and authority is very important in EPA. The QA staff must be able to elicit from the data users in the Agency clear statements of what constitutes "adequate quality" of the data supplied to them. Providing this information is a new challenge for many of the users, particularly those involved in regulation and enforcement rather than in scientific application of the data. Therefore the QA staff must be able to educate and work with the data users in an understanding manner to bring those statements of the needed quality--now called data quality objectives (DQOs)--into a form that can be used by the data suppliers. This topic is addressed in detail in Chapters 5 and 6.

Education is another task that the QAMS must carry out. Initially, the concept of quality assurance and its role in the functioning of the Agency must be communicated to the accountable individuals and to those who have to explain "adequate quality" to the suppliers. When the first generation of these people understands quality assurance, one can expect that maintenance of their own best interests will keep this knowledge alive in the successors of that first generation. A different kind of training, a continuing program, will be required for the QA officers. This is a task that cannot be left to haphazard learning-by-doing. New QA officers should receive the benefit of some supervised experience before they are considered trained for their tasks. A regular training program should be part of the QAMS responsibilities.

Short-term exchanges among QA staff from different agencies with QA programs could be a beneficial adjunct to an internal training program.

HOW DOES EPA'S QA PROGRAM COMPARE WITH THESE CHARACTERISTICS?

When the panel began its review, the QA officers were working generally only part-time in that capacity and were frequently working for the people they were supposed to be overseeing. It was usual for QA officers to be on the payrolls of the people from whom they should be most independent. The position of QA officer was considered a drain on the budget and was sometimes used as a place to put people who could not contribute to the substantive work of the Agency. It was easy to see that this situation arose naturally because there was no clear accountability for data quality and, therefore, little sense of any need for the protection whose provision is the main reason for a QA program. In fact, when the panel began its tasks, the distinction between quality control and quality assurance was not well understood in the EPA.

Much progress has been made to correct this situation insofar as the administrator's office and QAMS recognize the problem. However, the panel feels that the accountability for data quality has not yet been established, and, until that is done, no QA program will be able to function as it should. The role of quality assurance is still not apparent in the administrative chart of the EPA.

The responsibilities of data suppliers are not yet understood. At present, it seems to the panel that the QA program encourages those responsible for supplying data to write long documents, often largely formal restatements of standard model documents, which at best say how quality assurance and quality control will be maintained. However the QA officers do not in many cases have the authority to inspect and audit contractors, to see whether there is any relation between the statements and reality. The panel encourages the Agency to put much more emphasis on the field activity of the QA officers and much less emphasis on the formal documentation through lengthy written QA program plans and QA project plans.

Some of the QA officers are very competent, responsible, and dedicated individuals. Others are in their positions by default or for other improper reasons. Assignment of accountability for data quality to the data supplier would motivate the supplier to insist on the technical competence of the QA officer.

The educational component of the QA program no longer exists. This is clearly inconsistent with what the panel considers necessary for the program to function.

The panel recommends that EPA restore a training program, carried out by QAMS, for its QA officers and that this program draw in part on experienced individuals who have participated in successful QA programs elsewhere. QAMS should also provide technical training and assistance to the data users, but in order to do this it will need a more technically skilled staff than it now has.

The authority of the QA officers is not clear. The mandates are not well specified, and the officers are often in very uncomfortable positions in which they simply cannot make critical reports. Some of them do not have the technical competence to provide scientific assistance to their colleagues. Again, the panel returns to the point that the present situation, although changing, leaves some QA officers in situations of strong conflict of interest.

RESPONSIBILITIES: WHICH SHOULD BE CENTRALIZED AND WHICH DISTRIBUTED?

Whenever there is a need for Agency-wide uniformity, there must be a centrally coordinated program or effort.

Quality Control

The panel was shown, especially in its earlier visits, a number of documents generated in the laboratories and regions in reference to quality control and "good laboratory practices." These did not necessarily have Agency-wide acceptance. In contrast, the EMSL/Las Vegas

staff showed the panel a guidance document valid on an Agency-wide level. The EPA is encouraged to prepare, as much as possible, guidance documents concerning measurements and data practices that have Agency-wide application. The preparation of such documents should be given to a group with the required expertise and responsibility for the subject, perhaps drawn together just for this purpose. However, QAMS should encourage and coach the units in the preparation of these documents, for it must bear the ultimate responsibility for their preparation, distribution, and utility. Those who draw up the documents should consult with future users of the documents from all relevant sectors of the Agency and should respond to their needs. The Agency should also consult representatives from the community of EPA's contractors and from technically competent, relevant, independent environmental organizations. The document itself should reflect equivalencies of different measurement approaches and should allow flexibility, where applicable, among technical options. This kind of general, Agency-wide guide alleviates ambiguities, reduces errors in the handling and use of data, and eliminates both redundant effort in writing documents and conflicting instructions. EPA personnel and contractors must understand that if the data are requested for EPA's purposes, then the measurements must be made in harmony with EPA guidelines and practices. Application of the guidelines is then the responsibility of the distributed units responsible for the measurements.

Quality Assurance

While the responsibilities of the QA officers are strictly to those individuals who require QA protection and further centralization of this protective mechanism is not required, the function of oversight, education, and scientific/technical support for quality assurance as described in this report should be carried out by QAMS. Without strong QAMS support in these areas, quality assurance may have mixed results, and EPA's QA effort may receive poor overall recognition from those it should be serving. It also may not be possible for the Science Advisory Board to review adequately the QA activities that are distributed throughout the Agency, and QAMS must be the primary focus of interaction for this board.

Data Management

Centralization of data has already been under way at the EPA in data bases such as STORET, SAROAD, and now BIOSTORET. Uniformity of data practices, as well as data quality control, quality documentation, and quality descriptions, is essential to the specification of the data ("meta data"); centralization of the responsibility for rules and guidelines is the key to uniformity here, too. It must be added here that simply transferring data gathered by the laboratories, states, regions, and contractors merely produces unusable data dumps. Access to and use of data in such repositories are extremely difficult, if possible at all. The Agency must provide adequate support for maintenance and further development of these data bases, which it will certainly have to use in the future. Some issues to be addressed by a central office include:

What data are worth keeping, what data can or should be compacted, and what should be discarded? When is application of expert systems worthwhile? To what level of detail do modelers need to know each data element? These and a host of other broad data issues must be addressed by the managers of these Agency-wide data bases, in consultation with data users.

"CRISIS" PANELS

The panel has discussed the creation of "crisis" panels, or standing panels of experts, to allow EPA to have access to a preselected voluntary group of experts as advisors in an emergency. EPA should not maintain in-house expertise on the entire spectrum of potentially hazardous acute situations it might face. But EPA is responsible for coping with such crises. The intent of this recommendation is to reduce EPA's response times in crisis situations that require immediate data gathering and to improve the quality of the data gathered. The panel has no specific structure in mind for such crisis panels. A single large panel could be on call to the QAMS office, or about three experts could be on call to each assistant administrator. Other ways to implement this intent are also possible. These experts could then identify other advisors especially suitable for addressing the emergency at hand.

The selection of these crisis panel experts could be assisted by obtaining recommendations from the scientific community, particularly from members of the Science Advisory Board, the Council on Environmental Quality, and the National Research Council, and from other interested parties such as the American Statistical Association. It is proposed that appointment as a crisis panel member would be an honorary position and that scientists in that position would provide voluntary service, with reimbursement for out-of-pocket expenses only. As the EPA's crisis response becomes established and takes over labor-intensive work, these volunteers could step back, while continuing to give advice.

An existing crisis panel or panels should reduce both the time of reaction and the risk of inappropriate first actions in these particularly crucial times for EPA and the public by making better data available on shorter notice.

ROLE OF THE SCIENCE ADVISORY BOARD

Prior to the establishment of this NRC panel for the EPA, the Science Advisory Board (SAB) had an Environmental Measurements Committee, which assisted the EPA with measurement data aspects during the crisis of Love Canal and with other data matters. At the time of Administrator Gorsuch, this committee was disbanded while the NRC panel was created. Consequently, the expertise of SAB on quality assurance has been reduced so that SAB involvement in matters related to QAMS is now practically nonexistent.

