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QUALITY ASSURANCE RESEARCH PLAN

FY-1978 - FY-1982

by

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ABSTRACT

The Office of Research and Development (ORD), through its Office of Monitoring and Technical Support, is responsible for developing an Agency-wide quality assurance program to enable the U.S. Environmental Protection Agency (EPA) to implement its regulatory mission and associated monitoring functions. The major thrust of this document is to identify and justify the resources required by ORD to develop the quality assurance tools, techniques, and services needed by other program offices, the Regions, and the States to generate valid data. This five-year planning document describes the quality assurance program in terms of goals, objectives, and functional elements; summarizes the current status of ORD's ongoing quality assurance efforts; discusses Agency and program needs; and delineates the resources and approaches required to develop and carry out a dynamic quality assurance program which will ensure scientifically valid environmental measurements.

This report is intended as a guide for planning the resources required to develop the quality assurance tools, techniques and services needed by other EPA program offices, the Regions, and the States to generate valid data. This document is not intended to establish organizational responsibilities within the Agency, or to identify the resources required to implement quality assurance within the various EPA monitoring programs and the Regional offices.

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INTRODUCTION

The Office of Research and Development (ORD), through its Office of Monitoring and Technical Support (OMTS), is responsible for developing an Agency-wide quality assurance program to enable the U.S. Environmental Protection Agency (EPA) to implement its regulatory mission and associated monitoring functions.

Over the past several years, EPA has promulgated many regulations and standards that require frequent or routine monitoring of ambient air and water, wastewater discharges, public drinking water supplies, emissions from stationary and mobile pollution sources, lead and phosphorus in gasoline, and special categories of hazardous substances such as radionuclides, pesticides, and carcinogens. To meet these monitoring requirements, EPA's quality assurance program must provide validated measurement systems, reference standards, and the necessary quality control materials and services.

This multiyear planning document:

- Describes the quality assurance program in terms of goals, objectives, and functional elements.
- Summarizes the current status of ORD's ongoing quality assurance efforts.
- Discusses Agency and program needs.
- Delineates the resources and approaches required to develop and carry out a dynamic quality assurance program which will ensure scientifically valid environmental measurements.

This document is not intended to establish organizational responsibilities within the Agency, or identify the resources required to implement quality assurance within the various EPA monitoring programs and the Regional Offices. The major thrust of this document is to identify and justify the resources required by ORD to develop the quality assurance tools, techniques, and services that other program offices, the Regions, and the States need to generate valid data.

Goals and Objectives

The overall goal of the quality assurance program is to ensure that the environmental data EPA uses are sufficiently accurate, precise, and reliable to meet Agency needs at a reasonable cost. To achieve this goal, the EPA quality assurance program must:

- Provide precise, accurate, reliable, and cost-effective sampling techniques, analytical methods, and data formatting procedures to all organizations upon whom the Agency depends for its environmental monitoring data.

- Provide quality control materials, guidelines, and services to ensure that all environmental data based upon these techniques, methods, and procedures are statistically valid and legally defensible.

- Provide for continuous review and evaluation of monitoring programs to ensure that an approved quality assurance program is being implemented throughout the Agency.

Elements of a Quality Assurance Program

The quality assurance program covers two major functions:

- Standardization and validation of total measurement systems.

- Development and implementation of quality control practices and techniques to document data quality and systems performance.

A detailed description of the EPA quality assurance effort, along with implementation plans and organizational responsibilities, was set forth in two separate strategy documents approved by the Agency in 1973.[1,2]

CURRENT STATUS AND RESEARCH NEEDS

EPA's quality assurance program was not identified as a separate program element until FY-1973, although many related activities were in operation long before. Since that time, the quality assurance program has tried desperately to increase its outputs to meet the requirements of established environmental regulations and standards.

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[1] Measurement Methods Standardization Strategy Document, September 1973.

[2] Development of Agency-wide Quality Control Program, February 1973.

Some of the program goals and objectives cited above have been realized for measurements of ambient air and surface water quality. Also, notable progress has been made in developing reference samples and testing measurement systems for stationary air pollution sources and for wastewater discharges. In addition to the standardization efforts, quality control efforts have resulted in increased availability of reference samples and materials, on-site evaluations of all Regional laboratories, regularly scheduled interlaboratory performance tests, procedures and criteria for evaluating and certifying water supply laboratories, and automated laboratory systems.

Although much progress has been made, many Agency quality assurance needs have not been met. Among the important unmet needs are:

- Development of a comprehensive methods standardization and quality control effort to support the water supply program, including laboratory certification.

- Validation and approval of test procedures, promulgated under Section 304(g) of the Federal Water Pollution Control Act Amendments of 1972, for guidelines regulations and the development of an interlaboratory quality control to support the validity of the Discharge Monitoring Reports.

- Development and expansion of quality assurance efforts for noncriteria air pollutants, research monitoring programs, Consent Decree Pollutants, and toxic substances.

- Development of quality assurance training and establishment of a mechanism for improved coordination between EPA program offices, Regional Offices, and laboratories.

- Development of guidance manuals for siting and validating monitoring stations and optimizing environmental monitoring networks.

RESOURCE LEVELS AND IMPLEMENTATION OPTIONS

Quality assurance is, for the most part, a "level-of-effort" activity, and the resources (dollars and positions) directly impact the scope of work with respect to the number and types of monitoring programs that can be covered. An optimum quality assurance program should provide:

- Valid measurement and quality control systems to support implementation by program offices and the Regions of regulations and standards at reasonable cost.

- o Continuous review and evaluation of the performance and data quality of monitoring systems.

- o Support for monitoring emergency episodes, environmental quality trends, and special research studies.

Since there are major differences among some of the various types of monitoring activities, many of the quality assurance functions and research outputs must be duplicated to meet specific requirements with respect to pollutants measured, source and concentration levels, environmental matrix in which the pollutant is found, and purpose for which the data are being obtained. Therefore, the quality assurance effort may appear the same from year to year, while, in reality, it is addressing radically different monitoring and data quality problems.

Summary of Resources and Implementation Options

A summary of resource options along with implementation approaches is given below:

Option 1

	FY-1977	FY-1978	FY-1979	FY-1980	FY-1981	FY-1982
$M	5.3	5.3	6.3	8.5	10.0	10.0
MY	67	67	67	67	67	67

Under Option 1, the FY-1978 program will not change substantially from the FY-1977 program. In fact, there will need to be some curtailment and/or redirection in current activities to provide a critical mass for addressing "highest" priority areas. For example, in the water measurements area, emphasis will be given to meeting critical needs for the programs on water supply and National Pollution Discharge Elimination System permits.

In the air measurements area, the quality assurance efforts will concentrate primarily on standardization and improvement of measurement methods for stationary sources, limited performance audits of source measurements, maintenance of reference samples and materials, and continuation of the interlaboratory tests for ambient air measurements.

Also, under Option 1, the ongoing quality assurance efforts for measurements of biological materials and other environmental media will continue at the same level as in FY-1977. Primary emphasis will be upon support of the pesticide residue monitoring program and of radiochemical measurements for milk, food, and soil.

In later years, and projecting no change in man-years, the quality assurance effort will be expanded and improved in those areas that can be done extramurally: laboratory and field evaluation of sampling and analysis systems; preparation and distribution of quality control samples for routine use; and development and publication of quality control procedures, methods

manuals, and the like. Those efforts requiring dedicated in-house personnel will not substantially improve validation of measurement methods and approval of alternate test procedures; on-site evaluation of laboratories; interlaboratory performance tests and development of the associated standard reference samples; and direct technical assistance to laboratories that need to improve performance and data quality.

Option 2

	FY-1977	FY-1978	FY-1979	FY-1980	FY-1981	FY-1982
$M	5.3	6.3	8.5	10.0	10.0	10.0
MY	67	77	87	87	87	87

Resource Option 2 represents an increase of $1M and 10 positions for FY-1978. This increase will be allocated to support Standards of Performance for New Stationary Sources under the Clean Air Act, effluent guidelines regulations under Section 304(g) of the Federal Water Pollution Control Act Amendments, and the Safe Drinking Water Act. More specifically, $500K and 5.5MY will be allocated to support the water supply program, including test procedures, reference samples, and laboratory certification. The remainder of the FY-1978 increase, $500K and 4.5MY will be used to support effluent guidelines regulations, performance audits for air pollution source measurements, and critical measurements of noncriteria air pollutants.

The Option 2 resources in FY-1978 are not adequate, in dollars or man-years, to provide a comprehensive quality assurance effort to support existing regulations, and the resources certainly do not provide coverage of Consent Decree Pollutants, ocean dumping regulations, etc.

The resource allocation of Option 2 in later years allows for gradual development, implementation, and maintenance of a national quality assurance effort covering all existing and currently planned air and water regulations, standards, and monitoring requirements.

Option 3

	FY-1977	FY-1978	FY-1979	FY-1980	FY-1981	FY-1982
$M	5.3	8.5	9.5	10.5	11.5	12.0
MY	67	87	90	90	90	90

Under Option 3, the gaps in the current program can be quickly closed and a comprehensive quality assurance program developed for all existing and currently planned environmental monitoring regulations and standards.

The $3.2M and 20MY increase requested in FY-1978 would be allocated approximately as shown below.

Activity Funded	$K(MY)
Standardization of water supply measurement methods reference samples, guidelines, and assistance to Regions and States for laboratory certification	1,200(5)
Quality assurance program for monitoring reports on wastewater discharges, including some on-site inspections of laboratories	200(3)
Standardization and approval of Section 304(g) test procedures and establishment of a measurement methods equivalency program	450(3)
Performance audits for stationary source measurements	260(4)
Performance audits and measurement system evaluation for hazardous substances and other noncriteria air pollutants	340(3)
Standardization and optimization of measurement systems for Consent Decree Pollutants in water and wastewater discharges	700(1)
Ancillary activities (reports, data audits, coordination, meetings, workshops)	50(1)

At the Option 3 level of resource allocation, the program in later years is designed to provide the reference or standard monitoring methods, quality control procedures, associated standard reference materials, and quality control program audits that are needed by either the Agency's operational monitoring programs or the States. Also provided are expert advice and technical assistance to correct deficiencies in the performance of measurements systems and operators.

SUMMARY HIGHLIGHTS OF REGIONAL COMMENTS

This document attempts to focus on the needs of the EPA Regional Offices as the primary users of the quality assurance research outputs and services. The Regions require these outputs in order to carry out the Agency's mandated monitoring requirements and/or to assist the States. Therefore, the last section of this document presents a brief summary of comments on future quality assurance plans received from the 10 EPA Regional Offices. These comments have been tabulated and arranged according to the number of Regions identifying the same area of concern. For example, most, or all Regions, have identified four common needs: (1) comprehensive long-term quality assurance plans for the Regions; (2) standardization protocols for measurement methods and an approval mechanism for methods suggested as alternatives to those promulgated with regulations and standards; (3) a system to quantify data quality and to reject data out of control; and (4) quality control and reference samples for routine use. Other Regional

comments range from needs for validating more of the test procedures for Section 304(g) to certifying laboratories analyzing public drinking water. This document attempts to address the Regional and other quality assurance needs through the development of a reasonable plan for the research that will be done over the next 5 years.

ACKNOWLEDGMENTS

Acknowledgment is made to the Environmental Monitoring and Support Laboratories at Cincinnati, Ohio, Las Vegas, Nevada, and Research Triangle Park, North Carolina for their participation and inputs in the preparation of this document. Appreciation is extended to Bob Booth, John Clements, Arthur Jarvis, Gene Esterly, Wayne Ott and Linda Smith for their suggestions and comments.

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I. INTRODUCTION

The Office of Research and Development (ORD), through its Office of Monitoring and Technical Support (OMTS), is responsible for developing the measurement systems and the quality control techniques and services that the United States Environmental Protection Agency (EPA) needs to implement an Agency-wide quality assurance program. This multiyear planning document:

- Describes the quality assurance program in terms of goals, objectives, and functional elements.
- Summarizes the current status of ORD's ongoing quality assurance efforts.
- Discusses Agency and program needs.
- Delineates the resources and approaches required to develop and carry out a dynamic quality assurance program that will ensure scientifically valid environmental measurements.

