

FY 1982 and 1983

IMPLEMENTATION STRATEGY

FOR THE

MANDATORY QUALITY ASSURANCE PROGRAM

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Introduction

In May 1979, the Agency initiated a mandatory quality assurance (QA) program. This program was designed to assure that all environmental measurements conducted by the regional offices, program offices, EPA laboratories, contractors, grantees, or other extramural sources resulted in scientifically valid data of documented precision, accuracy, representativeness, comparability, and completeness. In May 1980, an implementation strategy was developed covering the development of the mandatory program through FY '81. That strategy concentrated on getting the essential elements of the program in place through the issuance of guidance documents and the amendment of EPA orders and regulations, etc.

This document addresses the implementation of the mandatory QA program for the balance of FY '82 and for FY '83. It describes, in general, the total program effort and specifies the major QA responsibilities of EPA program offices, regional offices, and laboratories in assuring that the goal of well-documented, and valid scientific data is achieved.

Quality Assurance Goals and Objectives

The primary goal of the QA program is to assure that all environmentally-related measurements supported or required by the EPA result in data of known and acceptable quality. To meet this goal, the QA program must provide for establishment and use of reliable monitoring and measurement systems to obtain requisite data quality.

For FY '82 and '83, emphasis will be on the achievement of the following major objectives:

1. Implement QA program plans in all program and regional offices and EPA laboratory's to ensure that QA goals will be achieved nationally.
2. Prepare QA project plans for each environmental measurement project with priority for National Monitoring Programs. To the maximum extent possible, these plans will be written prior to the initiation of the environmental measurements.
3. Revise EPA grant regulations to require participation in the mandatory QA program by all federally assisted activities involving environmentally related measurements.
4. Promote and develop uniform approaches, standard operating procedures and techniques, reporting methods, etc. across media and across regional

offices, program offices, and EPA laboratories to the maximum extent possible. It is important (and most efficient and effective) for all organizations within EPA to employ consistent QA language, policies, procedures, and techniques when interacting with the States, industry, the public, contractors, grantees, QA-involved professional societies, other Governmental agencies, and national and international organizations.

5. Conduct annual QA systems audits of all program offices, regional offices, EPA laboratories, and selected contractors and grantees in order to assess the status and implementation of the mandatory QA program and the validity of the Agency's data bases.
6. Assist the program offices in the development and implementation of procedures for incorporating precision and accuracy estimates into each major environmental data base.
7. Establish data acceptance criteria and minimum performance standards for environmental measurements made by or for EPA.
8. Establish and implement a mechanism to assure that corrective actions are taken when QA problems are identified through PE studies, systems evaluations, or QA program audits.
9. Develop procedures for measuring the actual cost for carrying out a sufficient level of QA/QC to ensure adequate documentation of data quality and conduct an Agency-wide study to determine these costs.

10. Develop procedures and perform a study to determine the "failure cost" to EPA associated with the rejection or revision of environmental standards or regulations, or the loss of lawsuits due to the use of inadequate data.
11. Perform technical reviews of major EPA monitoring and measurement regulations during the development stage (prior to public notice) to assure that QA requirements for environmental measurements are adequately defined.
12. Develop training programs to educate different organizational levels of EPA personnel (Project Officers, QA Officers, Regional Administrators, Deputy Assistant Administrators, etc.) on the uses, misuses, and benefits of QA. Conduct at least four pilot training programs involving ERC-Cincinnati, Ohio; ERC-Research Triangle Park, NC; HQ's Washington, DC; and Region V, Chicago.

Philosophy

The guiding principle of good QA is strong support and continued attention by all levels of management. Agency management is responsible for the quality of the data used to make decisions. Managers, therefore, have direct responsibility for specifying the quality of the data desired and for providing sufficient resources and authority to their Quality Assurance Officers (QAOs) to assure that their data quality objectives are met. The program also is based upon the premise of complete staff work. This means

that the person responsible for an environmental measurement project has stated an objective, prepared a plan of work that describes his project, documented what he did and why he did it, including any changes to the original plan, and prepared a written report on the outcome.

Finally, it should be recognized by all members of EPA that the documentation of environmentally related measurements activities is necessary to satisfy the public sector that this Agency is doing its job properly. EPA must establish and maintain the highest level of confidence and credibility with the regulated community.

