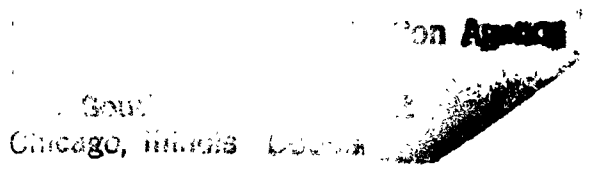
Strategy for the Implementation of the Environmental Protection Agency's Mandatory Quality Assurance Program

FY 1980 and FY 1981

QAMS-001/80

Quality Assurance Management Staff
Office of Monitoring and Technical Support
Office of Research and Development
U.S. Environmental Protection Agency



March 11, 1980

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Strategy for the Implementation of the Environmental Protection Agency's Mandatory Quality Assurance (QA) Program

I. Introduction

The EPA must have a comprehensive QA program to provide for the generation, storage, and use of environmental data. Valid data of verifiable quality must be available to provide a sound basis for effective decisions concerning environmental quality, pollution abatement, and control measures. The QA program can succeed only through rigorous adherence to established QA techniques and practices.

In the past, there has been a high degree of fragmentation, lack of coordination, poorly identified needs and resources, and duplication of efforts in the QA program. For these reasons, it is now Agency policy, as enunciated by the Administrator in memoranda of May 30, 1979 and June 14, 1979, that all Regional Offices, Program Offices, EPA Laboratories, and those monitoring and measurement efforts supported or mandated through contracts, regulations, or other formalized agreements participate in a centrally managed QA program. Regional Offices should work cooperatively with States to assist them in developing and implementing QA programs.

The mandatory QA program covers all environmentally-related measurements. Environmentally-related measurements are defined as "essentially all field and laboratory investigations that generate data involving the measurement of chemical, physical, or biological parameters in the environment; determining the presence or absence of pollutants in waste streams; health and ecological effect studies; clinical and epidemiological investigations; engineering and process evaluations;

studies involving laboratory simulation of environmental events; and studies r measurem[illegible]s on pollutant transport, including diffusion models.

This document presents the strategy for the development of an Agency QA program in accordance with the Agency policy. This strategy describes, in general, the total program effort with respect to what must be done. This strategy does not attempt to describe how, in detail, the program is to be implemented within the individual Program and Regional Offices, or the EPA Laboratories. Subsequent guidance documents will enable the Program and Regional Offices and the EPA Laboratories to develop detailed QA plans.

II. Quality Assurance Goals and Objectives

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

Initial objectives are the development and implementation of QA program plans by each of the Program and Regional Offices and EPA Laboratories which will ensure that the QA goal can be achieved nationally.

Long-term objectives include (1) providing quantitative estimates of the quality of all data supported or required by the Agency, (2) improving data quality where indicated, and (3) documenting progress in achieving data quality.

A continuing objective is to promote and develop optimally uniform approaches,

procedures, techniques, reporting methods, etc., across media and across Regional Offices, Program Offices, and EPA Laboratories. It is important (and most efficient and effective) for all organizations within EPA to employ the same QA language, consistent 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.

III. Quality Assurance Management, Organization, and Responsibilities

The QA program can succeed only if it is given attention by top management and provided sufficient authority and resources to support a national program effort. Therefore, the Assistant Administrators and Regional Administrators share the major responsibility for implementing the Agency's QA policies and directives.

The Agency-wide QA program will be implemented through the establishment of 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 Quality Assurance Management Staff and the two Environmental Monitoring Systems Laboratories and one Environmental Monitoring Support Laboratory of the Office of Monitoring and Technical Support. The other agency organizations involved in the management of the mandatory QA program are Program Offices, Regional Offices, and Laboratories.