This document is not intended to establish organizational responsibilities within the Agency or to identify the resources required to implement quality assurance within the various monitoring programs and EPA Regional Offices. Nonetheless, ORD is fully aware that the success of any quality assurance effort rests with the individual monitoring activities and that a significant amount of its effort must be expended to control and document data quality. Recognizing that quality assurance resources should be identified and planned for, this document emphasizes the identification and justification of the resources required by ORD to develop the quality assurance tools, techniques, and services that other program offices, the Regions, and the States need to generate valid data.

GOALS AND OBJECTIVES

The overall goal of the quality assurance program is to ensure that the environmental data EPA uses are sufficiently accurate, precise, and reliable to meet Agency needs at a reasonable cost. To achieve this goal, the EPA quality assurance program must:

- Provide precise, accurate, reliable, and cost-effective sampling techniques, analytical methods, and data formatting procedures to all organizations upon whom the Agency depends for its environmental monitoring data.

- Provide quality control materials, guidelines and services to ensure that all environmental data based upon these techniques, methods, and procedures are statistically valid and legally defensible.

- Provide continuous review and evaluation of monitoring programs to ensure that an approved quality assurance program is being implemented Agency-wide.

ELEMENTS OF A QUALITY ASSURANCE PROGRAM

The quality assurance program covers two major functions:

- Standardization and validation of total measurement systems.

- Development and implementation of quality control practices and techniques to document data quality and systems performance.

A detailed description of the EPA quality assurance effort, along with implementation plans and organizational responsibilities, was set forth in two separate strategy documents approved by the Agency in 1973.[1,2] These documents need to be updated to reflect the many changes that have occurred within EPA since 1973; only the elements of the quality assurance program described in this document have remained fairly constant. However, the descriptions of the quality assurance elements have been condensed and placed in the forepart of this document to aid the reader in understanding the research effort described herein.

Standardization and Validation of Measurement Systems

The efforts to standardize measurement systems are directed towards improving the basic monitoring tool -- the measurement method -- which consists of five closely related modules:

- Criteria for selecting sampling sites.
- Sampling techniques.
- Sample work-up.
- Analysis of the sample.
- Presentation of the data.

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[1]Measurement Methods Standardization Strategy Document, September 1973.

[2]Development of Agency-wide Quality Control Program, February 1973.

The two major elements of a program of measurement method standardization are protocols for system standardization and for measurement method equivalency.

System Standardization Protocol

A number of steps are involved in development and implementation of the system standardization protocol:

Identification of methodology needs -- Methodology needs arise from statutory requirements, needs identified within the Agency, and needs identified outside the Agency. The methodology needs identified must be responsive to the Agency's priority missions. The standardization process is both costly and lengthy. Therefore, identification of specific needs must be done well in advance of deadlines to allow coordination of the standardization process with the schedules of the activities requiring standardized measurement systems. Methodology needs are solicited from program offices and Regional Offices, as well as from all ORD technical support elements. Methods standardization needs can be specifically identified as a single need or they can be highlighted in relation to other areas such as development of criteria and standards. Measurement methodology needs can also be identified by evaluating new priority pollutants and by the experience gained from field programs, as well as from health and ecological effects and other research groups.

Selection of candidate methods* - Once a task for the standardization of a method for measuring a pollutant has been approved and funded, existing methods applicable to the pollutant of concern are subjected to critical theoretical analysis and preliminary laboratory and field testing. This process yields a first approximation of the applicability and limitations of the method -- that is, detection limit, sensitivity, and susceptibility to interferents. Measurement methods from the literature may be considered for inclusion on the list of candidate methods. Also, measurement methods from any other source (for example, methods developed by EPA's Office of Air, Land, and Water Use or by independent suppliers) may be considered for inclusion. When this process identifies no satisfactory method, research requirements will be identified and communicated to those responsible for research on methods development in ORD.

Evaluation and testing to select tentative methods -- Candidate methods are then subjected to intensive testing in a single laboratory to

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*A candidate method is any method of sampling or analysis advanced by a requesting party or selected by EPA as suitable for adoption as a standardized method and eventual designation as a reference method of measurement for criteria pollutants.

verify predictions made by theoretical analysis. Tentative methods will be identified that meet minimum requirements in terms of accuracy, precision, specificity, reliability, operational efficiency, and cost. A tentative method should represent the best state-of-the-art and show acceptable performance under a number of conditions that simulate those of the prospective user.

Collaborative testing -- Collaborative testing is an important step in validation of any method of measurement to determine, on a statistical basis, the limits of error that can be expected when the method is used by a typical group of investigators. Collaborative testing is generally quite expensive. Accordingly, only those methods deemed to be particularly critical to the Agency's regulatory functions will be selected from the list of tentative methods for collaborative testing.

The collaborative or interlaboratory testing of a method is a vital part of the development and standardization of analytical procedures. It ensures that the procedure is clear and complete and establishes with confidence the limits of precision and accuracy that may be claimed for the method. High-purity reference materials, standard reference samples, and spiked samples are used as required to validate the method. All of the data obtained are statistically analyzed and evaluated. The total measurement system (sampling, flow measurements, analysis, etc.) is fully characterized as to its sensitivity, accuracy, precision, reliability, range, and limits of detection. Interferents, stability of reagents, and maintenance may also be considered during method validation.

Endorsements and publication -- Once the method has been validated, it is reviewed and endorsed by the quality assurance activity and other appropriate Agency elements for technical content and adherence to the standardization protocol. For methods that are not part of regulations, this is the highest level of endorsement required before the method is declared a "standardized method" and is published in the EPA Environmental Monitoring Series or in other publications. For methods that support standards and are to be promulgated or cited in regulations, the method is transmitted through normal channels for approval, for example, working groups and Steering Committee. Final endorsement is made by the Steering Committee. The method is then transmitted to the Administrator for approval as a "standardized reference method" and is published or cited in the Federal Register. Copies of a reference method will be widely distributed within EPA so that the method may be quickly and conveniently integrated into the appropriate monitoring programs.

Measurement Method Equivalency Protocol

Promulgation of a reference method(s) in any environmental standard requires determining "equivalency" of alternate methods. The equivalency will be determined through use of an official EPA test protocol that will provide a legally credible basis for comparison of the two methods. The basic premise is that, within the provisions of the protocol, the proof of equivalence rests with the individual, organization, or company submitting a candidate method for approval as an equivalent method. This requires that

the requesting party demonstrate that his candidate method meets certain performance specifications and/or generates valid data that have a consistent relationship with the published reference method. EPA then systematically reviews these data, possibly with limited in-house testing, and either accepts the evidence or indicates where performance specifications have not been met; in-house testing may be necessary to make some judgments. Considering the large number of air quality, water quality, and other emission standards that will be published and the large number of instruments or methods that will be proposed for each standard, this activity will require substantial manpower and laboratory facilities in future years.

Discussion

Standardization and validation of measurement methods are costly and time-consuming. However, the availability and selection of scientifically proven, appropriate, and cost-effective measurement methods very often impinge on a variety of EPA decisions and actions -- setting of standards, promulgation of many regulations, evidence for enforcement, guidance to State and local agencies, and the like. The lack of adequate and consistent methodology may seriously impair these activities. The lack of a good measurement method may delay promulgation of a given standard or result in later modification or withdrawal of an established standard. Regulations concerning ambient and source standards must specify the measurement methods to be used in determining compliance, and these methods must be routinely applicable, at a reasonable cost if possible. EPA guidance to State and local agencies regarding the measurement methodology to be used must be consistent throughout the Agency. Also, the Agency could not fulfill its enforcement responsibilities if an accused polluter could successfully attack and discredit EPA's method for gathering environmental data. For these reasons, EPA must verify its measurement methodology through a laboratory-oriented scientific standardization effort that meets all challenges. EPA's measurement methods can best be defended through the implementation of a standardization protocol -- the exhaustive, collaborative, replicative, interlaboratory testing of the method for its accuracy and precision under the conditions required by environmental standards or other EPA requirements, and the statistical analysis of these tests to validate the performance of the method in the hands of typical analysts under a variety of anticipated conditions.

Activities included in standardization of measurement systems are:

- Selection of measurement systems that EPA and others have demonstrated to be cost-effective and reliable for routine monitoring of regulated environmental pollutants.

- Thorough and rigorous evaluations of measurement systems under real or simulated laboratory and field conditions.

- o Preparation of statistically valid test procedures that can be used to establish the precision and accuracy of the total measurement system, including the error contributed by its various components (sample collection, sample stability, sample presentation, analysis, and data handling and reduction).

- o Interlaboratory comparison of the measurement system to determine the precision and accuracy.

- o Promulgation of the measurement system(s) as an EPA reference or recommended method for regulated pollutants.

- o Establishment and operation of a mechanism to allow demonstration and use of equivalent methods.

- o Coordination of a national standardization effort through participation in intra- and inter-Agency committees and national and international standard-setting organizations.

In the context of these activities, measurement method standardization is a key part of the quality assurance activity. To assure the quality of environmental measurement data, methodology must be available and used that has demonstrated capability to make reliable measurements for its intended purpose. Measurement method standardization stands between research and quality control. EPA's research program conceptualizes and creates measurement methodology based upon state-of-the-art scientific and engineering knowledge. Standardization operates independently of research and is closely related to quality control. The vital statistics that are necessary to quantify and control the data generated by a measurement system are provided through the standardization efforts.

Quality Control

The quality control effort completes the Agency's quality assurance program by ensuring that validated methods are used in production of environmental data and that laboratories maintain and document the acceptable levels of performance established for measurement systems through the standardization efforts.

The basic elements of a quality control program are:

- o Development and issuance of quality control guidelines and procedures.
- o Intralaboratory quality control.
- o Interlaboratory quality control.
- o Quality control coordination and training.
- o Laboratory certification (evaluation procedures and acceptance criteria).

All these elements are important to the success of the quality control activity, and each element should be developed and carried out simultaneously.

Development and Issuance of Guidelines and Procedures

A basic requirement of a quality control program is a series of guideline manuals describing the procedures to be followed in sampling, analysis, and data handling. Such prescribed procedures provide a uniform approach in the various monitoring programs and allow evaluation of the validity of data produced. Procedures are needed for all the facets of a monitoring program -- from criteria to be used in locating stations to the formats to be used in reporting the data. The required procedures may be grouped into three categories:

- Sampling.
- Methods selection.
- Laboratory.

Sampling procedures -- A number of separate requirements is a necessary part of sampling procedures:

- Site selection. The selection of sampling/monitoring sites is the responsibility of each monitoring program. However, guidelines are needed that govern the placement of monitors or the location where the sample is to be taken to meet specific monitoring objectives. Such guidelines are necessary to ensure that the measurements made or the samples taken are representative and comparable. For example, in the case of air pollution monitoring, criteria must be established specifying the allowable nearness of inlet probes to buildings or, in the case of water monitoring, the depth at which samples are taken.

- Station or instrument. Measurements may be severely affected by the type and configuration of the facilities used in collecting the sample. For example, in some situations, variability in voltage, temperature, and humidity can influence the measurements. Consequently, operational parameters must be specified and controlled, and calibration procedures must be developed and used. Similarly, design characteristics must specify the types of monitors and special equipment that must be accommodated. Adherence to criteria for designing stations will ensure optimum use of equipment, ease of operation, minimum maintenance, and reduced data losses.

- o Sampling and preservation criteria. Procedures must be established that govern the manner in which samples are collected and handled. These procedures should include the following:

    - Use of equipment and materials for collecting, preserving, and transporting the samples.
    - Length of sampling periods.
    - Types of accompanying information needed.