Organization and Management

The Agency-wide QA program will continue to be implemented by a central management authority supported by a well-defined organizational structure with clearly delineated areas of responsibility. The Administrator has delegated to the Office of Research and Development (ORD) the authority and responsibility for developing and coordinating the national mandatory QA program and directing its implementation. Within ORD, the responsibility has been delegated to the Office of Monitoring Systems and Quality Assurance (OMSQA). Operational responsibility for the QA program is assigned to the Quality Assurance Management Staff (QAMS) and the two Environmental Monitoring Systems Laboratories and one Environmental Monitoring and Support Laboratory of OMSQA. The Agency organizations involved in the management of the mandatory QA program are program offices,

regional offices, and laboratories responsible for environmental monitoring or data generation.

In an effort to assure that the mandatory QA program is consistent with the Agency's mission and objectives, a QA Policy Review Group has been formed. This group will be convened as necessary to address QA Management and policy issues.

ACTIVITIES

A. QA Program Plans

The QA program plans prepared by each program office, regional office, and laboratory will be updated for each fiscal year and submitted to QAMS for approval. These plans include the overall policies, organization objectives, functional responsibilities designed to achieve data quality goals for the activities for which the particular organization is responsible and milestones for implementing QA for each project.

These QA program plans conform to the "Guidelines and Specifications for Preparing Quality Assurance Program Plans, QAMS-004/80."

B. QA Project Plans

QA project plans, one for each specific environmental measurement projects or each continuing environmental measurement operation (or group of very similar projects or continuing operations), shall be prepared by the responsible Project Officer. These plans describe in specific terms the requisite procedures, responsibilities, functional activities, and specific QA and quality control (QC) activities necessary to achieve the data quality goals of each specific project(s) or continuing operation(s). QA project plans are to address the 16 elements identified in the "Guidelines and Specifications for Preparing Quality Assurance Project Plans, QAMS-005/80," dated December, 1980.

The QA project plan can be prepared as either an integral part of the plan of study (work plan, task plan, operations plan) or as a separate document. The plan should be prepared by the principal investigator or project officer and approved by the appropriate QAO for intramural environmental projects; or prepared by the contractor/grantee and approved by the project officer and QAO for extramural projects.

QA project plans should be written prior to the initiation of environmental measurements whenever possible. In particular, for those environmental measurement projects that are identified as a part of the FY '82 or '83 budget cycles, the plan study, including a QA project plan, should be written and approved before the project begins. In few exceptional circumstances, it is recognized that the QA project plan cannot always be prepared ahead of time. However, standard operating procedures (SOPs) should be prepared on as many of the required technical, scientific, or administrative operations as possible and should be available to personnel conducting the environmental measurements.

For FY '82 and '83, the first priority is to prepare QA project plans for all new environmental measurement projects and the second priority is to prepare QA project plans for all continuing environmental measurement operations. The national program offices have the responsibility for preparing the QA project plans for the national or international environmental measurement activities under their purview.

expected that the revised regulations will be published during the third quarter of FY '82. In preparation for these revisions, the program offices, with responsibility for State and local assistance grants, should prepare the appropriate guidance to the regions for implementing the QA requirements as soon as possible but no later than the FY '83 grants.

E. Audits

In FY '81, the QAMS initiated the annual QA program audits of all EPA organizations involved with environmental measurements. These audits are designed to evaluate the status of the QA program, the completeness of documentation, and the validity of environmental data. These audits will be continued on an annual basis. They will be conducted in accordance with the QAMS Audit Protocol, QAMS 007/81. It is also expected that the QAOs of the various EPA units will conduct audits of their major environmental measurement activities such as States, contractors, internal laboratories, etc., at least once each fiscal year.