The panel believes, after the period it has spent with QAMS, that the progress made is encouraging, so that further continuous panel assistance may not be required, at least in the near future. EPA might, however,

call upon the NRC two or three years from now to evaluate the QA program and make further recommendations. The panel believes that it is a proper part of SAB's mission to advise QAMS and to monitor the progress of the Agency in achieving the objectives of this report. In order to do so, SAB must include members with expertise in statistics, sampling, measurement protocol, and guidelines preparation, and especially also in the conduct of QA programs. Possibly, a separate committee or subgroup of SAB should be assigned the responsibility of regular interaction with QAMS.

5. DEFINITION OF ADEQUATE QUALITY AND THE PURPOSE OF DATA: THE DQO

The amount of effort to be devoted to data gathering must be carefully tailored to the specific purposes for which the data are intended. Section III of the interim report (see Appendix B) describes the reasons for this and reflects the situation at that time, namely the great need for two-way communication between the administrators and regulators who use the data and the laboratories in the regions and states and the contractors who generate the data.

At the time of the writing of the interim report, the concept of data quality objectives (DQOs) had just been introduced in EPA by QAMS. This was a major step in a direction strongly endorsed by the panel but not yet implemented at that time. Since then, the panel has followed some of the attempts at establishing the DQO mechanism to assure that data-gathering efforts are neither inadequate for the intended purpose nor exorbitant:

1. At a meeting held on November 25-26, 1985, at the EMSL in Cincinnati, an example was shown in which a DQO document was completed at the laboratory. It appeared to the panel that, while a paper product resulted, in reality the necessary two-way dialog was not achieved to guide the EMSL so that it could translate the intended use of the data into requirements placed on the data-gathering effort. A better two-way dialog must be achieved between data users and data suppliers in order for the DQO system to effectively function as "translator" between the two. The panel certainly does not intend that senior administrators spend excessive time learning scientific formulations and jargon and recognizes that technical implementation of DQOs is the scientists' task. However, the provision of data cannot function in a vacuum. This issue of translation from the language of regulation and policy into scientific language is not just an EPA problem, it is a major issue of our time. The EPA is notable here because of its especially intensive need for quantitative scientific input into its decision making; for this Agency, making the translation is crucial. The panel believes that properly drawn DQOs will provide a useful, realistic vehicle for achieving these goals.

2. At a meeting held at EPA headquarters on March 18, 1986, the panel specifically requested the presence of senior management representatives from policy and regulatory offices to discuss how they present their needs to those who collect the data they use in order to assure that the data will meet these users' requirements. This meeting was disappointing. No deputy assistant administrators or their senior representatives were present. The panel did become aware that some discussion takes place among scientists and lower-level administrative personnel regarding acquisition of data for a variety of purposes including modeling. There does seem to be communication among scientists in different laboratories at a more or less horizontal level, but no dialog involving people at other levels of responsibility or, most important, between data users and data suppliers at a level where programs that supply data are planned. In

other words, the panel has the impression that data suppliers (measurers) talk to data suppliers and data users (administrators) to data users, but that a bridge does not yet exist between these groups and that the status quo ante has not yet been affected by the introduction of the DQO process.

If it is to have a chance to fulfill its intended function, the DQO mechanism should be implemented whole-heartedly. The panel realizes that this is a difficult task requiring patience and education. QAMS should play an active, substantive role in this process, especially in supplying sympathetic, technical aid to data users unfamiliar with communicating their needs to technical workers. The panel hopes that in the end EPA will have a mechanism to assure that enforcement and regulatory tasks of the Agency are always stated in terms that allow those who supply the essential data for these tasks to translate the data needs into meaningful, usually quantitative terms that they can implement.

The Quality Assurance Management Staff has indicated to the panel that it sees its future role in the DQO process as one of auditing, not of engaging itself actively in DQO production. This is consistent with the concept that the data users should carry the responsibility for articulating their needs. QAMS also will deal with, or should take responsibility for, the training of others in DQO development. QAMS indicated it does not want to take on the responsibility of actually translating the end purpose of the data into quantitative statements of adequacy of data quality. This panel is not comfortable with that position. The panel believes it is unrealistic to expect the DQO process to be embraced by EPA if QAMS limits its role to audits and training, excluding the very heart of the process. *The panel believes that QAMS, at least for the foreseeable future, should take a strong initiative in all aspects of the DQO process, particularly in the central, substantive tasks. If QAMS does not now have people with the skills needed for this work, EPA has the responsibility to add them. This should be explicitly stated by the administrator as one of QAMS's responsibilities. QA programs elsewhere have been successful when part of their function is the provision of advice and assistance.*

A clear distinction should be kept in mind between DQOs and a QA project plan. The former involves the data user (regulator, administrator, modeler, or other); the latter is strictly a part of developing the details of a project plan that achieves the objectives. QA project plans can be formulated at the project level with overview by QAMS. These plans should address details to the degree of detail called for by the objectives.

Data quality objectives are more general statements of the degree of quality of data required for the transformation of data to Agency directives and actions. Accordingly, where the occasion presents itself, DQOs could be applicable to more than one use, thus reducing the long-term load on DQO development.

6. IMPLEMENTATION OF THE DATA QUALITY OBJECTIVE PROGRAM: THE PURPOSES OF DATA AND THE ADEQUACY OF THEIR QUALITY

Within QAMS, there has long been a realization that a data-generating and data-management system is effective only if it serves the needs of those who need those services. This panel urged from its beginnings that the data users of EPA convey to the data suppliers what kinds of data, meaning what quality of data, would be adequate for their uses. QAMS has proposed a means to achieve this goal in the form of specified data quality objectives (DQOs), to be provided by the data users to the data suppliers. Accomplishing this will break new ground in the way in which data are incorporated into decision making. It may be very important, and it is not a simple or trivial job, to create a DQO program that does what it should. The panel has welcomed and encouraged this QAMS initiative.

However, to date this panel has not been able to find any office of EPA that has established adequate DQOs or any other means by which data suppliers learn from the users what the users' needs are. A memorandum of November 14, 1986, from the deputy administrator to the assistant administrators urges this implementation as had been directed in a May 1984 memorandum from the same office. However, this implementation still seems to be happening more slowly than this panel considers reasonable.

The panel has discussed this problem with many data users and data suppliers at several levels within EPA. As a result of these discussions and of its own deliberations and experience, the panel now offers some recommendations to help achieve this goal of institutionalizing a mechanism to educate data suppliers about the needs of the data users.

This goal seems so obviously desirable to everyone concerned that it is difficult at first to understand why there is any hesitation at all in trying enthusiastically to achieve it. The reasons for the hesitation have to be examined to see why there has been no rush to set up a DQO system and, more important, to understand what can be done to make the users and suppliers want to use it. If it is not established on this basis, a DQO system will be treated as a bureaucratic harassment by all the participants on both sides and will not be used to achieve its purpose; it will simply add to the paperwork burden and reduce the efficiency of the agency. The people for whom the program is created must want it.

QAMS has described three stages through which it believes the data users and suppliers must go, in order that the DQO system can come into effective operation:

Stage 1. The data user formulates what decision will be made, what information is needed, how the information will be used in making the decision, what the consequences would be of having inadequate or incorrect data, and what resources can be made available to provide those data.

Stage 2. The program staff of the data user determines which elements of the decision depend on environmental data; specifies the data needed;

determines the domain, in time, space, and technical characteristics, from which the data should be taken; defines the technical form in which the data should be presented and used; specifies the "desired performance" of the data in terms of what kinds of errors or uncertainties are tolerable and what are not; and then determines any needs for new data.

Stage 3. The data supplier implements a program to meet the needs defined by Stage 2, in the form of a prescribed data-gathering program.

The memorandum of November 14, 1986, asks each assistant administrator in the program offices to work with the Assistant Administrator for Research and Development (AARD) and the Assistant Administrator for Policy, Planning and Education (AAPPE) to assure that each program office understands what the DQO process is and what its utility is, to reach agreement with each program and regional office on developing DQOs for their proposed major data collection activities, and to set up reasonable schedules for preparing DQOs for each major data collection activity. The memorandum also asks that responsibilities for working out the DQOs be assigned specifically and that the AARD and AAPPE review progress on DQOs and report quarterly to the deputy administrator on that progress.

To this panel, it seems that the most essential and most difficult (but not the most expensive or lengthy) parts of the activity are in Stage 1. Furthermore the memoranda that the panel has seen directed at the individuals responsible for carrying out Stage 1--the decision makers, among the data users--are not convincing. The documents did not explain what these people should be doing or why they should be motivated to do what seems like a very burdensome task for purposes that seem unclear from the viewpoint of carrying out their primary jobs.