In order to obtain meaningful data, a sound statistical basis for determining the frequency and duration of sampling/monitoring must be used in the design of monitoring programs. Such procedures must be provided in the manuals. Specific procedures must also be established that document the chain-of-custody of wastewater samples collected for enforcement actions and for samples of receiving water taken at or near points of suspected violations.

- o Calibration procedures. To ensure that data generated by automatic or integrating field sampler-analyzers are valid, procedures must be specified for routine field calibration of these instruments. The calibration frequency, as well as the procedures used, should be identified and described.

- o Special procedures. With the proliferation of continuous monitors, automated samplers, and in situ analyzers, procedures need to be developed for procurement of advanced monitors based upon performance specifications. Such technical procedures should be based upon performance testing under real conditions. This activity is closely related to development of test protocols for equivalency determination. Also, other procedures are needed to provide uniform chain-of-custody for handling enforcement action samples, performance specifications for automatic samplers for effluents and surface waters, and procedures for evaluating the adequacy and accuracy of flow measurement devices.

Methods selection procedures -- Many different methods are available for measuring pollutants in environmental media. Some have been promulgated by EPA, while others have been published by groups such as the American Public Health Association (water), the American Society for Testing Materials (air/water), and the Inter-Society Committee (air). EPA has the statutory responsibility to promulgate environmental, emission source, and waste effluent standards, including specifications of the appropriate method of measurement, collection, and analysis. To ensure the use of standard, reference, or equivalent methods throughout the Agency, an approved compendium must be developed for all pollutants in all media and published for all

monitoring activities. To ensure that this requirement is prescribed as Agency policy and uniformly followed, an intra-Agency committee on measurement method standardization should be established.

Laboratory procedures -- Where routine monitoring of regulated pollutants is concerned, all EPA laboratories will be requested to utilize methods described in an EPA-approved compendium or document any alternate procedures employed. Where more than one method is available, the selection criteria will be based upon the applicability of the method, its comparability with methods used in other laboratories, and its ability to meet requirements of the data user. Specific guidelines for selection of alternative methods and test procedures for routine monitoring should be developed and distributed Agency-wide. Also, it is extremely important that quality control procedures concerning standard laboratory requirements and practices be developed, promulgated, and followed. These guidelines should cover all facets of routine laboratory operations and maintenance of equipment and apparatus.

Intralaboratory Quality Control

To maintain a high level of competence in daily activities, quality control must be implemented in the field and at the bench using a system of checks to document the accuracy and precision of results and the performance of monitors and analysts. Intralaboratory quality control is a continuing requirement to ensure the output of data for which statistical confidence limits can be shown. The specific objectives of the program are to adopt and implement procedures that:

- Ensure use of proper procedures and measurement methods.
- Measure and control the precision of procedures and instruments.
- Measure and control the accuracy of analytical results.
- Ensure data output is uniform and/or compatible with Agency and national outputs.
- Present data in proper format.
- Document performance of instruments and analysts.
- Document training needs.
- Identify weak methodology and, consequently, research needs.
- Ensure that quality assurance practices are followed and documented in those laboratories supplying data to EPA.

The ORD quality assurance program is directed, in part, toward providing the materials and services to support intralaboratory quality control activities.

Interlaboratory Quality Control

An interlaboratory quality control program serves to continuously evaluate measurement methods to characterize their precision and accuracy, as well as to provide data for evaluating measurement methods, laboratories, and analyst performance. This aspect of quality control is referred to as cross-check sample studies and/or interlaboratory performance tests. Specific objectives of the program are to:

- Provide a credible repository of standard reference samples and materials for testing performance of total measurement systems.
- Measure the precision or reproducibility of methods of analysis within various laboratories and programs.
- Measure the precision and accuracy of results between laboratories.
- Provide a mechanism for evaluation of laboratories and analysts.
- Detect weak, improper, or impractical methodology.

Participating laboratories are provided standard reference samples, instructions, and data forms necessary to test measurement methods under certain prescribed conditions. The results are submitted to a central coordinating laboratory where they are statistically evaluated to determine the accuracy and precision of the method. Moreover, the test data are evaluated to determine the general applicability of the method for a specific purpose, and to evaluate and compare the performance of laboratories and analysts.

This type of activity involving laboratories in evaluating methods is necessary to provide a sound statistical model. Single laboratory tests introduce both method and laboratory bias, and the results obtained may have little relationship to the "true" reliability. All operating quality control programs have used an interlaboratory quality control program as a mechanism for methods standardization and selection.

Quality Control Coordination and Training

To succeed, a quality control program requires coordination to ensure adequate and timely exchange of information, and training to correct deficiencies identified via laboratory performance tests and on-site evaluations. The following types of activities are included:

- o Reports from meetings of quality assurance committees.
- o Reports from central files on requests and use of Standard Reference Materials and Standard Reference Samples.
- o Reports of quality control conferences.
- o Quality control newsletters.
- o Quality control workshops and seminars.
- o Reports on training needs.

Laboratory Certification

Certification is an important subelement of the quality assurance management activity and involves formal approval and/or endorsement of acceptable performance by a laboratory or analyst. Certification is directly relatable to the interlaboratory quality control. Certification of a laboratory documents that the laboratory has met all of the prescribed acceptance criteria of a certifying authority such as EPA. These acceptance criteria include: proper equipment and facilities; the required personnel with adequate training and experience; the necessary instrumentation, properly calibrated and maintained; documentation that quality control is being practiced; and documentation that the analysts/technicians have performed an acceptable analysis of blind standard reference samples.

Discussion

Quality assurance practices are a critical part of any reliable environmental monitoring operation -- reliable measurement systems must be used, instruments must be calibrated and maintained, uniform quality control procedures must be established and followed, performance and data must be audited, and personnel must be trained. Thus, the elements of any viable monitoring strategy must be directly linked to the essential elements of the quality assurance strategy, as shown in Figure 1.

The current quality assurance program is unable to validate all of the measurement systems necessary to support existing regulations and standards or to provide the quality control guides and tools needed by individual monitoring programs.

The growth of monitoring programs, the rapid expansion of the energy program, the promulgation of the interim drinking water regulations, the impending water supply laboratory certification program, and the Agency's growing interest and concern with heavy metals, trace elements, organic carcinogens, and other hazardous substances -- all present new challenges to the quality assurance program. The increasing complexity of interaction, liaison, and communication between EPA and other Federal, State, and local agencies involved in or concerned with environmental monitoring points to the critical need for a well-planned, coordinated, comprehensive, integrated, multimedia quality assurance program.

ENVIRONMENTAL MONITORING PROGRAMS

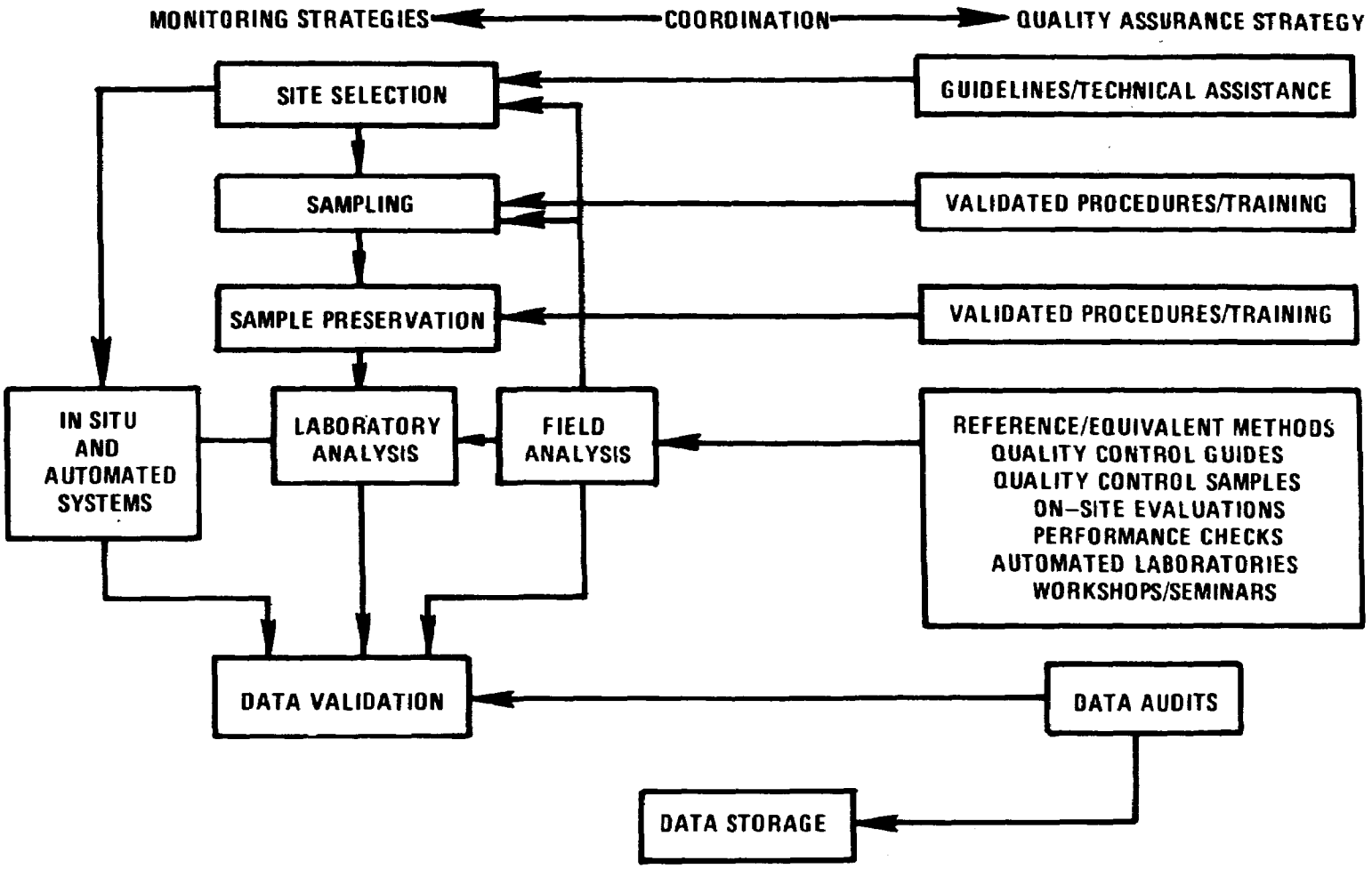

Figure 1

II. CURRENT STATUS AND RESEARCH NEEDS

This section examines the progress made in implementing an Agency-wide quality assurance program and the future research required to provide adequate support for existing and planned environmental monitoring activities. The current status and future research needs of the two major elements of the ongoing quality assurance program are described as they relate to air, water, and other environmental media of concern. In addition, new directions in quality assurance programs for research laboratories and energy programs are discussed briefly.

EPA's quality assurance program was not identified as a significant program element until FY-1973, although many related activities were in operation long before. Since that time, the program has tried desperately to increase its outputs to meet the requirements of established environmental regulations and standards. Major progress towards providing support for EPA's regulatory mission has resulted since formalization and recognition of the quality assurance program. Major highlights of the accomplishments from very late FY-1973 and early FY-1974, as well as the current status of the quality assurance program, are described below.

STANDARDIZATION AND VALIDATION OF MEASUREMENT SYSTEMS

The major efforts of concern in the measurement system standardization area are:

- Development and implementation of formal standardization protocols for "reference" measurement systems required by EPA regulations and standards.
- Statistical validation of measurement systems with respect to precision and accuracy.
- Development of equivalency protocols to ensure efficacy of methods used as alternatives to those promulgated by EPA.

In these major areas of activity, the current status and future research needs are described below for pollution measurements related to air, water, and biological materials and other environmental media.

Air

Standardization efforts related to air pollution have focused on measurement methods to support the National Ambient Air Quality Standards (NAAQS),

Standards of Performance for New Stationary Sources (SPNSS), National Emission Standards for Hazardous Air Pollutants (NESHAP), Fuel and Fuel Additives Regulations (FFAR), and Mobile Source Emission Standards (MSES).