A. Office of Monitoring and Technical Support (OMTS)

1) The Quality Assurance Management Staff (QAMS)

The QAMS will manage the mandatory program. Major functions of the QAMS are to:

- Develop model QA plans and guidelines for use by data generating offices and laboratories in preparing QA plans.
- Review and approve QA plans of data generating offices and laboratories.
- Conduct periodic reviews of Agency QA Programs to determine if deficiencies exist and recommend corrective actions.
- Provide assistance to Agency components developing and implementing QA plans, including assistance in identifying resources and outputs needed for the fulfillment of the mandatory QA program.
- Provide annual report to the Administrator and others as required.
- Chair and provide administrative support to the Agency Quality Assurance Advisory Committee (AQAAC).
- Review selected Agency regulations containing QA requirements for monitoring and measurements.
- Coordinate and assist in development of QA training programs.
- Maintain reference files of QA plans and procedures and serve as a clearinghouse for QA information.
- Coordinate the development and approval of laboratory certification procedures and criteria as part of the design of the mandatory QA program.
- Coordinate liaison and support for QA plans and programs with other agencies and professional societies, including cooperation with national and international standards setting organizations.

2) Environmental Monitoring Systems Laboratories and Environmental Monitoring Support Laboratory (EMSL)

The EMSLs of the OMTS work closely with the QAMS and will have Agency-wide technical responsibility for the mandatory QA program for their respective media or area of expertise. These responsibilities include:

- Provision of technical assistance to the QAMS
- Development of sampling and measurement methods and procedures
- Selection, testing, and validation of measurement methodology
- Development and implementation of procedures for assessing equivalent and alternate measurement procedures
- Preparation of QA guidelines, handbooks, and other reference information
- Development and implementation of criteria and procedures for evaluations of routine performance of measurement systems and operations
  1) Provision of standards and reference materials including all performance evaluation samples
  2) Conducting performance evaluations

In some specialized areas, such as biomedical and pesticide residues, QA responsibilities may be delegated to other ORD Laboratories.

B. Offices Generating Data (Program Offices, Regional Offices, and EPA Laboratories)

Each office or laboratory generating data has the minimum responsibility to implement procedures to assure that precision, accuracy, completeness, and representativeness of its data are known and documented. In addition, an organization should specify the quality data must meet in order to be acceptable.

Each office or laboratory generating data will designate a QA Officer. This person will be responsible for QA functions within his area of responsibility and provide liaison with the QAMS and other QA groups. The functions of the QA Officer will be consistent with those of the QAMS as described above but limited to a specific area of responsibility. Specific responsibilities shall include (1) liaison with the QAMS and other QA groups; (2) preparation of QA program plans; (3) preparation or review and approval of QA requirements for grants, cooperative agreements, and contracts; and (4) preparation of QA reports including data quality assessment.

Each operating program (office, Region, or laboratory) will notify the QAMS of any new or planned monitoring or measurement activities. Each operating program will also have a mechanism for accurately accounting and tracking resources for QA. (For example, Region V has identified a QA office for this purpose.)

1) Program Offices

Based upon guidelines established by the QAMS, the Program Offices, in conjunction with their related laboratories, Regional programs, Regional QA Offices, and other field units will develop and implement QA Program Plans. These QA Program Plans will be submitted to the QAMS for review and approval.

2) Regional Offices

Based upon guidelines established by the QAMS and the guidance from the National Program Managers, each of the Regional Offices will develop and implement consistent QA Program Plans. These plans will address the responsibilities for the Regions, State and local agencies, and the private sector. QA plans will be

reviewed and approved by the QAMS. QA programs for the States will be cooperatively developed with them through the appropriate Region. Continual oversight of State QA programs will be a Regional responsibility with guidance and assistance by the QAMS.

3) Laboratories

Based upon guidelines established by the QAMS, each Laboratory will develop and implement a QA Program Plan for its organization. These QA Program Plans will be submitted to the QAMS for review and approval.

IV. Quality Assurance Plans

The implementation of a strong QA program will depend, in large measure, upon the development of general management plans for each distinct program area along with explicitly detailed plans for each individual project or study. It is essential to understand the differences between the two types of plans.

QA Program Plans are written documents to be prepared by each Program Office, Regional Office, and Laboratory which include the overall policies, organization, objectives, and functional responsibilities designed to achieve data quality goals for the activities for which the particular organization is responsible. These QA Program Plans are to be developed in conformance with the "Guidelines and Specifications for Preparing QA Program Plans, QAMS-004/80."