If a DQO program, or anything else meant to achieve a similar end, is to succeed, it must have the support of the people it is most meant to help. It must have the support of the data users. The data users must understand that the data suppliers are trying to serve them and can serve them most effectively if the suppliers know what they should be supplying. Heretofore, the provision of information about what data users need has been meager and haphazard. The panel has encountered more than a little cynicism from people in enforcement and regulatory roles about the role of data and the importance of adequate quality; some such people have expressed openly their feelings that regulatory and especially enforcement decisions are made so commonly on grounds irrelevant to the validity of data that it is wasteful to be concerned at all about data quality, so long as reasonable everyday professional standards are maintained in situations where such standards exist. In other words, some of the users would, it seems, be satisfied with a simple quality control program.

One important reason why data users can hold such views is the lack of accountability, which has been discussed elsewhere in this report. The accountability meant here is accountability for the claims of adequate quality of data. There are surely situations in which the supplier simply cannot provide data of quality as high as the user wishes; in such cases, it is exceedingly important that the user know from the supplier what the data quality really is. Unless there is accountability at this level, nobody needs to be motivated to go beyond simple quality control. But, of course, the administrator is eventually accountable for the performance of the agency, so it seems reasonable to the panel that the administrator

would wish to assign accountability within the agency, and the rest of the logic follows, leading to the creation of the DQO system or something like it.

To make the DQO system work, it is absolutely necessary for the data suppliers and especially QAM's to work with data users, on a person-to-person basis, to carry out the heavy responsibilities that have been put under QAMS's Stage 1. The tasks may at first reading seem well defined in the "Draft Information Guide on Data Quality Objectives"* of November 4, 1986, but it seems to the panel that carrying out these tasks is not at all easy and that it would be rather difficult for someone working in enforcement or in drafting regulations to decide even what is meant by the statements of the various tasks when they are to be applied to specific kinds of decisions. The development of DQOs must be carried out in a cooperative, participatory way with individuals from QAMS learning the viewpoints and problems of the data users at the same time that the data users learn from QAMS and the data suppliers what they need to know in order to give users what they most want. Putting a formal plan into words, however well ordered, is not going to make a plan into a real activity, especially when it is not understood or appreciated by the people who are being told to do the work. They have to have the support of regular, face-to-face interaction with people who understand the directions while they work out the implementation <u>together</u>. Bluntly put, the formal steps of Stage 1 simply do not necessarily apply to the tasks and responsibilities of many of the data users. Furthermore, QAMS has to approach the data users in a manner that lets the QAMS people first listen to the users rather than tell the users what they must do. Then the DQO plan can be developed <u>in collaboration with the users</u> so that the users consider the DQO program as something really meant to help them rather than to harass them.

The development of DQO procedures in each program office should be done through direct, person-to-person collaboration among the data user and his QAO, someone from QAMS, and perhaps, one or two data suppliers.

It may be helpful to start with the "Draft Information Guide," but the people developing the means to achieve DQOs should be allowed to work with the flexibility to learn by doing.

A second important point is the matter of the level of generality at which the DQOs should be written. The lack of clarity about this point appears in the November 14 memorandum from the deputy administrator, which contains the expression "develop a <u>reasonable</u> <u>schedule</u> for preparing DQOs for each <u>major</u> <u>data</u> <u>collection</u> <u>activity</u>" (underline ours). What is meant by the underlined expressions is left undefined. This panel believes strongly that the principle of DQOs is sound but that there are two extremes to be avoided, either of which could undermine the approach. One is to make DQOs so general that they become hollow. The other, which the panel believes is the greater threat at this time, is the danger of trying to do too many, and to make them too case-specific. The panel

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*Limited availability, unpublished. One copy was circulated among panel members.

urges that broad areas of data use be defined by the data users, areas such as the regulation of nonradioactive dumps for toxic waste or the enforcement of industrial point-source emission regulations. The EPA should not need a DQO for each kind of hazardous waste or for each indexed air pollutant, although air pollutants or hazardous wastes may be so various that more than one category is required and therefore more than one DQO is required to describe the corresponding data needs. The DQOs should be written so that the data suppliers, with the help of QAMS or of QA officers for the appropriate program, can infer how to carry out, for each particular case, data-gathering efforts that keep the data quality at the appropriate level. Because the establishment of an effective DQO system is new, it will require a period of learning by doing. To go through this, some trial-and-error will probably be needed. Some first approximations to Stage 1 can be worked out at a general level; then QAMS and data suppliers can develop specific interpretations for test cases, and the result of these can be brought back to the data users to see whether the procedure achieved its goals from their viewpoints.

Whenever possible, each DQO should be written for a whole class of problems, not for a single case or a single pollutant. EPA should, by iterative, close interactions among data users, data suppliers, QAOs, and QAMS, develop the skills for writing DQOs and interpreting them for specific situations.

7. PRIORITIES IN ALLOCATING EFFORTS TOWARD DATA GATHERING

It is important for EPA to allocate effort and funding for data in a way that assures that all the requisite data, insofar as possible, are of the quality needed for their intended use. On several occasions, EPA staff members themselves have expressed their frustrations to the panel about the difficulty of making such allocations in proportion to what is required to achieve their quantitative relevance to the issue at hand (see Figure 1). There is a tendency to spend less, rather than more, on the more difficult aspects, which offer smaller apparent returns for a given effort.

For example, measuring lead content quantitatively in soils is done with ease in comparison with developing models for human exposure, which in turn is frequently easier than assessing health effects, which in turn is easier than evaluating effects on the quality of life. Yet, EPA spends larger amounts of manpower on assessment of chemical contamination than on assessments of exposure or of biological or health effects (of course, the Centers for Disease Control have some responsibility in health effects assessment as well). The concern here is that the precision of chemical measurements may far exceed the precision that the total assessment can achieve: a waste in measurement and thus budget. Again, a DQO would control the scope set for the data-gathering effort. In the above example, the higher precision may still be required to measure changes in contamination, but a need for this measurement must then have been expressed as part of the original plan. Panel members in their visits to regions in the earlier phase of this study noted that the data gatherers often were unaware of the purpose for which the data would be used.

Other examples in which there is inverse proportionality of needs to spending include carbon dioxide assessment, for which measurement is easy in relation to model development.

EPA is pressed on one side to economize on data collection and evaluation (as it is pressed to economize on all things) and on the other side to collect and provide environmental data for a broad clientele, present and potential. The panel supports the collection of data with long-term use but no immediate application, particularly in situations where the data are likely to be important either as baselines or as indicators of long-term trends. However, EPA is not a service Agency for the entire scientific community and cannot be expected to collect and maintain data sets on every aspect of the environment. Users of long-term data who wish EPA to provide those data should provide DQOs to those offices of EPA that could supply the data they need.

8. ESTABLISHING COMMON PRACTICES

It is important that Agency-wide common practices be established and implemented as much as possible for numerical data-intensive activities. These common practices would include guidelines, codes, or standards for data nomenclature, units, measurements, and handling (including statistical treatments) and for data validation/computerization/management. Equivalent procedures for which alternatives are in common but competitive use should be issued. A good start was made in this direction with a "Chapter 5" document shown to the panel at its meeting at the EMSL in Las Vegas. The panel urges the EPA to continue this effort. Agency-wide setting of guidelines, standards, and codes should be an ongoing activity with continual feedback from scientists in the field both within the EPA and outside. An Agency-wide document stating a standard code or practice would be very helpful and could replace much of the repetitive documentation now required to accompany the QA plans and programs that laboratories and contractors must present. The common practices must also be subject to continuous revision to satisfy the needs of the DQO. With time, new techniques and concepts become available whose possible adoption requires timely response, flexibility, and judgment.* (When the subject at hand does not involve Agency-wide interest, common practices should be prepared and agreed upon by those parts of EPA to which they pertain; however, statistical practices and definitions are by their nature Agency-wide.)