Current Status

Standardization protocols for air pollution measurements systems have evolved from various contractual efforts underway since FY-1973. However, the testing and evaluation procedures used to validate measurement methods have not been documented and endorsed for general use by organizations outside ORD. Consequently, there are presently no written test protocols and criteria for acceptance of standardized measurement systems except those systems standardized by EPA.

A number of measurement systems related to air standards and regulations have been standardized. Ambient air methods have been evaluated, collaboratively tested, and approved for five pollutants:

Pollutant	Method
Suspended particulate	High-volume samples
CO	NDIR
SO_2	Pararosaniline
Oxidant	Chemiluminescent
NO_2	Chemiluminescent
	Sodium arsenite
	TGS-ANSA
	Continuous Saltzman

In addition to collaborative testing of methods, problems concerning calibration of continuous air monitors and stability of manually collected samples have been investigated and documented in ORD program reports to the general air pollution monitoring community, including the EPA Regional Offices and the States. Methods have been evaluated and collaboratively tested for several types of stationary sources:

Source	Pollutant	EPA Method No.
Power plants	Particulate	5
	SO_2	6
	NO_x	7
	Opacity	9
Municipal incinerators	Particulate	5
Cement plants	Particulate	5
	Opacity	9
Sulfuric acid plants	SO_2/SO_3 Sulfuric acid mist	8
Nitric acid plants	NO_x	7
	Opacity	9
Chlor-alkali plants	Mercury	101
Ceramic plants	Beryllium	104

In addition, the problems associated with use of one specific measurement method for a variety of source types have been and continue to be investigated. For example, one measurement method for particulate matter is generally proposed for use in a multitude of industrial sources. Extensive revisions have been proposed for a number of reference methods (Federal Register 41 23060, June 8, 1976), and much of the information in the suggested revisions results from these investigations and the collaborative tests that were conducted. An equivalency program is operational for measurements in ambient air, and many instrumental methods have been approved as equivalent or reference procedures.

Along with promulgation of SPNSS and NESHAP, EPA has adopted a series of reference test methods. These include not only manual and instrumental methods, but also such methods as visual opacity determinations. At present, requests to approve equivalent methods have been limited. Nevertheless, the Office of Air Quality Planning and Standards has expressed the need to provide the States with criteria or guidelines to apply in determining equivalency for approval of measurement methods for stationary sources of air pollution. The Agency should actively pursue development of such criteria or guidelines.

Future Research Needs

It is important that EPA seriously consider development and promulgation of protocols that will at a minimum establish performance and other acceptance criteria for those measurement methods designated as reference or equivalent.

Standardization efforts, while establishing validated methods, have also uncovered flaws in measurement methods that must be corrected. In anticipation of future regulations and to acquire air quality data for making important environmental decisions, standardized methodology (both for ambient air and for stationary sources) is needed for the following air pollutants: hydrogen sulfide, sulfates, nitrates, sulfuric acid, particulate by size, reactive hydrocarbons, benzidine, vinylidene chloride, ethylene dibromide, vinyl chloride, polynuclear aromatics, polychlorinated biphenyls, benzene, trichloroethylene, dichlorobenzidine, chlorinated naphthalenes, lead, arsenic, chromium, cadmium, mercury, plutonium, krypton-85, and asbestos.

Measurement equivalency efforts should be expanded to cover SPNSS and NESHAP for situations such as the following:

- In States that have requested delegation of authority to enforce SPNSS or NESHAP, equivalency of State-adopted methods must be determined.

- For sources where the frequency of testing is high (for example, fluoride or vinyl chloride) and where EPA methods are required, either directly or indirectly (for example, under Section 111(d) of the Clean Air Act Amendments), the equivalency of less expensive techniques must be determined.

- Equivalency must be assessed of new instrumental or manual techniques that evolve which are potentially superior (e.g., less costly, more precise, or of greater utility in enforcement) to current measurement methods.

Water and Water Supply

Most recent standardization efforts in the water pollution measurements area have been directed towards meeting the monitoring requirements of the Federal Water Pollution Control Act Amendments of 1972, Public Law 92-500. Under Section 304(g) of this Act, more than 120 test procedures for wastewater analyses have been promulgated. Program emphasis and priorities have focused on evaluation of the measurement methods required to show compliance with permit conditions for wastewater effluents.

In addition, the Safe Drinking Water Act of 1974, Public Law 93-523, requires that test procedures and quality control be a part of the primary drinking water standards. Immediate consideration must be given to validation of test procedures that have been promulgated to show compliance with maximum contaminant levels for trace inorganics, trace organics (including pesticides), and bacteria.

Also, the Marine Protection, Research, and Sanctuaries Act of 1972, Public Law 92-532, requires in Section 102(a) that quality assurance on analytical methodology be developed as needed for the Administrator to establish criteria for evaluating discharge permits that "shall consider ... the effects on human life and values, the effects on fisheries, all marine life, shorelines and beaches...[and] the effect on marine ecosystems". A major new effort in the coming years must include validation and standardization of test procedures that can be used for physical, chemical, radiological, and biological measurement of marine waters and ecosystems.

Current Status

In the areas of water and wastewater analyses, formal interlaboratory studies have been completed for validating methods for minerals, nutrients, biochemical oxygen demand, mercury, and cyanide. Validation studies will be completed in early FY-1977 for trace metals, petroleum hydrocarbons in brine, and chlorophyll. Tentative reference methods have been collaboratively tested for radioactive pollutants (including gross alpha and gross beta activities, tritium, total radium, radium-226, strontium-89, and

strontium 90) in water and wastewater. Two methods for analysis of plutonium in soil, pyrosulfate fusion and dissolution by acid digestion, were collaboratively tested. A round-robin study involving measurement of aqueous solutions of polonium-210 was conducted. Manuals of recommended radioanalytical methods are available for general and specific radiation measurements. Manuals are also available for physical, chemical, biological, and microbiological measurements of water and wastewater.

To improve the efficiency of laboratories and increase the level of quality control over the data produced, one Regional, one research, and one quality assurance laboratory have been automated. Automated laboratory systems use minicomputers to operate standard laboratory instruments, ensure quality control of the data, manage sample control, and prepare timely reports. Feasibility studies have been conducted in several other Regional laboratories and the National Enforcement and Investigation Center to determine the need and cost-effectiveness of automated laboratory systems.

Future Research Needs

Some of the most critical research needs in the water pollution measurements area include:

- Development of protocols/criteria for validation and standardization of the total water measurement system (as previously described for air pollution measurements).
- Evaluation and validation of measurement methods and monitoring system support standards and regulations for municipal and industrial effluents, ocean disposal, drinking water, ambient water quality, and hazardous substances.
- Evaluation and validation of methods for analysis of radium-228, iodine-131 (low levels), cesium-134, plutonium, uranium, and americium in water.
- Evaluation of current water measurement methods for applicability to leachates from solid waste disposal sites.
- Continuation of support for development of automated quality control laboratory systems.
- Development and standardization of a computerized system for evaluating, analyzing, and reporting interlaboratory performance test data.
- Statistical validation of flow measurements, sampling, sample preservation procedures, and equivalency protocols as appropriate.

- o Development and evaluation of screening methods for hazardous substances.

- o Evaluation and development of performance specifications for automatic sampling and monitoring instrumentation.

- o Development and implementation of an equivalency program for water measurement methods.

Biological Materials and Other Environmental Media

Standardization activities outside the air and water area include measurements of a variety of pollutants and/or their metabolites in plant and animal tissues, blood, urine, and soil. This effort supports studies to determine transport mechanisms and fate of pollutants, critical receptors, and the like.

Current Status

To date, major emphasis has focused on pesticide residues and radionuclides. Among the major outputs are:

- o A manual of methods for the analysis of pesticide residues has been published, and many of the measurement methods have been thoroughly evaluated and subjected to collaborative testing.

- o Various gas chromatographic columns and column materials have been standardized for separation of pesticides.

- o Two methods for plutonium in soil -- pyrosulfate fusion and dissolution by acid digestion -- have been collaboratively tested.

- o Manuals of recommended radioanalytical methods have been prepared for general and specific radiation measurements.

Future Research Needs

Future needs for standard reference methods for measurement of radioactive pollutants include: strontium-89 and -90, gamma emitters, and iodine-131 (low levels) in milk; radium-228, cesium-134, iodine-131, and uranium in water; and uranium and thorium in soil. Also, existing collection and analysis methods for sediments must be evaluated.

In the area of pesticide residue analysis, future efforts should include evaluation and validation of measurement methods routinely used by the Regions and States for residues in soils, tissues, etc. Also, some measurement method (to be identified by the Office of Pesticide Programs)

for pesticides in mothers' milk, animal tissues, blood, urine, and soils needs to be collaboratively tested.

In addition to new starts and/or expansions of efforts, current ongoing quality assurance efforts -- for example, reference samples and cross-check sample studies -- should be continued. In the radiation performance measurements area, program efforts will include support for the Nuclear Regulatory Commission. Also, there is a continuing need to develop and make available standard reference samples of pesticides, radionuclides, and other hazardous materials in biological materials and other environmental media.

QUALITY CONTROL

Quality control activities focus on the timely provision of instructional guides, reference materials, systems performance evaluations, and technical assistance needed to assure the validity and legal defensibility of all the data required by the Agency to carry out its regulatory mission. Emphasis is given to current compliance monitoring for wastewater, potable water, ambient air, stationary source emissions, etc. The major outputs include:

- Updated and improved guidelines and manuals for quality control of analytical techniques/data, and sampling/siting.
- Certification procedures and acceptance criteria for laboratories and analysts.
- Development and provision of reference samples and materials, with increased emphasis on hazardous and toxic substances.
- Continuation of interlaboratory performance tests for measurement of pollutants in biological materials and other environmental media, as well as for special monitoring studies in the western energy corridor.

The current status and research needs are described below for the quality control activity in air, water, and biological materials and other environmental media.

Air

Currently, development activities are primarily concerned with the quality control systems, guidelines, and reference material needed to assure the quality of data from ambient air and stationary source measurements. Program emphasis is directed towards criteria pollutants for which regulations and standards have been established. However, during most fiscal years, some emergency efforts are needed for special studies -- for example, vinyl chloride, kepone, ethylene dibromide, and lead. Therefore, plans based upon currently known needs and priorities must be flexible enough to meet

crisis situations without disrupting the total quality assurance program.

Current Status

Development and issuance of information and procedures include guidelines for development of quality assurance programs for ambient air and stationary sources, a quality control handbook for air pollution measurements, and guidelines for on-site evaluation of laboratories.

Intralaboratory quality control is being supported through development of reference materials, standards, and instrumentation for use by individual laboratories and monitoring activities. Among the major outputs are:

Pollutant	Device or Material
SO_2	Freeze-dried sulfite-TCM
NO_2	Aqueous sodium nitrite
Particulate	Flow audit device for high-volume samples
CO	CO/air in cylinders
Sulfate/nitrate	Glass fiber filter strips containing SO_4 NO_3 ions
Lead	Glass fiber filter strips containing lead
Lead-Gasoline	
Phosphorus--Gasoline	
Gross alpha/beta	2" or 4" diameter air filters
Plutonium-239	2" or 4" diameter air filters
Krypton-85	Cylinders of krypton-85 in air

Although resources for energy programs are handled separately, there is a heavy involvement in intralaboratory quality control in support of 25 agencies monitoring air in eight western States where new energy sources are being developed. Included are on-site evaluations, quarterly performance audits, and analytical support for a number of pollutants.

The Assistant Administrator for Research and Development has directed all ORD laboratories to develop quality assurance plans covering all appropriate research and monitoring activities. Support for these intralaboratory quality control efforts is provided as requested.