QA Project Plans are written documents, one for each specific project or each continuing operation (or group of very similar projects or group of very similar continuing operations), to be prepared by the responsible Program Office, Regional

fice, Laboratory, Contractor. Grantee, or other organization which presents, n specific terms, the policies organization (where applicable), objectives, unctional activities, and specific QA and quality control (QC) activities designed o achieve the data quality goals of the specific project(s) or continuing operation(s). QA Project Plans are to be prepared in accordance with the "Guidelines nd Specifications for the Preparation of QA Project Plans, QAMS-005/80," to be ssued by June, 1980.

QA Program Plans only will be reviewed and approved by QAMS in accordance with he "Procedures for QA Program Plan Review and Approval (Standard Operating rocedure 001/80)." Project Plans are to be approved by the QA Officer of the esponsible organization. QAMS will examine selected QA Project Plans as part f the ongoing review of the QA program implementation.

A. Quality Assurance Program Plan

The QA Program Plans must contain, as a minimum, the following information:

1. A statement of policy recognizing the organization's intent to implement a QA program for their internal and extramural efforts to result in measurement data of known quality.

2. An organizational chart showing the position of the QA Officer who is accountable for the QA program. In establishing the organizational position of the QA Officer, the designating official (DAA, Laboratory Director, RA, etc.) should consider the need for open lines of communication. The desirability of avoiding a presumption of conflict of interest which might result if the QA Officer were not sufficiently removed organizationally from the direct generation of the majority of the data should also be considered.

3. A delineation of the responsibilities of the QA Officer and the data quality responsibilities of the functional groups of the organization.

4. General description of procedures or approach to be used to routinely assess and document the precision, accuracy, and completeness of measurement data.

5. General procedures whereby QA Project Plans are prepared, reviewed, and approved.

6. A listing of the substantial current and planned projects and continuing activities for which QA Project Plans will be prepared. Target dates for the completion of each QA Project Plan will be indicated.

QA Program Plans will be prepared by each of the following Offices and Laboratories:

Enforcement (NEIC-Denver)

Water Enforcement

General Enforcement

Mobile Source and Noise Enforcement

Water Planning and Standards

Water Program Operations

Drinking Water Programs

Solid Waste Programs

Noise Abatement and Control

Air Quality Planning and Standards

Mobile Source Air Pollution Control

Radiation Programs

Monitoring and Technical Support

Environmental Engineering and Technology

Health Research

Environmental Processes and Effects Research

Pesticides Programs

Chemical Control

Testing and Evaluation

Program Integration and Information

Regions I through X

ORD Laboratories (A Plan for Each of 15)

Note: See the "Guidelines and Specifications for Preparing QA Program Plans, QAMS-004/80" for more detail.

B. Quality Assurance Project Plans

QA Project Plans for monitoring and measurement projects should contain the following, as applicable:

1. Title Page, with provision for approval signatures
2. Table of Contents
3. Project Description
4. Project Organization and Responsibilities
5. QA Objectives for measurement data in terms of precision, accuracy, completeness, and representativeness
6. Sampling Procedures
7. Calibration Procedures and References
8. Analytical Procedures (manual and automated)
9. Data Analysis, Validation, and Reporting (manual and automated)
10. Internal Quality Control Checks
11. Performance and System Audits
12. Preventive Maintenance Procedures and Schedules
13. Sample Custody
14. Specific Procedures to be used to routinely assess and document data precision, accuracy, and completeness of specific measurement parameters involved
15. Corrective Action
16. Quality Assurance Reports to Management

The QA Project Plans will be prepared in document control format, with provision for revision, as needed, and with a record of the official distribution.

Note: See the "Guidelines and Specifications for Preparing QA Project Plans, QAMS-005/80" for more detail.

V. Quality Assurance Requirements for Contracts, Grants, and Cooperative Agreements

In accordance with the Administrator's policy of June 14, 1979, QA Project Plans are required for all contracts, grants, and cooperative agreements which include environmental measurements. Because of some procedural and legal differences, the QAMS will prepare two separate guidelines:

1. Guidelines for the Implementation of QA Requirements for Contracts
2. Guidelines for the Implementation of QA Requirements for Grants and Cooperative Agreements

These guidelines will be implemented by the beginning of FY 1981.