At its meetings, the panel has discussed practices regarding statistical handling of data. The Agency needs a uniform, deliberately adopted set of conventions or definitions concerning such terms as "bias," "precision," and "minimum detection limit (MDL)". Treatment of outliers needs to be put into a uniform code of practices as well, although this is

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*A case in point came up regarding measurement in Region III: the determination of total particulate nitrogen, phosphorus, and carbon contents of Chesapeake Bay waters. Such measurements were necessary for mass balance and modeling studies of the contractors. Yet the techniques that the EPA administration demanded were outmoded and indirect and lacked the necessary sensitivity for the needs of the investigation. For example, EPA methods involved measurement of total Kjeldahl nitrogen and Kjeldahl nitrogen in the filtered solution. The particulate nitrogen was determined by measuring the difference. Direct measurement of particulate nitrogen in a gas analyzer gives more accurate results with greater sensitivity. The contractors were prohibited from using this latter method. Informed judgment and rapid response to the needs of the contractors would allow a much more rational assessment of the problems at hand.

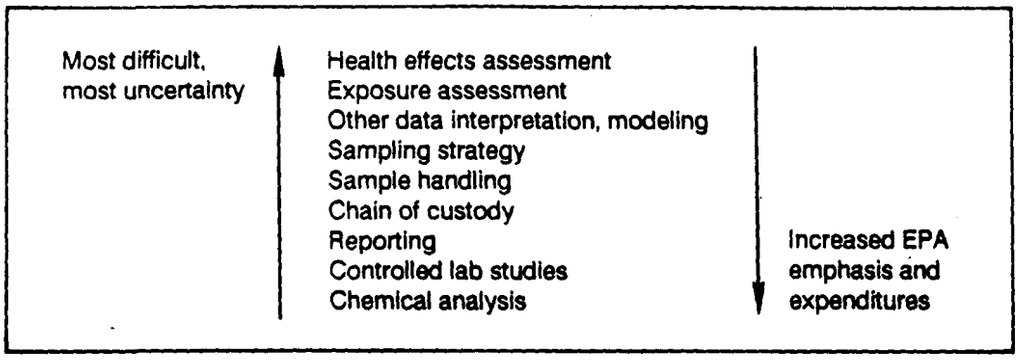

Figure 1. There is a tendency to emphasize those measurements for which increased precision and accuracy can be scientifically achieved, while expending relatively less effort on more difficult measurements (e.g., biological) and model development that are required for the assessment of total exposure and health effects. The word "relatively" is used here in the context of proportionality to the size of the error associated with the task or process given in the middle column of this figure.

not meant to imply that all outliers should be handled in the same way. A uniform code would spell out how to decide how to handle outliers. The approach of adopting a common practice of how to decide can be applied in other situations appropriate for a guide to uniform practices. One example might involve dealing with results obtained by different monitoring methods and showing systematic differences. A uniform code of practices would tell how to choose among available approaches. The EPA should seek outside expert assistance and evaluation in the preparation of a guide to uniform practices.

Agency-wide use of such terms and practices is important to EPA (1) in reducing the high costs of duplication of effort in preparing the definitions and the supporting documents, particularly in the contexts of QA program and project plans, and (2) in reduced ambiguity and misuse of the data and, hence, increased data utility. Preparation of common practices is relevant not only to the data collection process but also to program plans, project plans, and data quality objectives; thus the advantages are wide-ranging.

Project plans and program plans seemed to the panel to have been carried much too far. Instead of drawing on existing literature and definitions, and developing only the specifics necessary for a particular project or program, these documents are enormous and consist of large amounts of "boiler plate," repeating standard material that should be part of a uniform code of practice for the EPA and its contractors. Because these documents were, in many instances, so large and unwieldy, the panel had some doubt about whether anyone could use them effectively.

EPA should consider the adoption, whenever possible, of definitions and practices prepared by well-recognized organizations outside the Agency. Major efforts toward standardization have been made at the national and international levels (e.g., by the American Society for Testing and Materials (ASTM) and the International Union of Pure and Applied Chemistry (IUPAC)). While these standardization programs have attracted a number of notable statisticians, agreement on definitions is yet to become a reality after many years of discussion. However, it now appears that the IUPAC is nearing agreement on definitions for bias, precision, and minimum detection limit.* At least one other international organization, CODATA,** looks to these definitions as perhaps not perfect but nevertheless useful in the absence of universal agreement. Data measurers and reporters cannot proceed without a working definition; utilization of an agreed-upon set such as the IUPAC's proposed set should be implemented for those instances for which these definitions are technically appropriate. Application of common practices on an international scale not only reduces duplication of work within the EPA

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*"Recommendations for Nomenclature in Evaluation of Analytical Methods", IUPAC Commission V.3, Draft Report, 1988 (in review).

**The Committee on Data for Science and Technology of the International Council of Scientific Unions (ICSU). The IUPAC is a union of ICSU as well.

but also enhances data exchange and utilization on an international scale. This point should not be forgotten, particularly for data that deal with shared resources (e.g., contaminants in air and shared waters).

It is recommended that EPA develop a uniform set of definitions of "bias," "precision," and "minimum detection limit" and other terms and practices not only with personnel within the EPA but also with consultation and review by outside expert statisticians. EPA should study and adopt, where appropriate, work done by existing organizations that have convened world experts on the subject. These organizations include the IUPAC, the International Standards Organization (ISO), and the ASTM. Adopting inappropriate or misleading definitions could do a large and unnecessary disservice to the EPA's data gathering efforts and QAMS's image within the Agency.

9. ARCHIVING AND DISSEMINATING QUALITY-CHARACTERIZED DATA

Much of the environmental data now gathered by EPA (and other governmental agencies) are stored in computer banks. Most of these numbers are stored without indicators of quality. Similar to Gresham's Law of Economics, there is a "First Law of Environmental Science" enunciated by S.O. Makarov, the noted Russian oceanographer, about a century ago: "One careless observation will spoil 100 good ones" (S.O. Makarov and the significance of his research in oceanography. Bull. Inst. Oceanogr. Monaco, Special Volume No. 2, pp. 615-625 (1968)). Many of the data in storage (e.g., STORET) are poor. The panel was particularly disappointed during its visit to Cincinnati to learn that in the formation of BIOSTORET, an information bank of biological data, no quality control parameters would be associated with the entries.

The storage of environmental data, especially of data that can be used for decision making, should be done with appropriate screening and with enough information for the user to assess the reliability of the numbers. Clearly, measures of precision and of accuracy are essential. But more than this, files of analytical data on the substances present in water should tell the user what techniques were used, what primary standards were employed to calibrate the method, with what intercalibration exercises the laboratory was involved, and the dates and times of analysis.

The flagging of data with QC parameters will require a variety of resources. The storage needs will be greater. There is a cost to the procurement of information. Clearly there should be a complementary cost to the assessment of its worth. Further, an active and continuing group of scientists should be involved in the data validation process. The techniques most useful for data validation include screening for consistency and reasonableness as well as assessing the statistical and methodological parameters cited above. Intercomparisons with related data sets can often be used to identify or flag apparent discrepancies. Sampling or measurement problems or even errors of transcription can be discovered from such an assessment. Statistical methods such as regression analyses or even simple data plots are useful in many cases to verify good data or cast suspicion on poor data. Confidence-levels criteria for rejection should be adopted in advance as a matter of policy and should be strictly followed. Only if such measures are adopted can our data banks provide a useful and valid service to regulatory activities.

Data users outside the EPA have been actively working with some EPA staff to develop better methods for documentation of data quality in data bases. Particularly, two workshops were convened at the initiation of the Chemical Manufacturers Association (the Workshop on Data Quality Indicators, February 10-12, 1982, Gaithersburg, Maryland; the Workshop on Data Documentation Quality Indicators, May 8-9, 1984, Bethesda, Maryland). EPA participated in the organization and programs of these

workshops. However, there seems to be no active EPA effort at this time to follow up the recommendations of the workshops. This matter should be of primary interest to those responsible for data bases such as STORET, BIOSTORET, and SAROAD.

As a public Agency, EPA has the responsibility to make all nonsensitive data it has gathered available to the public in a responsible fashion. This includes notation of the assessed reliability of the data. Two workshops have, in fact, identified a practical approach in terms of procedures for documenting quality indicators. The EPA should develop the notations for quality indicators further and implement such indicators so that it can join the data base technology of the 1980s by providing useful machine access to its data bases.