Interlaboratory quality control efforts include: development and demonstration of techniques for on-site evaluation of monitoring support laboratories, all Regional laboratories, the National Enforcement and Investigation Center laboratories, and one State laboratory, as well as direct assistance to Regions in evaluation of radiation laboratories; and development of reference samples and materials that can be used for interlaboratory performance tests. The following performance surveys are carried out semiannually (except as noted):

Pollutant	No. of surveys to date	Approximate no. of participants
SO_2	5	165
CO	4	120
NO_2	3	120
Particulate (annually)	2	150
Sulfate/nitrate	2	60

The following special performance surveys are carried out as noted:

Program	Pollutant	Period
Radiation	Gross alpha/beta	Quarterly
	Plutonium-239	Quarterly
National Air Sampling Network	SO_2, NO_2	Quarterly
Los Angeles Automobile Catalyst Studies	SO_2, NO_2, SO_4/NO_3 ions, lead	Weekly
Community Health Environmental Surveillance Studies & Community Health Air Monitoring Program	SO_2, NO_2, SO_4/NO_3 ions	Weekly
Unleaded gasoline	Lead and phosphorus	On request

Regional teams have been providing on-site and classroom instruction in the conduct of field/laboratory inspections of air monitoring programs. Biennial technical meetings are held with all Regional quality control coordinators. Although Headquarters has provided some assistance to the Regions to conduct quality assurance workshops, the level of effort is not providing the training needed to improve State programs. There is no current plan or effort to certify air monitoring support laboratories.

Future Research Needs

ORD needs to develop an adequate program for air monitoring programs to use to strengthen their individual intralaboratory quality control of data on emissions from stationary sources. The Agency should expand significantly its ability to provide technical assistance and training on quality assurance. Stationary source measurements and all currently unaudited criteria pollutant measurements should be audited periodically.

Specific requirements include:

- Updates of quality control guides and manuals at least every 2 years. (A mechanism is needed for additions or deletions without publishing new manuals.)

- o Development and maintenance of reference materials and quality control samples for all criteria air pollutants and for hazardous substances.

- o Establishment of a standards laboratory to provide interlaboratory calibrations for air measurements and traceability of reference materials and samples to the national standard measurement system at the National Bureau of Standards (NBS).

- o Continuation of the current program of periodic performance audits and expansion of the program to include performance audits of dynamic gas delivery systems and stationary source measurements.

- o Improvement and expansion of the Air Pollution Training Institute's quality assurance courses.

- o Increased participation in development and conduct of Regional quality assurance workshops.

- o Development and expansion of capability and material for conduct of regularly scheduled special audits (external) of a variety of important monitoring programs (for example, RAMS, CHAMP, CHESS, exposure chambers).

- o Expansion of capability and conduct of laboratory evaluations, including air monitoring stations, and a reporting mechanism to assist Regions planning effective use of resources.

- o Development of a mechanism to screen air pollution monitoring data before they go into the national data banks.

Water and Water Supply

Development and implementation of a strong national quality control program are of vital importance to EPA's mission to protect and improve the quality of our national water resources. Over the past 3 years since the expansion of quality assurance efforts for water measurements, tremendous advances have been made towards improving the quality control for water and wastewater measurement data. However, additional efforts are needed to establish a viable national quality control effort, particularly for potable waters, marine waters, biological monitoring, self-monitoring wastewater programs, and toxic substances.

Current Status

The following guidelines and procedures have been developed and issued:

- Analytical quality control manual for water and wastewater laboratories.
- Procedures for on-site evaluation of water and wastewater laboratories.
- Procedures and acceptance criteria for certification of drinking water laboratories.
- Manual of measurement methods for water and wastewater.
- Biological methods manual.
- Microbiological methods manual.
- Brochure entitled "Environmental Radioactivity Laboratory Intercomparison Studies Program 1977," which describes the cross-check sample studies program for radioanalysis of environmental samples.
- Brochure entitled "Radioactivity Standards Distribution Program 1977," which describes the distribution and proper use of quality control samples and other reference materials.
- Preliminary quality control manual for radiation measurements.
- Contract reports on feasibility of laboratory certification, a handbook for sampling and preservation of water and wastewater samples, and procedures for evaluation of environmental monitoring laboratories.
- A procedures and criteria manual for certification of water supply laboratories.
- Interim radiochemical methodology for drinking water.

The responsibility for implementing intralaboratory quality control rests with the individual laboratory and monitoring programs. Intralaboratory quality control is identified in this plan to cover research outputs and technical services that are directly relatable to day-to-day conduct of quality control within the laboratory and in the field.

Development and implementation efforts in intralaboratory quality control include:

- Development and distribution to water laboratories each year of 5,000-7,000 sets of quality control samples for checking data from analysis of water and wastewater for minerals, nutrients, trace metals, biological oxygen demand, linear alkylate sulfonate, pitrilotriacetic acid, and chlorophyll.

- Contract development of 12,000 quality control reference samples for river sediment, suspended solids, and petroleum hydrocarbons.

- Contract development of 10,500 mineral, nutrient, trace metal, and oxygen demand reference samples; 5,000 samples for sludges.

- Distribution of approximately 1,500 calibrated samples containing radionuclides to State and private laboratories each year.

- Distribution to laboratories of mixed radionuclide solutions prepared by NBS for calibration of NaI detectors.

- Distribution, under an interagency agreement with NBS, of calibrated solutions of radium-228 to laboratories engaged in radioanalysis of public drinking water supplies.

- Continuation of cross-check samples program for radionuclides.

Interlaboratory quality control development and implementation efforts include:

- On-site evaluation of all EPA Regional laboratories and the National Enforcement and Investigation Center laboratories.

- Development of a computerized pilot system for increasing efficiency of interlaboratory performance tests, data analysis, and preparation of reports.

- Interlaboratory performance tests for water and wastewater measurements, including radioanalysis of gross alpha, gross beta, gamma, tritium, plutonium-239, and radium-226.

- Development and maintenance of standard reference materials and samples needed for interlaboratory calibrations and performance tests.

- Direct assistance to the Regions in on-site evaluations of radiochemistry laboratories.

- Formal agreement with NBS to establish and document the traceability of the Environmental Monitoring and Support Laboratories to the national measurement system for the analysis of selected radionuclides.

Quality control training and laboratory certification efforts include:

- Biennial technical meetings with all Regional quality control coordinators.

- Training of Regional laboratory evaluation teams in proper use of procedures and protocols for on-site inspection of water and wastewater laboratories.

- Evaluation of procedures and acceptance criteria for certification of drinking water laboratories.

Future Research Needs

As monitoring systems are improved, as systems are standardized and validated, and as monitoring programs expand or change emphasis, quality control guides, procedures, and manuals must be updated. Some specific needs are:

- Manual of validated sampling and sample preservation procedures.

- Updated manual of methods for water and wastewater.

- Guidelines for chain-of-custody of enforcement samples developed in cooperation with Office of Enforcement.

- Quality control guidelines for performance specifications, calibration, and maintenance for continuous water quality monitors and automatic samplers.

- Updated quality control manual to cover potable waters.

- Manual of measurement methods for sediments.

Intralaboratory quality control requires considerably more emphasis than it has received in the past. Some progress has been made as a result of the EPA Regional laboratory evaluations and the requirement for quality assurance plans in all ORD laboratories. However, in future planning, a timetable should be developed and the required resources provided for follow-up activities in the Regional laboratories and for the evaluation and assessment of quality control procedures in all EPA laboratories. The need for existing and new quality control samples continues to grow. In particular, the materials required for quality control of potable waters measurements (heavy metals, trace elements, radionuclides, pesticides, organic carcinogens, and other hazardous substances) must be produced and distributed on a national basis. Continued support for intergovernmental program assignments in water supply will be required through FY-1980. This arrangement provides support for the Regions in laboratory certification, and also provides on-the-job training for selected persons from many of the States.

The interlaboratory quality control program for water measurements has made progress in many important areas. As participation in the program grows, many additional reference materials must be produced, and traceability studies must be conducted to ensure their accuracy. Also, performance tests required by the pending water supply laboratory certification program must be conducted. Better coordination is required between the three Environmental Monitoring and Support Laboratories (EMSL) and the various monitoring programs underway in other parts of EPA. (Limited EMSL staff cannot maintain liaison with all monitoring programs.) The standardization of reporting definition(s) of minimum detectable limit(s), control limits, and uncertainties must be discussed and agreed upon if the Agency is to have an internally consistent interlaboratory quality control program. Some specific needs are:

- Traceability of measurements to the national measurement system at NBS, which was not discussed in the 1973 strategy document, should be addressed; resources should be included to ensure the traceability of Agency reference materials and samples, as far as possible.

- Standard reference samples and performance audit samples are needed to support existing and planned EPA standards and regulations for municipal and industrial effluents, ocean disposal, drinking water, and ambient water quality.

- Standard reference samples and performance audit samples are needed for hazardous substances promulgated in compliance with Section 307(a) of the Federal Water Pollution Control Act Amendments.

- The laboratory intercomparison studies program, which is designed to evaluate (audit) laboratory performance, assess the quality of analytical procedures, and ensure

that environmental data produced by Federal, State, and private laboratories are compatible, accurate, and legally defensible, should be continued.

- Development of data audit systems should be continued for all water quality information systems.

Quality assurance efforts for the energy program are considered separately. However, many of the outputs and activities discussed will be needed to support assessment of impact on water quality during the extensive development of energy sources in eight western States.

Biological Materials and Other Environmental Media

Quality control efforts in biological materials and other environmental media are focused on providing support for the monitoring of pesticides and radionuclides in tissues and other environmental media. Much of the effort in this area represents long standing commitments to the pesticides community studies program and the Radiation Alert Network. State, private, and contract laboratories are provided quality assurance research outputs and quality control services.

Current Status

Quality control guides and procedures include:

- Quality control manual for analysis of pesticide residues in plant and animal tissues, blood, urine, etc.
- A preliminary quality control manual for radiochemical analysis of milk, food, soil, etc.
- Brochures describing the use of standard reference samples of radionuclides and the interlaboratory cross-check sample program.

Intralaboratory quality control activities include:

- Provision of quality control samples for pesticides and radionuclides.
- Standardized gas chromatographic column packings for separation of pesticide residues.
- Direct technical assistance and consultation.

Interlaboratory quality control activities include:

- Regularly scheduled interlaboratory performance tests for 13 to 19 contract laboratories that service the pesticide community studies program.
- Monthly and quarterly cross-check sample studies for radiochemical analysis of milk, food, and soil.
- On-site evaluation of State radiochemical laboratories as requested by the Regions.
- Cross-check sample studies to support the Nuclear Regulatory Commission (NRC).

Quality control training and laboratory certification efforts include:

- Participation in national conferences and seminars.
- Consultation to Regions, NRC, Energy Research and Development Administration, etc.
- Provision of laboratory performance reports to NRC to support its licensees and licensees contract laboratories.

Future Research Needs

Monitoring strategies and research plans currently being prepared for pesticides, carcinogens, and hazardous materials will impact future needs in this important and diverse area of quality control. However, based upon current knowledge, projected needs are:

- Quality control guides and manuals to be updated at least once every 3 years.
- Provision of quality control samples for pesticide residues and radiochemical analysis to be continued and expanded.
- Interlaboratory comparison studies for pesticides and the cross-check sample program for radionuclides to be continued and repositories of standard reference samples to be maintained. The Regions will require assistance in conducting on-site evaluation of laboratories, performance, and data audits.
- Quality control training needs are critical in this area and include training for EPA, State personnel, and others in the complex analysis of pesticides and in quality control techniques for pesticide residue and

radiochemical measurements. Coordination and communication between program offices, Regions, and laboratories need to be improved.

Quality Control Training and Laboratory Certification

Although Headquarters participates in the conduct of Regional quality control workshops, the level of effort directed towards direct training in the use of quality control practices is far below what is needed. Immediate consideration should be given to expanding our national training programs to include quality control. Specific requirements are:

- Preparation of instructional materials for use both nationally and Regionally.
- Continuation of the biennial meetings of Regional quality control coordinators.
- Participation in Regional qaulity assurance workshops, seminars, and conferences.
- Publication of quality control information.
- Conduct of a national quality assurance conference and workshop.
- Conduct of workshops specifically for on-site evaluation of water supply laboratories.