F. Quality Assurance Reports

Each program and regional office and each laboratory will prepare an annual QA report which will be submitted to the QAMS in September of each year. QA reports will include such information as:

1. Status of QA program plan implementation
2. Status of QA project plan preparation and standard operating procedures used

3. Measures of data quality developed or incorporated into environmental monitoring and research projects and reports
4. Significant quality problems, quality accomplishments, and recommendations for program improvements
5. Results of performance audits conducted by the reporting unit
6. Results of systems audits
7. Correction actions resulting from unsatisfactory data
8. Summary of quality-related training

Detailed guidelines for preparing the annual report have been issued to all QAOs. These reports are primarily intended to inform the responsible officials of the status of QA within their program, region, or laboratory. Therefore, the QAO is to submit the report to QAMS through the chain-of-command so that management is aware of the successes and shortcomings within their realm of responsibility. The QAMS will, in turn, prepare an annual status report to the Administrator based on these reports and results of the audits and PE studies which will be circulated to all EPA offices and laboratories.

G. Special Quality Assurance Projects

In addition to the activities described above, the QAMS will conduct the following special projects during FY 1982 and 1983:

1. Complete a QA Costs and Benefits Study. A systematic study will be made of quality-related activities within EPA and the benefits in terms

of better data acceptability, better estimates of environmental quality, etc. Quality-related activities, as differentiated from other monitoring and measurement activities, will be carefully defined and costs for each quality-related activity determined or estimated. This study will result in management guidelines for determining costs and benefits for external and internal QA programs and activities.

2. Complete the evaluation of the Agency's PE Studies. This study, which was started in FY '81, will evaluate the differences between the methods and procedures used to carry out the PE studies in different media. The report will identify the differences, discuss the reason for those differences, and recommend standardization, where appropriate.

3. Develop national data acceptance criteria. A major effort for the next two years will be to coordinate the development of national data acceptance criteria. This activity is predicated on the premise that since EPA develops and validates the methods used, then it should specify the quality of data that is acceptable for the Agency actions and decisions. These criteria will be minimum acceptance levels with any program or project allowed to set more stringent criteria.

4. Develop training courses for QAOs. In FY '83, we will utilize a support contract to develop and present training courses for QAOs and Project Offices. These courses will address the principle elements of QA, such as preparing project plans, conducting QA audits, analyzing data

through statistical methods, etc. The courses will be tailored to fit the needs of the laboratory and regional QAOs and project officers who are more technically oriented and the program office QAOs who are more management and policy oriented.

5. Develop and Conduct Briefings on QA. In order to assist top management in understanding their role in the QA program, QAMS will conduct several briefings on the general theories, practices, and benefits of QA. These briefings will be oriented toward Assistant Administrators, Regional Administrators, Office Directors, and division directors since they bear the primary responsibility of QA.

6. Guidance on Biological QA. There is a recognized need to develop Agency guidance on the proper collection, use, and validation of biological data. In FY '83 a work group will be convened to summarize all the present Agency guidance on biological QA. This work group will be asked to issue a recommended practices manual for biological QA by the fourth quarter of FY '83. The work of this group will be benefited by extramural assistance.

7. Peer Review of QA Program Operations and Benefits. QAMS, through the use of a contract with the National Academy of Sciences will review the present QA program operations and prepare a report summarizing the strengths and weaknesses of the current approach along with any recommendations for improvements.

H. Quality Assurance Policy Issues. There are key policy issues which must be addressed before an effective QA program can be fully implemented.

Some of the more critical issues include the following:

- ° How can States be encouraged to adopt QA without providing additional resources?
 - Should QA be implemented at expense of the quantity of data rather than quality?
 - What mechanisms should be used for implementation of QA with the States?
 - grant conditions?
 - SEAs?
 - other?
- ° What oversight roll and authority should be vested in ORD/QAMS over Agency programs?
 - What mechanisms should be used to ensure that Agency programs will improve and document data quality?
- ° How can QA training programs be revitalized and funded? (With turnover of personnel, the Agency will be relying more and more on poorly trained and inexperienced individuals in the employ of States and others for collecting, analyzing samples and reporting data for environmental protection. Also, large environmental programs and extramural contracts are being managed by project officers with little or no training or knowledge of QA).

- ° Should QA requirements be incorporated in EPA regulations? (Such a measure would provide uniform guidance to the regions, States, and others for implementation of QA policies. As a precedence, the air programs office has written requirements for QA in its regulations for ambient air monitoring and for continuous emission monitors for stationary sources of air pollution.)