10. ILLUSTRATIVE EXAMPLE: THE RCRA "GROUND WATER MONITORING TECHNICAL ENFORCEMENT GUIDANCE" DOCUMENT--HOW THE SYSTEM COULD BE MADE TO WORK

The panel read a number of documents intended to present data quality objectives. A few were so far from the mark that they clearly were written by people who did not understand what was intended. None that the panel saw has achieved what the panel believes DQO statements should do. All were much too long and too vague. The best of them do begin to reflect an appreciation of the issues and the intent. However, the most consistent impression the documents gave the panel is that the EPA staff charged with providing these do not yet understand what the documents should do, so that those people simply provide a pack of paper formidable enough to satisfy a bureaucratic edict. Instead, they should be providing terse, clear statements of what they, as data users, want. If the language in such a DQO statement is not clear enough for the data supplier's guidance, the data supplier should be able to come back to the user, assisted by QAMS, and, through direct discussion, work out what the supplier should be doing to give the user what he or she needs. If QAMS cannot carry out this function, it is failing in its characteristic 2 (listed in Chapter 4 on Page 12) of technical competence and the capacity to assist, in this case, in one of the aspects of quality assurance that the panel considers central.

To describe the way a DQO document might be written, the panel presents here a discussion of one particular document.* It was initially given to the panel as a developing inspection manual, but compared with other documents identified as examples of DQO implementation, this document, although itself not a DQO document, serves at least as well, insofar as it has at least as much relevance to an interactive DQO process as those shown to the panel as DQO documents and is a moderately good report. The intent of this discussion is to show by example some of the aspects of DQOs that have not yet been understood and to indicate how EPA can make the DQO into a more useful tool to help achieve its mission.

At one point, the document in question states that its data quality objective is "to develop and implement procedures that will provide legally defensible results in a court of law." EPA staff will presumably be the primary users of the data if a decision is made to litigate. The litigated group(s) will probably be the ones that have contaminated the water supply. The necessary regulatory and legal requirements are stated explicitly and well : "the data are used to evaluate compliance

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*The RCRA (Resource Conservation and Recovery Act) Ground Water Monitoring Technical Enforcement Guidance Document (TEGD), EPA No. 530/SW-86-055, September, 1986.

with the National Interim Primary Drinking Water Regulations Standards and the applicable National Secondary Drinking Water Standards; for this purpose, they should have method detection limits that are below 20 percent of the maximum allowable levels on a parameter by parameter basis."

Some details of the action plan are left open, although in general it is well conceived. For example, the number of soil samples in composites is not given nor are any guidelines to the determination of the number provided. Here, details necessary for executing the plan are lacking. These are matters that should be worked out between users and suppliers of the data, which may require the technical expertise that QAMS should provide. On the other hand, there was adequate flexibility in the initial survey for levels of radiation at the site. The simple statement is made: "If radiation above 10 millirems per hour is recorded, the advice of a radiation health physicist will be obtained." Clearly, contamination by radioactivity could arise from a number of origins. Some knowledge of possibilities at a given site is necessary to make measurements with appropriate instrumentation. This again is a matter best dealt with by direct discussion rather than by formal documents.

This document was examined by the RCRA Groundwater Monitoring Technical Document Review Committee. They found a document that in general was technically sound but needed modest changes to make more effective the operation of the groundwater monitoring systems, i.e., QA/QC practices. In some cases, the review committee suggested making greater use of professional judgment. The committee recommends, for example, in studying well pollution that "EPA should allow substantially greater flexibility in the recommended length of well screens. The maximum limitation of 10 feet on well screen length, may not adequately accommodate all hydrogeologic situations which may be encountered in the field and may, in fact, lead to the collection of misleading samples. If the screen length is suitable given the hydrogeologic complexity, it should also be sufficient for water quality sampling."

On the other hand, the committee identified inadequacies in the specification of drilling methods: "Emphasis should be placed upon the selection of drilling methods which . . . present the least potential for introducing contamination . . . fluorocarbon resins (such as Teflon . . .) or stainless steel 304 or 316 should be specified for use in the saturated zone when potentially sorbing organics are to be determined. In such cases, and where potential for corrosion exists or is anticipated, fluorocarbon resins are preferable to stainless steel. PVC has utility when shown not to leach or absorb contaminants significantly." The panel supports these recommendations and again encourages DQO statements that are flexible and apply broadly.

The examples from this report and its review illustrate how a careful study of the tactics used in monitoring programs can reveal both a lack of detail and too much rigidity in the step-by-step methods. To ensure that QC and QA objectives are satisfied, it is crucial that QA/QC methodologies in EPA documents are periodically and critically reviewed by disinterested scientists, either internally or externally situated. Such reviews can be cost-effective in eliminating unnecessary activities with respect to development of DQOs and QA project plans. The panel has in mind here both redundant and excessively project-specific documents. Reviews can

pinpoint technically unsound practices that impinge upon quality control. They can identify areas in which the lack of flexibility in strategies available to the user can lead to misleading or inappropriate results. They can uncover practices that may not lead to accurate results and point out more effective methodologies. This may have to be an iterative process of review: the reviewers make recommendations for change; the authors of the document respond; the reviewers then review the responses. Such apparently was the case with the Environmental Engineering Committee of the Science Advisory Board, which reviewed the RCRA Groundwater Monitoring Document, and the result seems to have been salutory.

APPENDIX A

MEETING AGENDA

May 26, 1983	First organizational meeting, East Coast, at NAS/NRC, Wash., D.C.
June 27, 1983	First organizational meeting, West Coast, at San Francisco, Calif.
Aug. 8-12, 1983	Three panel representatives attend EPA Conference on Quality Assurance for Environmental Measurements, Boulder, Colo.
Aug. 12-13, 1983	Full panel meeting at NCAR, Boulder, Colo.
Days in Nov., 1983	Selected panel members visit regional offices nearest their residence. Regions II, V, VIII, and IX were visited
Dec. 7-8, 1983	Full panel meeting at EPA headquarters, Wash., D.C.
March 8-9, 1984	Panel chairman and two members attend EPA/QA workshop organized by QAMS
June 6-7, 1984	Full panel meeting at EMSL/Las Vegas, Nev.
July 12, 1984	Panel chairman and member meet with QAMS and EPA assistant administrator at EPA headquarters, Wash., D.C.
Feb. 27, 1985	Panel chairman meet with QAMS and EPA assistant administrator at EPA headquarters, Wash., D.C.
Nov. 25-26, 1985	Full panel meeting at EMSL/Cincinnati, Ohio
March 18, 1986	Full panel meeting at EPA headquarters, Wash., D.C.
Nov. 5, 1986	Panel members attend QAMS annual officers meeting at EPA headquarters, Wash., D.C.
March 27, 1987	Selected panel members meet with QAMS at EPA headquarters, Wash., D.C.
Summer 1988	Panel chairman to meet with QAMS or EPA assistant administrator for transmittal of final report and debriefing.

APPENDIX B

INTERIM REPORT
ON QUALITY ASSURANCE
to the
ENVIRONMENTAL PROTECTION AGENCY

Panel on Quality of Environmental Data
Numerical Data Advisory Board
Commission on Physical Sciences, Mathematics, and Resources
National Research Council

NATIONAL ACADEMY PRESS
Washington, D.C. 1985

NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

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Available from

NUMERICAL DATA ADVISORY BOARD
National Research Council
2101 Constitution Avenue, N.W.
Washington, D.C. 20418

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COMMISSION ON PHYSICAL SCIENCES, MATHEMATICS, AND RESOURCES

CONTENTS

I INTRODUCTION

In April 1983 the Environmental Protection Agency (EPA) contracted with the National Academy of Sciences (NAS) to review the Agency's control of the quality of its scientific data, and particularly its Quality Assurance (QA) program. The contract implemented an initiative of 1980 by the EPA requesting assistance from the National Academy of Sciences (NAS). The NAS delegated the responsibility to its operating arm, the National Research Council (NRC), which, in turn, called upon its own Numerical Data Advisory Board (NDAB) to carry out the task. To conduct the requested assistance and review, the NDAB established a panel of six scientists--with recognized expertise in one or more relevant fields--to work with EPA, under the guidance of the NDAB, for three years, to (1) engage in discussions and briefings to help the EPA establish a sound QA program, (2) review methods, methodology, and selected key EPA QA documents, and (3) present its findings and recommendations. The final report is to be distributed as an advisory document that EPA could use to strengthen its programs, particularly those involving numerical scientific data.

The panel's study is now essentially half done. The document in hand is an interim report to provide EPA with the findings that the panel has arrived at thus far and the recommendations it can firmly make on the basis of those findings. The interim report sets out matters that the panel believes can be addressed now by EPA, independently of other matters intended for the final report.