VI. Model QA Program Plan and Model QA Project Plans

Several model QA Program Plans will be jointly prepared by the QAMS and the responsible QA Officer and organization.

1. Ambient Air (OAQPS)
2. Ambient Water (OWPS)
3. A Region (IV)
4. Laboratories (HERL-RTP and ERL-Narragansett)

Similarly, several model QA Project Plans will be jointly prepared by the responsible QA Officer and Project Manager under the guidance of QAMS:

1. Ambient Air (Project or Pollutant Specific)
2. Ambient Water (Project or Pollutant Specific)
3. Region (Project or Pollutant Specific)
4. Laboratory (Project or Pollutant Specific)

These model QA Program Plans and model QA Project Plans will then be used as

models for the preparation of other QA Program Plans and QA Project ... ns. Models will be revised as needed to reflect new developments.

VII. Quality Assurance Reports

Each Program and Regional Office and each Laboratory will prepare a semiannual QA Report which will be submitted to the QAMS. Such QA reports will include such information as:

1. Status of QA Program Plans
2. Status of QA Project Plans
3. Measures of data quality from their projects
4. Significant quality problems, quality accomplishments, and recommendations
5. Results of Performance Audits
6. Results of Systems Audits
7. Summary of quality-related training

The QAMS will, in turn, prepare a consolidated summary report to the Administrator, the Assistant Administrators, and others.

VIII. Special Quality Assurance Projects

The QAMS will place priority on several special projects of major interest:

1. Conduct QA Workshops. To assist in the preparation of QA Program Plans and QA Project Plans and in the implementation of the QA requirements for contracts, grants, and other cooperative agreements, the QAMS will conduct, in cooperation with the Program and Regional Offices, EPA Laboratories, and Contract and Grant Administrations, a series of QA Workshops at Research Triangle Park, Cincinnati, and Las Vegas. Attendees at the workshops will include:

Regional QA Officers	Contract Administrators
Program QA Officers	Grants Administrators
Laboratory QA Officers	Project Officers

and Other Interested Persons

2. Establish QA Clearinghouse(s). Each clearinghouse will maintain listings of available reference materials, schedules of EPA interlaboratory performance audits, files of past and current QA Program Plans, QA Project Plans, annual QA reports, etc.

3. Conduct Quality Systems Audits. Specific Offices or Projects will be selected for on-site Quality System Audits. Audit teams will be composed of qualified individuals from offices or laboratories other than that being audited.

4. Perform a QA Cost Study. A systematic study will be made of the cost of quality-related activities within EPA. 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 cost benefits for external and internal QA programs and activities.

IX. Resources Requirements

In FY 1980 and FY 1981, ORD will provide minimum resources to support the QAMS and additional requirements placed on the EMSLs. These resources are estimated to be $500,000 and 7.0 FTE. Three positions (one each) will be assigned to the EMSLs.

Program Offices, Regional Offices, and Laboratories should continue to provide the resources to assure that the environmental measurements carried out by or for their purposes meet their QA requirements and result in data of documented and known quality. ORD will provide assistance in defining the minimum requirements and resources needed to achieve these requirements. ORD will also provide information on the cost of improving data quality by April, 1981.

X. Implementation Requirements and Schedule

Table I shows the major tasks or outputs needed to implement the mandatory EPA QA program through FY 1981. The organization(s) responsible for each major task is (are) indicated along with the known or expected completion dates.