The evaluation procedures and acceptance criteria for certifying water supply laboratories are generally acceptable to user groups. However, the implementation and management of the program present many problems. Of particular concern to the Regions is their lack of expertise needed to conduct on-site evaluations of State and local radiochemical laboratories. Requests from the Regions indicate that they are going to depend upon EMSL-Las Vegas personnel to directly assist in this area.

QUALITY ASSURANCE IN RESEARCH LABORATORIES

The quality assurance program in EPA has concentrated on ambient and source measurements. Research activities, including dose-effects experiments, have historically not been addressed by this program. As a result, while the biological scientist in EPA uses accepted procedures, such as National Institutes of Health guidelines for animal handling and care, dose determinations have not been uniformly subjected to similarly rigid quality assurance procedures. For instance, the research laboratories do not routinely participate in formalized split sample programs, nor do they formally require careful documentation, including the purity of chemicals used in their research.

The need for a uniform approach to quality assurance, particularly in dose-effects experiments, has become very important in view of the present

emphasis on substances that may have carcinogenic or other toxic effects at very low doses, as well as the increasing reliance upon data obtained from extramural researchers. Experience indicates that any regulatory action (setting of standards, etc.) taken by the Agency will be scrutinized and challenged by industry, environmentalists, and even other Federal agencies.

It should be emphasized that the investigators who conduct experiments are, under all circumstances, responsible for the quality of their results and the use of appropriate quality assurance practices.

Current Status

All ORD laboratories are preparing quality assurance plans tailored to the specific research conducted in the individual laboratory. Also, recognizing the critical role played by the health-related research programs, EPA has awarded a contract for development of quality assurance protocols that the Health Effects Research Laboratories and their extramural investigators can use to control and document data quality.

Future Needs

The plans prepared by the EPA laboratories and the contract referred to will identify the specific needs that must be addressed and will be fundamental to the planning and implementation of this program in FY-1978.

QUALITY ASSURANCE EFFORTS RELATED TO THE ENERGY PROGRAM

ORD's Office of Energy, Minerals, and Industry coordinates a $100 million per year energy-related environmental research and development program. Various aspects of this interagency program require measurement and monitoring efforts to provide environmental quality data to EPA and other Federal agencies. Therefore, quality assurance support is required.

Current Status

Quality assurance was recognized as a key element in the formation and implementation of the interagency program. Quality assurance requirements of ongoing monitoring within the program are being coordinated with the appropriate Environmental Monitoring and Support Laboratory.

Future Needs

Funding the quality assurance efforts for the energy program is separate from other resource requirements discussed in this document.

III. RESOURCE LEVELS AND IMPLEMENTATION OPTIONS

Over the past several years, EPA has promulgated many regulations and standards that require frequent or routine monitoring of ambient air and water, wastewater discharges, public drinking water supplies, emissions from stationary and mobile pollution sources, lead and phosphorus in gasoline, and special categories of hazardous substances such as radionuclides, pesticides, and carcinogens. To meet these monitoring requirements, EPA's quality assurance program must provide validated measurement systems, reference standards, and the necessary quality control materials and services.

Quality Assurance is, for the most part, a level-of-effort activity, and the resources available directly impact the scope of work with respect to the number and types of monitoring functions that can be covered. An optimum quality assurance program should provide:

- Valid measurement and quality control systems to support implementation by program offices and the Regions of regulations and standards at reasonable cost.
- Continuous review and evaluation of the performance and data quality of monitoring systems.
- Support for monitoring emergency episodes, environmental quality trends, and special research studies.

The most essential activities and outputs include the following:

- An Agency-wide quality assurance management plan endorsed by the EPA Administrator.
- Repositories of standard reference samples and materials to support measurement methods validation, internal quality control of field and laboratory measurement systems, and external interlaboratory performance checks and audits of measurement systems and operators.
- Measurement standardization procedures and acceptance criteria that can be used internally, externally, and nationally for selection and endorsement of methods for official EPA use.

- Guidelines for development of minimum quality control programs for air, water, water supply, biological materials, and other environmental media.

- Standardized and validated total measurement systems for all current and planned regulations and standards that require compliance monitoring.

- Formal equivalency protocols for approval of measurement methods/systems as alternative to those methods promulgated by EPA.

- Quarterly interlaboratory performance tests covering routine measurements and special monitoring studies.

- Standardized laboratory evaluation guidelines and acceptance criteria that are acceptable to EPA Regional, State, and local laboratories.

- Annual on-site evaluation of Regional and other EPA laboratories.

- Annual instruction and support of Regional evaluation teams so that they can uniformly and effectively evaluate State and local laboratories and monitoring programs.

- Computerized system for screening out improbable values and documenting the statistical quality of the data from all monitoring systems that input to the EPA data banks.

- Compendia or manuals of measurement methods and systems approved by EPA and updated biennially.

- Continued and improved biennial meetings of the Regional quality control coordinators. Meetings should rotate among the 10 Regions with representation from those States in the Region where the meeting is held.

- The national work plan and committee for the Pilot Secretariat for Measurement of Pollution under the auspices of the International Organization of Legal Metrology. (This is an international treaty organization that the United States joined to protect a favorable balance of trade with other treaty nations.)

The above functions and research outputs are critical to successful implementation of a viable EPA quality assurance effort. Furthermore, since there are subtle but major differences among the various types of monitoring activities, many quality assurance functions and research outputs must be duplicated to meet specific requirements with respect to pollutants measured, source and concentration levels, environmental matrix in which the pollutant is found, and purpose for which the data are being obtained. For example, a measurement system and quality control program for measuring pesticides in industrial waste effluents will not be adequate for measurement of pesticides in public drinking water because of the extreme differences in the concentration levels of the pesticides and the interferents present. The same type of analogy can be made for ambient air measurements versus measurement of stationary and/or mobile source emissions.

In addition to those functions and research that are critical to the quality assurance program, other important types of outputs and ancillary efforts are needed:

- Provide improved program coordination by establishing an Intraagency Quality Assurance Advisory Committee.
- Develop instructional materials and support for national and Regional quality assurance training programs, workshops, and seminars to upgrade laboratory and field monitoring support activities.
- Develop system(s) for quantifying and reporting quality assurance progress in terms of data quality versus quantity, type, source, etc.
- Coordinate and support feasibility studies and, where appropriate, develop laboratory automation systems to improve efficiency of analytical operations, sample management, quality control, and preparation of laboratory reports.
- Develop and publish a statistical quality control handbook addressing the total needs of environmental monitoring, including special research monitoring studies and guides for interpretation of data, along with a glossary of terms.

While not absolutely essential, the above items represent reasonable requests made by the various national monitoring programs.

SUMMARY OF RESOURCES

Three options for funding the quality assurance effort are summarized below:

OPTION 1

	FY-1977	FY-1978	FY-1979	FY-1980	FY-1981	FY-1982
$M	5.3	5.3	6.3	8.5	10.0	10.0
MY	67	67	67	67	67	67

OPTION 2

$M	5.3	6.3	8.5	10.0	10.0	10.0
MY	67	77	87	87	87	87

OPTION 3

$M	5.3	8.5	9.5	10.5	11.5	12.0
MY	67	87	90	90	90	90

The national scope and complexity of the quality assurance effort require competent scientists to carry out the diverse functions of the program and to establish effective communication with the monitoring community. Staff requirements and funds must be considered in trying to arrive at a "hard needs" or "optimum" budget. Consider these facts: Maximum use will be made of contracts, grants, and interagency agreements for such efforts as development of computer hardware and software for analyzing and reporting data from collaborative tests and performance audits; quality control samples for operation of intralaboratory quality control; investigations of sampling site validations, sample collection, and sample preservation; field and laboratory evaluations and tests of analytical methods and instruments; and preparation and publication of guidelines, procedures, training materials, and methods manuals. About 45 percent of the dollar resources will be used for these types of extramural efforts. However, monitoring the cost-effective use of extramural funds requires a staff experienced in environmental methodologies and quality control.

On the other hand, EPA must maintain the responsibility for providing expert advice and guidance on the use, operation, performance, and data output for all monitoring methodologies and systems promulgated in suport of regulations and standards. This means that the Agency's quality assurance function must be adequately staffed to:

- Evaluate and validate measurement systems under real and adverse operating conditions.
- Design and conduct tests to determine the reliability and bias of measurement methods in the hands of a cross-section of users.
- Advise others on the proper calibration and operation of measurement systems based upon experience.
- Provide quality control guides and materials to document the validity and accuracy of the data produced.

- o Provide continual overview of operational monitoring systems, suggesting corrective actions when malfunctions occur.

IMPLEMENTATION UNDER THE VARIOUS RESOURCE OPTIONS

Option 1

Under Option 1, the FY-1978 program will not change substantially from the FY-1977 program. In fact, some curtailment and/or redirection in current activities may be needed to provide a critical mass for addressing "highest" priority areas. For example, in the water measurements area, emphasis will be given to meeting critical needs for the water supply and permit program. A level-of-effort activity will be carried out in the evaluation and validation of measurement methods that have been promulgated, and a minimum quality control program will be implemented. Program efforts that are most likely to be restricted under this option include: automated laboratory systems, provision of quality control samples, development of new standard reference samples, marine water measurement methods, the number of measurement methods that can be validated (participation in Regional quality assurance workshops), and direct assistance to the Regions in the certification of water supply laboratories. Under this option, all Agency quality assurance needs requiring in-house man-hours will have to compete on a priority basis for the limited manpower available.

In the air measurements area, the quality assurance efforts will concentrate primarily on standardization and improvement of measurement methods for stationary sources, limited performance audits of source measurements, maintenance of reference samples and materials, and continuation of the interlaboratory tests for ambient air measurements.

Also, under this option, the ongoing quality assurance efforts for measurements of tissues and other environmental media will continue at the same level as in FY-1977. Primary emphasis will be on the support of the pesticide residue monitoring program and on the radiochemical measurements for milk, food, and soil.

In the years beyond FY-1978, and projecting no change in man-years, the quality assurance effort will be expanded and improved in those areas that can be done extramurally: laboratory and field evaluation of sampling and analysis systems; preparation and distribution of quality control samples for routine use; and development and publication of quality control procedures, methods manuals, and the like. Those efforts that require dedicated in-house personnel will not substantially improve: measurement methods validation and approval of alternate test procedures; on-site evaluation of laboratories; interlaboratory performance tests and development of the associated standard reference samples; and direct technical assistance to laboratories that need to improve performance and data quality.

Activities and outputs under this resource option are summarized in Charts 1 - 4.

Option 2

Option 2 represents an increase of $1M and 10 positions for FY-1978. This increase will be allocated to support Standards of Performance for New Stationary Sources under the Clean Air Act, effluent guidelines regulations under Section 304(g) of the Federal Water Pollution Control Act Amendments, and the Safe Drinking Water Act. More specifically, $500K and 5.5MY will be allocated to support the water supply program, including test procedures, reference samples, and laboratory certification. The remainder of the FY-1978 increase, $500K and 4.5MY, will be used to support effluent guidelines regulations, performance audits for air pollution source measurements, and critical measurements of noncriteria air pollutants.

The FY-1978 level of resources in Option 2 is not adequate, in dollars or man-years, to provide a comprehensive quality assurance effort to support existing regulations, and it certainly does not provide for coverage of the Consent Decree pollutants, ocean dumping regulations, etc.

In the years beyond FY-1978, the resource allocation of Option 2 allows a gradual development, implementation, and maintenance of a national quality assurance effort covering all existing and currently planned air and water regulations, standards, and monitoring requirements.

The activities and outputs under this option are summarized in Charts 5 - 8.