- ° How can QA requirements be incorporated in the budget process for program offices? (With only a few exceptions, e.g., NPDES, QA, where it is practiced at all, is more or less run as a bootleg operation because there are no identifiable resources for this function. Identifying QA as a bona fide expenditure of program operations would legitimate this activity and make it more acceptable uniform QA work load models for all agency monitoring and measurement programs appears as a viable, though partial, approach.)

Other policy issues, to be considered are the following:

Quality Assurance Resources

Program Offices responsible for major monitoring and measurement activities should support a full time quality assurance position. Also, each office manager should ensure that national program directives include sufficient resources to cover QA oversight of all regulated, special purpose, and projected emergency monitoring activities.

Regional Offices should provide for an independent QA oversight function consistent with the above.

Office of Research and Development, in addition to providing QA development and operational support for QA/QC, should develop and standardize QA protocols for inclusion in peer reviews; continue staffing plans for a viable QAMS; and consider reprogramming to provide increased resources for FY 1983 as described below:

ADDITIONAL RESOURCES - FY 1983

\$300K - (Priority 1) - Complete development and provide QA instructional materials to EPA regions and States to satisfy laboratory certification requirements for Drinking Water.

National Interim Primary Drinking Water Regulations require that any laboratory analyzing public drinking water must be approved by EPA or the State. ORD, prior to 82 budget cuts, provided instructions for EPA personnel/States for evaluating labs and determining if they could be certified as capable of monitoring the safety of public water supplies. The States and EPA Regions desperately need mobile audio/visual and self instructions to meet this minimum but critical qualification requirement.

\$250K - Develop a manual of statistical data quality indicator models for Regions, program offices, States and ORD laboratories.

Develop statistical models for data quality assessment within predictable confidence limits based on the intended use of the data. Wherein States, Regions, and most environmental programs demand certain creative rights and reduction in the QA paper burden, the need is often and urgently expressed for QA assistance in the critical area of documenting and improving data quality.

\$275K - Develop a manual(s) for program office QA officers to serve as a model for State QA work plans. The States, while involved in environmental measurements in support of regulatory requirements, are reluctant to develop their own QA work plans (program, project, SOPs) because of the paper burden involved and general lack of resources. Consequently, much of the data generated by the States is of unknown quality, e.g. the data stored in STORET. This effort would produce a model plan for each major program (TSCA, NPDES, Superfund, Drinking Water, etc) which the States can adopt with very little expenditure of resources on their part. In addition to assisting the States, these model plans will serve the Agency by establishing uniform national quality criteria for all regulated environmental monitoring. Further, it would automatically lead to data entered into storage systems which satisfy minimum data quality criteria. The absence of these criteria represents a major continuing unresolved problem for EPA.

\$50K - Establish cooperative relationships with leading voluntary consensus standards-setting organizations. As a regulatory agency, EPA must prevail on the private sector to accept regulatory guidelines for

environmental monitoring, including use of standard methods and quality assurance practices on the quality of data generated. There are many professional organizations committed to the principle of developing voluntary consensus standards whose work is supported by almost the entire private sector. Many of these organizations (APHA, ACS, ASQC, ASTM, etc) are engaged in technical areas which overlap EPA concerns. This Agency, by coordinating work in these areas - QA and standards development - with this pool of organizations, can gain broad public support for its activities. This support will materially assist EPA in dealing with the States and private sector.

The nature of cooperative efforts can take many forms from joint development and collaborative testing of methods to joint sponsorship of technical seminars. Initially, it is proposed to approach several key organizations to develop a mutual working relationship and help co-sponsor technical meetings.

\$150K - Develop practical standard reference materials for hazardous wastes. A great need exists for these materials since the pollutants of interest in hazardous wastes often exist in matrixes which interfere with analyses thereby making recoveries difficult and results inconsistent. At present we know very little about these materials and their chemical properties and dynamics.

NBS is pre-eminently qualified to study these pollutant-matrix systems and to develop, prepare, and manage environmental standards for the

Agency's Hazardous Waste Program. We propose to establish a continuing EPA NBS cooperative effort leading to standard methods and materials for analyzing hazardous wastes.

\$35K - This seeks to restore funds eliminated from the FY '83 budget for the National Academy of Sciences (NAS) to continue its efforts to review EPA data generation and data management activities and the general data quality control operations.