Three topics are discussed here:

1. structural problems: what are the roles of quality control (QC) and quality assurance (QA) in EPA, and what do these roles imply? Why have a quality assurance program, and who is it for?
2. specification of objectives: how can "adequate" quality of data be determined and what should a QA program and QC accomplish?
3. management of budgeting, staffing, and documentation for EPA's quality assurance program: how can the aims of the two previous questions best be achieved?

These topics are not the only issues that have concerned the panel, but they are the ones regarding which the panel feels sufficiently informed to make statements at this time. These and other matters will be covered in the final report.

Before turning to the body of the report, the panel would like to make explicit two fundamental assumptions that have guided it. Mentioning the first seems obtuse, but it is no less important for being obvious:

1. Scientific data gathered by, for, or under the auspices of EPA are used for purposes requiring specific levels of known validity of those data.
2. A clear line of accountability is in place so that the lines of responsibility for scientific data quality are known to all participants in the relevant EPA activities.

Without clear lines of accountability, a quality assurance program for scientific data is ineffective. If scientific questions were the only ones EPA faced, it might be possible for EPA to leave such accountability diffuse or undefined and rely on professional standards of data quality control. However, EPA's responsibilities are to the public to protect its health and the quality of the environment. Consequently, the panel considers such an informal course inconsistent with implications of EPA Order 5360.1 labeled "Policy and Program Requirements to Implement the Quality Assurance Program." The panel agrees with this Order, that the matter of accountability must be examined by the EPA administrator, in order for the Agency to fulfill its responsibilities. So long as there is accountability for failure to maintain specified levels of data quality, the service performed by a QA program in EPA becomes essential.

II. STRUCTURAL PROBLEMS: THE ROLES OF QUALITY CONTROL AND QUALITY ASSURANCE IN EPA

Quality control (QC) and quality assurance (QA) are instruments used by institutions to maintain the quality of the goods or services those institutions provide at the level desired by the institutions' managers. QC encompasses all the means by which line workers achieve and maintain a desired level of quality in the products. QA consists of the means used by the institutions' managers to guarantee to their own satisfaction that the quality of the products is indeed being maintained at the desired level and at the level claimed by the line workers. These two functions are widely recognized and distinguished. The former is the consequence of the skill and sense of responsibility of a professional carrying out a task conscientiously. The latter is a kind of insurance that management constructs to protect itself and its institution against failures or weaknesses in QC. It is predicated on accountability for such failures and weaknesses.

To see what these functions mean in the context of EPA, it is useful to draw parallels with the pre-1984 Bell System, which had a highly developed QA program. In some respects the parallels are limited, but they provide a useful starting point. Understanding what QC and QA are requires identifying the suppliers, the goods, and the customers. In the Bell System, the suppliers were the manufacturers of telephone equipment and those who maintained the operation of the telephone system. The intermediate goods were devices and operations; the ultimate goods, telecommunication services. The customers were of two kinds: intermediate customers, including the Western Electric plants in which the devices were made and the operating companies that bought and sold devices; and ultimate customers, the customers purchasing the telephone services or ultimate goods.

In the EPA, the suppliers are those who provide environmental data, and the intermediate goods are the data themselves. The intermediate customers are the compliance officials of EPA and others, such as researchers within EPA and outside and people drafting proposed regulations and laws for environmental management, whether in EPA, in Congress, or in the private world. The data (intermediate products) are used by the intermediate customer to produce the ultimate product of environmental protection and enhancement to the ultimate consumer, the taxpayer. Environmental protection is achieved by deciding what the data mean and taking actions appropriate to that meaning.

QC in EPA must thus be equated with the means the suppliers of data use to check and control the quality of those data, through control over all the technical aspects of their work, beginning with decisions about what, where, when, and how to sample, going through analyses of samples, to maintenance of the integrity of lines of custody and data storage, and, finally, to documentation of the data. A QA program constitutes the activities of oversight and monitoring that ensure that the quality of the data does indeed meet the expectations of its intermediate customers. The purpose of the QA program, crassly put, is to prevent any embarrassing situation in which the data fail to serve their intended function because their quality turns out to be too far from what was expected. Stated more generously, QA for data in EPA is the certification, independent of the data supplier, that those data are adequate for their intended purposes.

Within EPA, the panel found some offices where the distinction between QC and QA is clearly understood. In other parts of the Agency, the distinction between the two activities was not so clearly understood. Nowhere in the parts of EPA visited by the panel did the panel feel that the roles of the participants were distinguished enough for the two functions to be carried out in a healthy, complementary way. One specific recommendation of the panel is as follows: *The roles of quality control and quality assurance should be clearly understood throughout EPA, and implemented in a manner that keeps the two clearly separated.*

QC is primarily a technical matter of sound scientific practices. QA is also partly technical but at least equally institutional. That aspect is discussed in more detail here.

Because QA is a service to management, specifically a kind of protective insurance, any QA program must have certain characteristics:

1. Independence from those groups whose performance it is scrutinizing.
2. Technical competence and ability to evaluate and assist those groups.
3. Clearly understood authority.
4. Vigorous management.

These characteristics have emerged from many years of industrial experience with QA programs. The panel is persuaded that the same characteristics are required for a successful QA program in EPA.

In the Bell System, there was a single QA program, integrated throughout the system and headquartered in Bell Laboratories. The QA personnel reported to the central management of the Bell System; the perception was that it was the managers of the System who were being served by the QA staff.

EPA is quite a different sort of institution. Many of its activities and responsibilities go on in regional administrations or laboratories. The structure of the Agency and the distribution of responsibilities within it differs enough from most private firms that the panel felt that it should not make a simple, explicit recommendation regarding the structure of the Agency's QA program. However, the panel

does make a very strong recommendation, one that it feels is one of its most important, regarding the structure of EPA's QA program: *The administrator must determine who it is that the quality assurance program should be serving and protecting, and design the program so that it carries out that function.*

The panel has drawn up two options for EPA's QA program that it considers viable, and has described a third situation, corresponding to the status quo, that it believes cannot achieve the purposes of a QA program.

Option 1: In each assistant administrator's office associated with an EPA program there would be a chief QA Officer (QAO) responsible for QA in that program throughout the Agency. The person served by that QAO and those QA staff reporting to that QAO would be the assistant administrator. QA staff members from each program office would be located in each region and relevant Environmental Monitoring Systems Laboratory (EMSL) to assure the assistant administrator of the program of the quality of data. A headquarters QA staff would be maintained in a form similar to the present Quality Assurance Management Staff (QAMS), with responsibilities for coordination, Agency-wide guidelines, procedures, and audits. In this option, the number of individuals to be associated with QA in the program offices and central QAMS staff should probably be roughly half the present number of full-time equivalents (FTE) identified with QA activities. The regional directors and other senior staff would be free to establish their own QA programs, in manners that they would see as protecting them. To assist the implementation of this option, uniform documentation of recommended QA and QC practices should be widely available to all branches of EPA and to its contractors.

This first option is based on the panel's understanding that in EPA, as it now functions, the principal data users--enforcement staffs, drafters of standards and regulations, and analyzers of trends--work within the specific program offices and get any data they need from suppliers primarily in that same program office. The option is drawn on the supposition that the assistant administrator for each program would be the person accountable for a failure in performance due to inadequate or misrepresented data quality. It is the panel's impression that the regional administrators might also be accountable for such failures within their own regions and would consequently find it very much to their own advantage to establish their own QA programs. The panel would strongly recommend that the regional administrators use funds under their control for this purpose.

In the case of the assistant administrators for programs, the panel recommends that the establishment of QA activity for the programs be mandatory and not optional, for the following reason. While the assistant administrators can be accountable to the administrator for program inadequacies, the person ultimately accountable as a public official is the administrator. Short of going to the second option (below), it seems to the panel that the administrator must mandate the effective operation of QA activities centered at the program level as insurance of the integrity of the Agency.

The third Section of this report returns to the matter of specific forms of management for this option. It is the option that the panel believes most effectively meets the aims of a QA program within the style of governance that places responsibility and authority at the lowest level where it will be effective.