Option 3

Under Option 3, the gaps in the current program can be quickly closed and a comprehensive quality assurance program developed for all existing and currently planned environmental monitoring. This option includes quality assurance support for programs implementing the mandates of the Safe Drinking Water Act, the Federal Water Pollution Control Act Amendments of 1972, the Clean Air Act Amendments, the Federal Insecticides, Fungicides, and Rodenticides Act, the Marine Protection, Research, and Sanctuaries Act of 1972, and the Settlement Agreement and Consent Decree pollutants. This option also includes the support and ancillary requirements associated with radionuclide measurements as they apply to the above Acts, to the Atomic Energy Act and amendments, and to EPA support to the Nuclear Regulatory Commission. In FY-1978, the $3.2M and 20MY increases requested would be allocated approximately as shown below:

Activity Funded	$K(MY)
Standardization of water supply measurement methods, reference samples, guidelines, and assistance to Regions and States for laboratory certification	1,200(5)

Quality assurance program for monitoring reports on wastewater discharges, including some on-site inspections	200(3)
Standardization of Section 304(g) test procedures and establishment of a measurement methods equivalency program	450(3)
Performance audits for stationary source measurements	260(4)
Performance audits and measurement system evaluation for Consent Decree pollutants and other noncriteria air pollutants	340(3)
Standardization and optimization of measurement systems for Consent Decree pollutants in water and wastewater discharges	700(1)
Ancillary activities (reports, data, coordination, conferences)	50(1)

At the Option 3 level of resource allocation, the program in the years beyond FY-1978 is designed to provide the reference or standard monitoring methods, quality control procedures, associated standard reference materials, quality control program audits, and expert advice and assistance needed by either the Agency's operational monitoring programs or the States in carrying out their mandated monitoring requirements.

Under this option, more attention will be given to developing and carrying out a quality assurance effort to meet the needs of research laboratories and special monitoring studies.

It should be reemphasized that a successful quality assurance effort requires a competent multidisciplinary staff along with an adequate allocation of funds. Only then can EPA accurately assess changes in the environment. The challenge of rapid changes in advanced technologies, diversification of industries, population changes and migrations, and new energy sources demand a quality assurance effort flexible enough to meet long-term, short-term, and emergency monitoring data requirements. As improved or new monitoring systems are developed, and monitoring initiatives and emphasis change, the quality assurance functions and research outputs, in a generic sense, will be repeated. Therefore, from year to year, the quality assurance program and outputs will look the same, while meeting the demands for assuring data quality from radically different and new types of monitoring activities.

Activities and outputs under this option are summarized in Charts 9 - 12.

CHART 1 - OPTION (1) QUALITY ASSURANCE IMPLEMENTATION PLAN* - GENERAL

Quality Assurance Activity/Output	FY 1977	FY 1978	FY 1979	FY 1980	FY 1981	FY 1982
Agency-wide Quality Assurance Management Plan	-	-	I	U	U	U
Measurement System Standardization Protocols	-	-	-	I	-	U
Pilot Secretariat for Measurement of Pollution	I	IC	-	-	-	-
Regional Quality Control Coordinators Meetings	I	I	-	-	-	-
Materials and Support for Regional/National Training	-	-	-	I	-	-
Intraagency Quality Assurance Coordinating Committee	-	-	-	-	-	-
Agency Quality Assurance Progress Reports	-	-	-	-	-	-
Statistical Quality Control Handbook/Glossary	-	-	I	-	-	-
Laboratory Automation Systems	I	ID	Future needs to be determined			
National Quality Assurance Conference	-	-	-	-	-	-
Regional Quality Assurance Workshops	-	-	-	-	-	-
Quality Assurance Reports to the Regions and States	-	-	-	-	-	-
Quality Assurance Support for Research Laboratories	I	ID	I	-	-	-

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E = Expanded to adequate level
U = Updated

CHART 2 - OPTION (1) QUALITY ASSURANCE IMPLEMENTATION PLAN* - AIR

Quality Assurance Activity/Output	FY 1977	FY 1978	FY 1979	FY 1980	FY 1981	FY 1982
Base Program						
Guidelines, Procedures, Manuals	I	I	I	IE		
System Standardization/Validation	I	ID	C	I	by contract	
Reference Samples and Materials	ID	ID	IC	I	as practicable	
Interlaboratory Quality Control	IC	ID	C	I		
Performance Audits for Special Studies	ID	ID	C	I		
Projected Program						
o Measurement System Standardization, Validation Reference Samples, Performance Audits for Consent Decree Pollutants	-	-	I		by contract as practicable	
o Performance Audits for Stationary Sources Measurements for New Source Performance Standards	ID	ID	C	ID	ID	ID
o Measurement Method Evaluations Testing, Reference Samples, and Materials for Non-criteria Pollutants Including Sulfates	-	-	I	by contract as practicable		
o On-site Evaluation of Monitoring Stations and System for Validation of Sites	-	-	I	-	-	-
o Technical Assistance and Follow-up on Unsatisfactory On-site Evaluation and Interlaboratory Performance Tests	-	-	I	-	-	-

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CHART 3 - OPTION (1) QUALITY ASSURANCE IMPLEMENTATION PLAN* - WATER

Quality Assurance Activity/Output	FY 1977	FY 1978	FY 1979	FY 1980	FY 1981	FY 1982
Base Program						
Guidelines, Procedures, Manuals	I	-	-	I	by contract	
System Standardization/Validation	ID	ID	ID	I	as practicable	
Performance Specification for Samplers/Monitors	ID	ID	ID	I		
Reference Samples and Materials	ID	IC	IC	I		
Interlaboratory Quality Control	ID	-	ID	I		
Projected Program						
o Water Supply Measurement Methods Standardization; Reference Samples Performance Tests; On-site Evaluations; Certification Procedures	ID	ID	ID	I		
o Measurement Methods Equivalency Program for Effluent Guidelines, Others	-	-	-	I		
o Quality Assurance Support for Discharge Monitoring Reports Including Some On-site Evaluations	-	-	-	I		
o Measurement System Validation and Performance Tests for Consent Decree Pollutants	-	-	-	I	by contract as practicable	
o Quality Assurance Support for Biological and Microbiological Monitoring Efforts	ID	C	C	I		
o Technical Assistance/Follow-up Unsatisfactory On-site Inspections and Performance Evaluations	-	-	-	I		
o Quality Assurance Program for Marine Waters, Ocean Dumping	-	-	-	I		

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CHART 4 - OPTION (1) QUALITY ASSURANCE IMPLEMENTATION PLAN* - BIOLOGICAL MATERIALS & OTHER ENVIRONMENTAL MEDIA

Quality Assurance Activity/Output	FY 1977	FY 1978	FY 1979	FY 1980	FY 1981	FY 1982
Base Program						
Guidelines, Procedures, Manuals	I	ID	C	I	by contract	
System Standardization/Validation	ID	ID	C	I	as practicable	
Reference Samples and Materials	ID	ID	C	I		
Interlaboratory Quality Control:						
Cross-check Sample Studies	I	ID	C	I		
On-site Evaluations	ID	ID				
Projected Program						
o Provide Measurement System Standardization Support for the Consent Decree Pollutants	-	-	-	-	-	-
o Develop and Provide Standard Reference Samples and Materials for the Consent Decree Pollutants	-	-	-	-	-	-
o Develop and Provide Reference Samples for Radionuclides in Milk, Food, Soil and River Bottom Sediments	ID	C	I	by contract as practicable		
o Develop and Provide Reference Samples of Pesticides in Mothers' Milk, Animal Tissues, Blood, Urine, and Soil	ID	C	I			
o Provide Support for the Nuclear Regulatory Commission	ID	I				
o Assist Regions in On-site Evaluations of Radiochemical Laboratories	ID	-	-	-	-	-
o Develop Quality Effort to Cover the Analysis of Pesticide Formulations	-	-	-	-	-	-

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CHART 5 - OPTION (2) QUALITY ASSURANCE IMPLEMENTATION PLAN* - GENERAL

Quality Assurance Activity/Output	FY 1977	FY 1978	FY 1979	FY 1980	FY 1981	FY 1982
Agency-wide Quality Assurance Management Plan	-	I	U	U	U	U
Measurement System Standardization Protocols	-	-	-	-	-	-
Pilot Secretariat for Measurement of Pollution	I	I	I	I	I	I
Regional Quality Control Coordinators Meetings	I	I	I	I	IE	IE
Materials and Support for Regional/National Training	-	-	-	-	I	I
Intraagency Quality Assurance Coordinating Committee	-	-	I	IC	IC	IC
Agency Quality Assurance Progress Reports	-	-	I	I	I	I
Statistical Quality Control Handbook/Glossary	-	-	-	-	I	-
Laboratory Automation Systems	I	ID	I	I	I	I
National Quality Assurance Conference	-	-	I	-	-	I
Regional Quality Assurance Workshops	-	-	-	-	-	-
Quality Assurance Reports to the Regions and States	-	-	-	-	-	-
Quality Assurance Support for Research Laboratories	-	-	-	I	IC	-

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CHART 6 - OPTION (2) QUALITY ASSURANCE IMPLEMENTATION PLAN* - AIR

Quality Assurance Activity/Output	FY 1977	FY 1978	FY 1979	FY 1980	FY 1981	FY 1982
Base Program						
Guidelines, Procedures, Manuals	I	I	C	C	C	C
System Standardization/Validation	I	I	IE	IE	IE	IE
Reference Samples and Materials	I	I	IE	IE	IE	IE
Interlaboratory Quality Control	I	ID	IE	IE	IE	C
Performance Audits for Special Studies	ID	ID	IE	IE	IE	IE
Projected Program						
o Measurement System Standardization, Validation Reference Samples, Performance Audits for Consent Decree Pollutants	-	ID	I	IE	IE	IE
o Performance Audits for Stationary Sources Measurements for New Source Performance Standards	ID	I	IE	IE	C	C
o Measurement Method Evaluations Testing, Reference Samples, and Materials for Non-criteria Pollutants Including Sulfates	-	I	C	C	C	C
o On-site Evaluation of Monitoring Stations and System for Validation of Sites	-	-	IC	IC	IC	IC
o Technical Assistance and Follow-up on Unsatisfactory On-site Evaluation and Interlaboratory Performance Tests	-	-	-	-	-	-

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CHART 7 - OPTION (2) QUALITY ASSURANCE IMPLEMENTATION PLAN* - WATER

Quality Assurance Activity/Output	FY 1977	FY 1978	FY 1979	FY 1980	FY 1981	FY 1982
Base Program						
Guidelines, Procedures, Manuals	I	I	IE	IE	C	C
System Standardization/Validation	ID	ID	I	I	I	I
Performance Specification for Samplers/Monitors	ID	ID	I	IE	IE	IE
Reference Samples and Materials	ID	ID	ID	IE	IE	IE
Interlaboratory Quality Control	ID	ID	IE	IE	IE	IE
Projected Program						
o Water Supply Measurement Methods Standardization; Reference Samples Performance Tests; On-site Evaluations; Certification Procedures	ID	ID	IE	IE	C	C
o Measurement Methods Equivalency Program for Effluent Guidelines, Others	-	-	I	C	C	C
o Quality Assurance Support for Discharge Monitoring Reports Including Some On-site Evaluations	-	ID	C	C	C	C
o Measurement System Validation and Performance Tests for Consent Decree Pollutants	-	ID	IE	C	C	C
o Quality Assurance Support for Biological and Microbiological Monitoring Efforts	ID	ID	C	IE	IE	IE
o Technical Assistance/Follow-up Unsatisfactory On-site Inspections and Performance Evaluations	-	-	ID	IE	IE	IE
o Quality Assurance Program for Marine Waters, Ocean Dumping	-	-	ID	IE	IE	IE

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CHART 8 - OPTION (2) QUALITY ASSURANCE IMPLEMENTATION PLAN* - BIOLOGICAL MATERIALS & OTHER ENVIRONMENTAL MEDIA