TABLE I

IMPLEMENTATION REQUIREMENTS AND SCHEDULE

Major Task or Output	Responsibility	Completion Target Date
Agency QA Policy - General	Administrator	May 30, 1979
Agency QA Policy - Contracts and Grants	Administrator	June 14, 1979
Draft Strategy for Developing Mandatory QA Program	ORD/Work Group	February 13, 1980
Draft Guidelines and Specifications for Preparing QA Program Plans	OMTS/QAMS	February 22, 1980
Draft Guidelines for Implementing QA Requirements for Contracts	OMTS/QAMS	February 22, 1980
Designation of QA Officers	DAAs, Labs, RAs	March 1, 1980
Model QA Program Plans (Ambient Air, Water, Region, (Laboratory)	ORD POs, ROs	May 19, 1980
Draft Guidelines for QA Project Plans	OMTS/QAMS	May 5, 1980
Draft Model QA Project Plan	OMTS/QAMS	May 5, 1980
Quality Assurance Clearinghouse	OMTS/QAMS	May 1, 1980
Semiannual Agency Quality Assurance Report	OMTS/QAMS	June 2, 1980
Draft QA Program Plans Submitted	POs, Labs, ROs	June 6, 1980
Agency QA Program Plans Approved	OMTS/QAMS	September 15, 1980
QA Cost Study Report	ORD Labs. ROs	September 15 1980
Draft Guidelines for Implementing QA Requirements for Grants	OMTS/QAMS	September 15. 1980
QA Workshops (QA Officers, Project Officers, Grants Administrators)	OMTS/QAMS	(To Be Planned)
QA Project Plans Prepared	Labs, POs, ROs	October 1, 1980 and continuing

ajor Task or Output	Responsibility	Completion Target Date
rocedures for Implementation of Agency-wide QA Audit Program	OMTS/QAMS	December 1, 1980 (Start)
tatistical Data Quality Assessment Procedures - Precision and Accuracy	QAMS /OPM	December 1, 1980
emiannual Agency QA Report	OMTS/QAMS	January 8, 1981
QA Workshop(s)	QAMS/EMSLs	February, 1981
QA Reporting System Proposed for Agency Adoption and Use	QAMS/OPM	March 2, 1981
QA Cost Analysis System and Guidance	OMTS/QAMS	March 30, 1981
QAMS Workshop(s)	OMTS/EMSLs	April, 1981
Guidelines for Establishing Data Quality Acceptance Criteria	QAMS/POs, EMSLs	May 4, 1981
Semiannual Agency QA Report	OMTS/QAMS	June 8, 1981
EPA's QA Program - A Description and Assessment	OMTS/QAMS	October 1, 1981

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

OCT 09 1980

OFFICE OF
RESEARCH AND DEVELOPMENT

SUBJECT: Implementation Strategy for the Quality Assurance (QA) Program

FROM: Stephen J. Gage
Assistant Administrator
for Research and Development (RD-672)

TO: The Administrator

THRU: AX-101

We have completed the "red border" review process for the subject strategy document. The reactions by the reviewing offices are shown on the clearance record shown in Tab A.

We have since met with the staffs of the two nonconcurring offices and modified the strategy in response to their concerns and the concerns raised in the comments from the other reviewing offices. A copy of the revised strategy is shown in Tab B. Our specific actions in the nonconcurrences are summarized in Tab C. The specific responses from each office are contained in Tab D.

A major concern of all the responding offices was the potential resource required to implement the mandatory QA program. Specifically, there was concern that the strategy was not in accord with your policy to "make optimum use of existing Agency resources and expertise and provide for the least disruption of ongoing activities." We have responded to this by including a section on resources that details the Office of Research and Development's support to the mandatory program and reiterates your directive that the Assistant Administrators and Regional Administrators must provide sufficient QA resources to assure that we use data of known quality in our decisions.

Another point raised by several reviewers was the vagueness of the strategy and implementation schedule with respect to specific activities. In response, we revised the strategy to cover FY 1980-81 only and expanded the implementation schedule accordingly. There were many comments raised concerning the need to provide more specific guidance in the strategy. Since we are preparing separate guidance documents for implementing the key parts of the QA program, we incorporated them in the strategy by reference where appropriate.

DATE

U.S. Environmental Protection Agency
Region
23
Chicago

Finally, there were objections raised regarding the requirements that the QA Officers for each unit be independent of the functional groups making environmental measurements. An independent QA review is essential to the success of the program; however, we have revised the document to allow more flexibility to officials in designating QA Officers.

We believe that the revisions of the strategy document respond to the concerns of the reviewing offices. It provides a clear explanation of the activities and requirements of the QA program for the next two years. Therefore, I recommend that you sign the attached ACTION MEMORANDUM. Upon your concurrence, I will issue the strategy for Agency use.

Attachments