Option 2: This option is predicated on a supposition that much of EPA's scientific data is used in parts of the Agency well separated from those parts responsible for gathering and evaluating data. If this is the case, the panel recommends centralization of the primary responsibilities for QA so that the chief QAO reports directly to someone in the administrator's office. In the model supposed for this option, which the panel believes did apply to EPA for some time, there is nobody below the level of the administrator's office who could be held accountable by the intermediate and ultimate data users for a failure due to inadequate or inadequately represented data quality. It would be the administrator who would need the assurance that one side of the house was supplying goods as specified to the users on the other side.

According to this option, lines of responsibility would run from the chief QAO to all the program offices, regional offices, and EMSLs. Unless a large part of the use of scientific data occurs in offices well separated from data collection, such as the Office of Enforcement and Compliance Monitoring, the panel would recommend against this option, in favor of the first.

The third situation, which we do not consider a serious option, is to maintain the status quo in the QA program, with responsibilities delegated in terms of performance at the lowest level of management. The panel considers this unacceptable because it creates self-contradictory, self-defeating situations that are likely to thwart the purposes of QA. By defining (implicitly) the performance of QA activities at the low levels where these responsibilities frequently fall now, EPA has exposed a confusion between QC and QA. The function of QC is indeed carried out, and properly so, at the level of the sampling, laboratory testing, sample handling, transmission and storage, and data analysis. The function of QA is an activity of service directly to a manager at some well-defined level of accountability. In Option 1, this is the level of the assistant administrators. In allowing responsibility for "quality assurance" to be distributed all the way to the level of laboratory directors, EPA has at present put the responsibility for surveillance and auditing into the hands of those who are being surveyed and audited. By allowing managers to make their QAOs part-time, QA personnel become part-time objects of review by the QA staff, i.e., by themselves. There is nothing wrong with having some people work part time in support of QA, but it is altogether incompatible with the function of a responsible QA officer to have loyalties divided between the manager being served by the QA function and the bench supervisor whom that manager oversees. The panel urges very strongly that the present structure be transformed as rapidly as can be done smoothly into one of the other options, preferably Option 1.

Whatever option is chosen, it is important that the QA staff are seen not only as police but also as skilled, helpful technical counsels to those whom they oversee. Policing and helpful counseling may appear to be incompatible roles but in practice, well-managed and staffed QA programs succeed in combining these tasks. Industrial experience has proven that this dual role can be carried out successfully. The panel sees no reason why it should not work in EPA.

One issue has come to the attention of the panel through its own interactions with EPA and through previous studies of the Agency. This is the difficulty the Agency has had with determining what constitutes "adequate" data in crisis situations. To cope with unpredictable crises, it is inefficient to try to maintain a permanent staff. Nevertheless, a high level of expertise is usually required to make a sound judgment in such situations. A standing board of expert scientists and engineers functioning as a "volunteer fire department" might alleviate this longstanding problem.

On this matter, the panel specifically recommends that within the structure of the QC and QA programs: *The EPA should establish a means to call up "crisis panels" of experts to advise on quality control and quality assurance in emergency or short-term extreme situations.*

The experience of the Agency with such "crises" in recent years indicates what value such panels would have. It would be relatively simple to maintain contact with rotating groups of outside experts willing to serve in emergency situations, groups who would function like volunteer fire departments and who could give the Agency guidance and credibility when needed.

III. SPECIFICATION OF OBJECTIVES: THE PURPOSE OF DATA

EPA must translate the scientific and regulatory objectives of programs that acquire environmental monitoring data into specific requirements for quality assurance and quality control.

Virtually every guideline and statement of QA principles and procedures issued by EPA officials and by QAMS over the past five years mentions the need to define the purpose of each environmental monitoring effort and therefrom derive requirements for the quality of the data. However, until the issuance by the deputy administrator of the May 24, 1984, memo on Data Quality Objectives, negligible emphasis had been given to this critical step in defining a QA program. None of the many QA program and project plans (including so-called model plans) that the panel has reviewed address this subject in a meaningful way; in fact, most totally ignore it.

For example, the Las Vegas EMSL is nominally responsible for QA and QC in support of the Superfund program. In point of fact, their QA and QC procedures are developed in a consensus forum by representatives from the contractor laboratories, regions, and headquarters Superfund staff without any significant input from the principal end-user, namely, the enforcement division of the Superfund Office. To quote one senior EMSL staff member: "We are somewhat blind to the end use of the data."

For example, the General Accounting Office Report, "Underlying Problems in Air Quality Monitoring Systems Affect Data Reliability" (GAO/CED-82-101, September 1982), places great emphasis on the importance of EPA's need for "accurate, reliable air quality data," and points to a lack of resources devoted by the federal EPA and the states to QA. In the GAO report the EPA counters that the National Air Monitoring Station network is "complete" and that current procedures are adequate for directing federal and state resources to QA. However, nowhere in this discourse is any attention paid to (1) the basis upon which the network itself was established, (2) current and anticipated future requirements for such data, and (3) the status of QA/QC efforts in terms of such needs.

For example, the Great Lakes Atmospheric Deposition (GLAD) network has been collecting wet and dry samples since the late 1970s, and plans are under way to expand the network. An impressive set of QC procedures are in place. Yet, there appears to be no documented scientific or regulatory rationale behind the network layout, sampling criteria, and specific QA/QC protocols.

The panel's reviews of headquarters programs, regional offices, and field laboratories consistently confirm this disregard of the purpose of environmental monitoring data and lack of critical user input in establishing related QA programs and QC protocols. The QAMS requirement that a QA plan be developed for each major program and research project is being met by the field offices and major EPA contractors. The panel has been told that several of the latter have set up special offices in Research Triangle Park, North Carolina, to generate such plans. Yet those plans reviewed by the panel uniformly begin with a statement of data requirements, void of any supporting rationale based on the ultimate purpose of the data.

There has been within EPA among line managers in headquarters and the field a widespread lack of support for QAMS and its QA directives. There has been, correspondingly, a reluctance to allocate adequate resources for QA and to provide adequate authority for those responsible for QA. The panel believes that the root of such attitudes is the lack of clear coupling between the objectives of the line regulatory programs and the imposed requirements for QA and QC. As long as there is no more than a vague understanding by the line management of the rationale behind the QA program and its specific directives, this situation will persist. Without well-understood objectives for data quality, QAMS lacks the necessary foundation for its whole program, so that its goal becomes assuring "data of known quality" instead of "data of appropriate quality." The former may have to suffice as an interim, pragmatic objective but must not be the long-term goal of EPA's data activities.

The panel is very much encouraged by the recent QAMS initiative to work with the programmatic assistant administrators and their senior staff in the development of "data quality objectives" for all significant environmental measurement activities, and it looks forward over the coming year to the opportunity to observe the progress of this critical effort. The panel emphasizes the importance of each of the following five steps:

1. The QAMS guidelines should be revised to place much greater emphasis on the requirement for a systematic analysis of the purposes of the project or program and of the data to be acquired, whether the data used be of legislative and regulatory or scientific and interdisciplinary nature.

2. A guideline for carrying out such analyses and for deriving specific QA and QC activities should be prepared by the QAMS management.

3. Prototypical project and program QA plans should be developed jointly by the program offices and QAMS to demonstrate the above.

4. A realistic schedule should be established to evaluate all major ongoing environmental monitoring networks in these terms.

5. The EPA QA program should be structured so that the assistant administrators responsible for individual regulatory programs have as one principal measure of their performance the implementation of effective QA programs for environmental monitoring data, where such QA activities derive from an understanding of the ultimate purposes of the data.

IV. BUDGET AND STAFF

The need for strong QA programs has been recognized by the EPA, although it is evident that many of the operating sections of the EPA have not yet assimilated this realization or determined the best manner in which to organize, and to benefit from, a strong QA program. There are probably several reasons for this. QA at EPA appears to have developed in response to a mandate that each program within the Agency must have its own QA program; in some cases these were added easily, without extensive change; in other cases, the transition was not so easy. The principal client of the program is not well identified in many cases, as is pointed out in Section I. This situation can lead to the development of a less-than-constructive adversary relationship between the QA officer and the Agency line personnel, unless the QA program is organized to protect the QA officer when she or he is in the vigorous pursuit of some well-recognized QA problem.