Quality Assurance Activity/Output	FY 1977	FY 1978	FY 1979	FY 1980	FY 1981	FY 1982
Base Program						
Guidelines, Procedures, Manuals	I	I	IE	IE	C	C
System Standardization/Validation	ID	ID	IE	IE	IE	IE
Reference Samples and Materials	ID	ID	IE	IE	IE	IE
Interlaboratory Quality Control:						
Cross-check Sample Studies	I	ID	IE	IE	IE	IE
On-site Evaluations	ID	C	IE	IE	C	C
Projected Program						
o Provide Measurement System Standardization Support for the Consent Decree Pollutants	-	-	ID	IE	IE	IE
o Develop and Provide Standard Reference Samples and Materials for the Consent Decree Pollutants	-	-	ID	IE	IE	IE
o Develop and Provide Reference Samples for Radionuclides in Milk, Food, Soil and River Bottom Sediments	ID	ID	IE	IE	IE	IE
o Develop and Provide Reference Samples of Pesticides in Mothers' Milk, Animal Tissues, Blood, Urine, and Soil	ID	ID	IE	IE	IE	IE
o Provide Support for the Nuclear Regulatory Commission	ID	I	C	C	C	C
o Assist Regions in On-site Evaluations of Radiochemical Laboratories	ID	-	ID	C	C	C
o Develop Quality Effort to Cover the Analysis of Pesticide Formulations	-	-	-	ID	C	C

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CHART 9 - OPTION (3) QUALITY ASSURANCE IMPLEMENTATION PLAN* - GENERAL

Quality Assurance Activity/Output	FY 1977	FY 1978	FY 1979	FY 1980	FY 1981	FY 1982
Agency-wide Quality Assurance Management Plan	-	I	U	U	U	U
Measurement System Standardization Protocols	-	I	U	U	U	U
Pilot Secretariat for Measurement of Pollution	I	IC	IC	IC	IC	IC
Regional Quality Control Coordinators Meetings	I	IE	IEC	IEC	IEC	IEC
Materials and Support for Regional/National Training	-	-	I	IE	IEC	IEC
Intraagency Quality Assurance Coordinating Committee	-	I	IC	IC	IC	IC
Agency Quality Assurance Progress Reports	-	I	IC	IEC	IEC	IEC
Statistical Quality Control Handbook/Glossary	-	-	I	-	-	-
Laboratory Automation Systems	-	I	IC	IC	IC	IC
National Quality Assurance Conference	-	I	-	IE	-	I
Regional Quality Assurance Workshops	-	I	IE	IE	IE	IE
Quality Assurance Reports to the Regions and States	-	I	IE	IE	C	C
Quality Assurance Support for Research Laboratories	-	I	IE	IE	IC	IC

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E = Expanded to adequate level
U = Updated

CHART 10 - OPTION (3) QUALITY ASSURANCE IMPLEMENTATION PLAN* - AIR

Quality Assurance Activity/Output	FY 1977	FY 1978	FY 1979	FY 1980	FY 1981	FY 1982
Base Program						
Guidelines, Procedures, Manuals	I	I	C	C	C	C
System Standardization/Validation	I	IE	IE	IE	IE	IE
Reference Samples and Materials	I	IE	IE	IE	IE	C
Interlaboratory Quality Control	I	IE	IE	IE	IE	C
Performance Audits for Special Studies	ID	IE	IE	C	C	C
Projected Program						
o Measurement System Standardization, Validation Reference Samples, Performance Audits for Consent Decree Pollutants	-	I	IE	IE	IE	C
o Performance Audits for Stationary Sources Measurements for New Source Performance Standards	ID	IE	IE	IE	IC	IE
o Measurement Method Evaluations Testing, Reference Samples, and Materials for Non-criteria Pollutants Including Sulfates	-	I	IE	IE	IE	IE
o On-site Evaluation of Monitoring Stations and System for Validation of Sites	-	I	IE	IE	C	C
o Technical Assistance and Follow-up on Unsatisfactory On-site Evaluations and Interlaboratory Performance Tests	-	I	IE	C	C	C

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C = Continuing at previous level
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E = Expanded to adequate level
U = Updated

CHART 11 - OPTION (3) QUALITY ASSURANCE IMPLEMENTATION PLAN* - WATER

Quality Assurance Activity/Output	FY 1977	FY 1978	FY 1979	FY 1980	FY 1981	FY 1982
Base Program						
Guidelines, Procedures, Manuals	I	IE	IE	C	C	C
System Standardization/Validation	ID	IE	IE	IE	IE	C
Performance Specification for Samplers/Monitors	ID	IE	IE	IE	C	C
Reference Samples and Materials	ID	IE	IE	IE	IE	IE
Interlaboratory Quality Control	ID	I	IE	IE	C	C
Projected Program						
o Water Supply Measurement Methods Standardization; Reference Samples Performance Tests; On-site Evaluations; Certification Procedures	ID	IE	IE	IE	C	C
o Measurement Methods Equivalency Program for Effluent Guidelines, Others	-	I	IE	C	C	C
o Quality Assurance Support for Discharge Monitoring Reports Including Some On-site Evaluations	-	ID	IE	IE	C	C
o Measurement System Validation and Performance Tests for Consent Decree Pollutants	-	I	IE	IE	IE	IE
o Quality Assurance Support for Biological and Microbiological Monitoring Efforts	ID	ID	I	IE	IE	IE
o Technical Assistance/Follow-up Unsatisfactory On-site Inspections and Performance Evaluations	-	ID	IE	IE	C	C
o Quality Assurance Program for Marine Waters, Ocean Dumping	-	ID	IE	IE	C	C

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E = Expanded to adequate level
U = Updated

CHART 12 - OPTION (3) QUALITY ASSURANCE IMPLEMENTATION PLAN*-BIOLOGICAL MATERIALS & OTHER ENVIRONMENTAL MEDIA

Quality Assurance Activity/Output	FY 1977	FY 1978	FY 1979	FY 1980	FY 1981	FY 1982
Base Program						
Guidelines, Procedures, Manuals	I	I	IE	IE	C	C
System Standardization/Validation	ID	I	IE	IE	IE	IE
Reference Samples and Materials	ID	I	IE	IE	IE	IE
Interlaboratory Quality Control:						
Cross-check Sample Studies	I	I	IE	IE	IE	IE
On-site Evaluations	ID	I	IE	IE	C	C
Projected Program						
o Provide Measurement System Standardization Support for the Concent Decree Pollutants	-	I	I	IE	IE	IE
o Develop and Provide Standard Reference Samples and Materials for the Consent Decree Pollutants	-	I	I	IE	IE	IE
o Develop and Provide Reference Samples for Radionuclides in Milk, Food, Soil and River Bottom Sediments	ID	I	IE	IE	IE	IE
o Develop and Provide Reference Samples of Pesticides in Mothers' Milk, Animal Tissues, Blood, Urine, and Soil	ID	I	IE	IE	IE	IE
o Provide Support for the Nuclear Regulatory Commission	ID	I	C	C	C	C
o Assist Regions in On-site Evaluations of Radiochemical Laboratories	ID	I	IE	C	C	C
o Develop Quality Effort to Cover the Analysis of Pesticide Formulations	-	ID	I	IE	C	C

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C = Continuing at previous level
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E = Expanded to adequate level
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IV. SUMMARY HIGHLIGHTS OF EPA REGIONAL COMMENTS

In developing this multiyear quality assurance research plan, the Regional offices were considered the primary users of the quality assurance outputs and services. Therefore, this document has attempted to address the specific needs of the Regions as expressed in their comments on an earlier draft. The Regional comments are presented in summary form in this final section. The comments that follow are arranged according to the number of Regions expressing the same or similar concern for specific types of quality assurance outputs:

- The Regional quality assurance efforts, resources, roles, and responsibilities are not identified and clarified in the plan. A similar plan is needed to cover the Regions and recommendations for the States.

- Protocols should be well defined and coordinated for measurement method standardization, measurement method equivalency determinations and alternate test procedure recommendations.

- A mechanism is needed to quantify data quality, establish procedures for handling data out of control, measure sampling reliability, and estimate progress and cost-effectiveness of quality assurance programs.

- Reference samples are critical to the success of a quality control program and should include samples for ambient waters, ocean disposal, air, pesticide residues, etc.

- More emphasis should be given to the evaluation and validation of all existing measurement methods, particularly the Section 304(g) test procedures and measurement methods for marine waters.

- Improved communication is needed between the quality assurance efforts of the Regions, the EMSL's, and Headquarters, including more frequent meetings of Regional quality assurance coordinators, and an intraagency quality assurance advisory committee.

- Training within the Agency needs to be expanded to include quality assurance, both test procedures and quality control, at the "grass roots" level -- an impossibility without travel funds.

- Guidelines are needed for development of minimum quality control requirements for air and water program managers and for research and monitoring contracts.

- There is a need to improve and continue the quality assurance program for pesticides in water, particularly methods evaluations, collaborative tests, and guidelines. Also, there is no quality assurance program for pesticide formulations.

- A mechanism is needed for establishing quality assurance priorities in terms of specific compounds, sampling methods, etc. A table of priorities should be established for all media, and an ORD effort should be made to coordinate all programs into a single set of priorities.

- Validated measurement methods are needed for sludge sampling, preservation, and analysis, and for sediment sampling and analysis.

- Greater emphasis should be given to validation of bioassay procedures, microbiological measurements, evaluation of methods being used routinely by EPA and others, and coordination of methods developed by other Federal agencies.

- Nationally consistent guidelines should be developed for chain-of-custody for water and wastewater samples.

- Quality assurance guidelines should be published for sample site selection, sampling techniques, flow measurements, and sampling frequencies under Section 208 of the Federal Water Pollution Control Act Amendments.

- There should be some consistency among the various quality assurance groups with respect to procedures, terminology, etc.

- There is a need to establish and adopt minimum acceptance criteria for approval of laboratories, particularly for water supply.

- Quality control guides are very good for air, but there is a need to improve guides for water measurements.

- Any laboratory certification program should be mandatory for both EPA and the States.

- Preplanning in the area of toxic substances is very good; field screening techniques and methods are needed for hazardous and toxic substances.

- More emphasis should be given to quality assurance related to mobile sources, for example, vapor recovery and unleaded fuel.

- In the view of the Regions, the concept of quality assurance for the research laboratories appears to be a very good idea!

- Quality assurance procedures are needed for continuous SO_2 analyzers and for their calibration in the range of 5 to 10 parts per million; also, improved measurement method calibration procedures are needed for NO_2 and ozone.

- EPA management needs to make a strong commitment to quality assurance throughout the Agency.

- Additional resources are needed by ORD and the Regions to provide more technical assistance to State air programs.

- The current funding of the Intergovernmental Personnel Act appointees for the Regional water supply program will be needed through 1980; however, the program should be reviewed each year for effectiveness.

- Ongoing efforts to automate laboratories should be reviewed for appropriateness as a part of the quality assurance program.

It should be noted that these comments are merely the views of the Regions on an earlier version of the quality assurance plan. Some of these comments raise issues that should be addressed by management at various levels of the Agency. Where possible, we have addressed these comments in the present version of the plan. We hope that we will have the opportunity to present some of the more critical issues to top levels of management for resolution.

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16. ABSTRACT

The Office of Research and Development (ORD), through its Office of Monitoring and Technical Support, is responsible for developing an Agency-wide quality assurance program to enable the U.S. Environmental Protection Agency (EPA) to implement its regulatory mission and associated monitoring functions. The major thrust of this document is to identify and justify the resources required by ORD to develop the quality assurance tools, techniques, and services needed by other program offices, the Regions, and the States to generate valid data. This five-year planning document describes the quality assurance program in terms of goals, objectives, and functional elements; summarizes the current status of ORD's ongoing quality assurance efforts; discusses Agency and program needs; and delineates the resources and approaches required to develop and carry out a dynamic quality assurance program which will ensure scientifically valid environmental measurements.

17. KEY WORDS AND DOCUMENT ANALYSIS

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