Of serious concern to the panel is the question of the adequacy of the Agency's financial commitment to the QA program as a result of the decentralization of responsibilities for QA. It appears to the panel that, in too many cases, the QA program has been treated as a meaningless, burdensome, bureaucratic formality. Because the QA budget must be derived from the existing program budget, which may have been planned without QA in mind, the responsible assistant administrator in some cases sees the QA program as undesirable baggage, competing with the "real" activity of his or her program. In some cases the panel has encountered very high quality in the designated QA officers; in other cases, the appointments appear to have been made to individuals who may not have fit in well elsewhere; such QA appointments served as convenient "dumping grounds." It is evident that if a QA program is to be of maximum benefit to the Agency, the personnel appointed to the QA officer positions must be highly enough qualified in the major areas of interest to his or her particular office or laboratory to have the respect of the people they advise and monitor. As the panel has stated previously, it is important that the QA officers be independent of the groups for which they have oversight and report to the individuals who seek the protection of the QA program (e.g., the assistant administrators). They must be on the payroll of the person to whom they report, not of the person they monitor.

Further, the panel is concerned about the undermanning of the QA offices in the regions as well as in the assistant administrator's office. Clearly, this diminishes the confidence that can be placed by the administrator in the programs. The very existence of part-time QA officers at the regional level reflects the confusion of QC and QA discussed in Section I. Part-time QA officers have divided loyalties even outside QA or QC and cannot provide the protection or advice that independent, skilled QA personnel should be giving. Carrying this point further, the panel recommends that at all levels the responsibilities for the application of QA/QC procedures be assigned in ways such that conflicts of interest are minimized.

At this point in the panel's review of the EPA's QA program, the panel does not wish to give precise recommendations to the Administrator regarding expenditures on QA since it does not yet have the necessary information regarding staff and budget to judge properly the present support for the QA program. It has been the experience of experts in private firms that about 0.5 percent of the total cost of a technical project should be spent for QA. This figure could serve as a guide for EPA in budgeting for its QA program.

As an aid to QA management (and, incidentally to the panel in its formulation of useful final recommendations to the Agency,) it would be useful for the Agency to compile some concise information on QA personnel and their roles and responsibilities in the QA program.

1. A list should be maintained for the officer responsible for QA of all employees of the Environmental Protection Agency and its associated laboratories and agencies who have responsibilities in any aspect of the QA program (site visits to check the QA procedures in contract laboratories, etc.). This list should indicate the educational degrees and previous experience of the personnel shown and the percentage of their time spent on QA activities, and assigned responsibilities to other offices.

2. An organizational chart of the QA personnel is important to the effective operation of the QA program. This should be prepared by the EPA administration and should designate clearly to whom each QA officer reports and from whom the money to support his or her position is received. The relationships (lines of reporting), if any, between the QA officers within the Agency's major laboratories, regional offices and laboratories, and the enforcement branches such as the National Enforcement and Investigations Center (NEIC) must be delineated.

3. At times of environmental crisis, it is essential that funds be available to the appropriate EPA office or laboratory to formulate the special QA/QC plans that will allow the collection of relevant and meaningful data to answer the needs as defined by the administrator or his or her deputy. As discussed in Section I, the panel recommends that a special emergency QA panel of experts be maintained on call, to be convened at time of crisis, to establish the necessary sampling and analytical protocols that will assure the quality of the data to be collected. It is at times like this that those responsible for QA may be especially helpful in advising on QC. Perhaps the present EPA contractors and consultants could be among those who serve in this

capacity, although their role as advisor may be compromised by self-serving interests for further work. It is important to establish the degree of precision necessary in the particular measurements, so as not to choose methods that result in wasteful overkill. Obviously, very precise analyses of large cost will be required for some cases, and less expensive, less precise analyses will do for others.

QAMS itself is beginning to function well now. However, a more effective QA program in EPA might result from placing a national office for QA in the EPA's Table of Organization, as opposed to the current situation where visibility and clout are lacking because QAMS is a small activity in the Office of Exploratory Research under the Office of Research and Development (ORD). Putting QAMS in the Table would help assure, as well as emphasize, its importance to all of the EPA regulatory activities. Centralization and unification of basic principles, methods, procedures, and criteria could more easily issue from above to the QA officers and their program, regional, or divisional activities. As the role of QAMS shifts from program development to the highest level of auditing, it can monitor the QA program and its own performance can be examined for effectiveness.

There are many compelling reasons for the preparation of nationally applicable documents relevant to required scientific data practices and the conduct of a sound QA program. For example, a national QA/QC Superfund volume could give better direction to regional activities in solid waste and toxics and would eliminate the need for regional offices to develop their individual (and differing) guidelines, such as were shown to panel members in visits to their regions. Wasteful incompatibilities among data sets originating from different regions would thus be reduced. Further, such a centralization of the preparation of nationally applicable documents may alleviate the situation described aptly by one panel member as the writing "of documents about documents," characteristic of the overwriting that one does when one's ideas are unclear. Often, such volumes produced by small in-house groups do not provide guidelines that reflect the cutting edge of present-day wisdom. In all fairness, some of EPA's documents presented to the panel display the Agency's use of most current well-grounded statistical methods, for which the Agency clearly deserves commendation. It would be advisable for EPA to draw on the most knowledgeable and substantial talent in <u>and outside</u> of EPA to develop such documents.

Generally, the panel has observed that there appear to be no strategies whatsoever for establishing statistically valid procedures for field collections. Samples are sometimes taken without having properly developed a statistically valid sampling design; rationales for locating sampling or monitoring stations are likewise often without logical underpinning. This is not only ineffective, but costly. Documentation of the strategy of sampling, not the tactics, would be extremely helpful, especially if it were reviewed and revised roughly every five years.

In summary, the panel feels that the EPA administration must insure that a firm and realistic budgetary commitment is provided to support the quality assurance program so that well-qualified personnel can be attracted into the quality assurance officer program and the necessary standards of an excellent quality assurance program can be supported. The amount of commitment should be guided in the interim by the private sector's policy that the expenditure on QA should be about 0.5 percent of the total operating costs of the office or laboratory.

The panel also recommends that the quality assurance program see to it that nationally applicable documents regarding data measurement, recording, and handling as well as QA procedures are generated by qualified persons and made widely available to the branches of the Agency and to its contractors.

A last but also important recommendation of this interim report is that the EPA take care to assign QA responsibilities to staff that has competence in this specialized task and has no other assignments that pose conflicts of interest.

APPENDIX C

LIST OF ABBREVIATIONS

AAPPE	Assistant Administrator for Policy, Planning and Education
AARD	Assistant Administrator for Research and Development
ASTM	American Society for Testing and Materials
BIOSTORET	Data bank on biological data
CODATA	Committee on Data for Science and Technology
DQO	Data quality objective
EMSL	Environmental Monitoring Systems Laboratory
EPA	Environmental Protection Agency
ICSU	International Council of Scientific Unions
ISO	International Standards Organization
IUPAC	International Union of Pure and Applied Chemistry
MDL	Minimum detection limit
NAS	National Academy of Sciences
NCAR	National Center for Atmopsheric Research
NDAB	Numerical Data Advisory Board
NRC	National Research Council
PVC	Polyvinyl chloride
QA	Quality assurance
QAMS	Quality Assurance Management Staff
QAO	Quality assurance officer
QC	Quality control
RCRA	Resource Conservation and Recovery Act
SAB	Science Advisory Board
SAROAD	A data bank of the EPA
STORET	A data bank on environmental data
TEDG	Technical Enforcement Guidance Document

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

DEC 5 1988

OFFICE OF
POLICY, PLANNING AND EVALUATION

MEMORANDUM

SUBJECT: GAO Transition Report

FROM: Robert Wayland III
Deputy Assistant Administrator

TO: Assistant Administrators
General Counsel
Inspector General
Regional Administrators
Staff Office Directors

Attached is a GAO report focusing on specific environmental issues prepared for the administrative transition at the Agency.

The report is a synopsis of selected GAO reports on major issues facing the Agency. GAO presents their concerns, suggestions, and recommendations in five basic areas:

- overall program management,
- RCRA and Superfund issues,
- reduced ozone levels,
- pesticide issues, and
- water issues.

This environmental transition report is one of 26 reports that GAO prepared to brief the incoming Administration. The other reports concern other significant issues facing the federal government.

GAO will be briefing the Administrator-designate and Assistant Administrator-designates on the issues discussed in the report in the coming months.

Should your office require additional reports, please call me or Steve Tiber, the EPA/GAO Liaison Officer, at 382-4010.

Attachments

cc: Lee M. Thomas
Dr. John A. Moore