

# **MEASUREMENT METHODS STANDARDIZATION STRATEGY DOCUMENT**



**September 1973**

**U.S. Environmental Protection Agency  
Office of Monitoring Systems  
Quality Assurance Division**

MEASUREMENT METHODS

STANDARDIZATION

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## Executive Summary

### STRATEGY FOR AGENCY-WIDE MEASUREMENT METHODS STANDARDIZATION

#### Introduction

To maintain and improve the quality of environmental monitoring measurements used by the Environmental Protection Agency (EPA), the Administrator assigned central responsibility for monitoring quality assurance activities to the Office of Monitoring Systems in EPA Order No. 1110.22B. A comprehensive plan for quality control of monitoring operations has been developed and approved. The present document describes a program of measurement methodology standardization designed to complement the quality control activities and, thus, provide complete quality assurance of environmental monitoring data.

The long-range goal of the standardization program is to assure that accurate, precise, reliable, and cost-effective methods (manual and/or automatic) are available for all of the Agency's environmental monitoring measurements. The plan does not address development of methodology, but covers selection and preliminary evaluation, focusing on collaborative, exhaustive, replicative, and statistically significant studies of method performance under a variety of conditions as applied by typical operating laboratory personnel. Such procedures provide the statistical and legal validity that enables EPA to set and enforce unequivocal environmental or source performance standards.

#### Current Status

EPA acquired a variety of standardization activities upon its formation and assigned most of them to the Office of Monitoring Systems. The oldest is the Analytical Quality Control Laboratory (now referred to as the Methods Development and Quality Assurance Research Laboratory) at the National Environmental Research Center in Cincinnati, which has developed a fairly complete manual of methods for water pollution measurements. Many of these methods have been



collaboratively tested. A more recent development is the reasonably well-supported activity for air pollution measurement standardization at the National Environmental Research Center at Research Triangle Park, North Carolina. This Facility is now working to overcome a backlog of methodology requirements stemming from the Clean Air Act. A number of smaller activities within the Office of Monitoring Systems are oriented specifically toward pesticides and radiation. Some standardization and testing activities are also carried out by the Office of Pesticides Programs and the Office of Air and Water Programs. A small extramural standardization activity has been initiated by the Office of Noise Abatement. Also, Regional as well as other EPA laboratories are continually modifying, testing, and developing methods, some of which may contain elements of the validation process.

#### Scope of Standardization Operations

At least three operations are necessary to obtain and utilize environmental data: (1) network design; (2) measurement of appropriate parameters; and, (3) analysis of the data. The standardization plan addresses only the second operation. While taking this approach, we still recognize that statistically-reliable networks are essential. However, such developments involve long-term efforts.

Our immediate concern is the quality of our basic monitoring tool, the measurement method, comprised of four closely related modules: (1) sampling techniques; (2) sample work-up; (3) analysis of the sample; and, (4) presentation of the data. Properly integrated and tested, these four modules comprise a standardized method. With this approach, the Agency can save resources in the short term by testing only those modules of a method that have not been previously tested. For example, atomic absorption spectrophotometers are commonly used for elemental analysis of both air and water samples--they need not be collaboratively tested over and over for each new method. In this way, problem areas in a method are more quickly highlighted and new methods may be approved after simpler, less-expensive testing. Under the modular concept, various programs within the Agency may utilize common methodology to the exact degree which provides the greatest practical benefits.

## Implementation

In order to meet the unsatisfied operational methodology requirements of monitoring activities throughout the Agency, available sampling techniques and analytical methods are being compiled. Experience gained with these methods will provide a valuable head start toward the required scientific validation while also identifying methods which need further development.

Preparation of an Agency standardization protocol will begin in the immediate future (utilizing existing practices wherever applicable). The protocol will describe a logical, step-by-step procedure for identifying, testing, and evaluating monitoring methodology. This protocol will be followed rigorously by quality assurance program personnel, and we have recommended that its use be mandatory throughout the Agency to ensure a consistent level of confidence in measurement methodology (see Action Memorandum).

Methodology equivalency protocols are in preparation. Adherence to these protocols will ensure intercomparability of environmental data generated by different methods.

All Agency programs will be required to report their standardization activities to the quality assurance program for coordination and review. In this way, improved methodology will achieve the widest distribution in the shortest time while unnecessary duplication of effort will be eliminated. An ideal vehicle for this coordination would be an Intra-agency Quality Assurance Coordinating Committee, which is being proposed separately.

## Resources

To meet the Agency's needs, the standardization program has had to allocate its resources to the highest priority requirements. Accordingly, response to many important requirements must be delayed. We have defined four levels of activities which are responsive to these requirements. The first level is our response to the highest priority items or Status Quo. At the Status Quo level (\$1,250K and 29 MY), we are unable to provide timely and reliable reference methods to support environmental standards when they are promulgated. At Level 2 (\$1,900K and 38 MY), we will meet the most critical needs of the Agency including support for

most environmental standards. Level 3 (\$2,440K and 42 MY) would provide an additional capability to evaluate several methods proposed as equivalent and to provide reference methods for a few widely used measurements, even if they are not associated with environmental standards. Finally, at Level 4 (\$2,870K and 48 MY), we could initiate validation activities for the most widely used methods employed in research or trend monitoring, in addition to the basic work included in all lower levels.

## I. INTRODUCTION

### Need for an Agency-wide Quality Assurance Program

The Administrator assigned monitoring quality assurance responsibilities in EPA Order No. 1110.22B to the Deputy Assistant Administrator for Monitoring Systems and directed that he develop and implement an Agency-wide measurement methods standardization and quality control program. The program would assure that environmental data produced by Federal, State, and local agencies are compatible, accurate, and legally defensible. The quality control portion of the program was approved for implementation on February 13, 1973. The standardization program now needs to be approved for implementation to fulfill the mandate delegated to the Office of Research and Development (ORD).

### Goals and Objectives

The single overall goal of the quality assurance program is to ensure that environmental quality data used by the Environmental Protection Agency (EPA) are sufficiently accurate, precise, and reliable to meet Agency needs at a reasonable cost.

Objectives leading to the achievement of this goal include: (1) designing and implementing an appropriate Agency-wide organizational framework for standardization; (2) developing a protocol for standardization; and, (3) implementing a vigorous standardization program.

### Existing Standardization Responsibilities

The standardization of a measurement method takes place after the research on that method has been completed and is done in support of operational monitoring and enforcement programs requiring reliable measurements. Due to the interdisciplinary and inter-program relationships, most of the standardization activities inherited by EPA are now located at the National Environmental Research Centers (NERC) and their satellite laboratories under the management of the Office of Monitoring Systems (OMS). Some additional standardization and quality control activities are carried out by other EPA programs.

1. Activities of the Office of Research and Development

The Office of Research and Development maintains centralized programs for methods standardization designed to support the critical measurement methods needs of the Office of Air and Water Programs (OAWP), the Office of Hazardous Materials Control (OHMC), the Office of Enforcement and General Counsel (OEGC), and the Regions. These activities are located at NERC-Research Triangle Park (RTP), NERC-Cincinnati, and NERC-Las Vegas. With increasingly effective communications and coordination within our ORD programs, we are realizing significant benefits over past efforts in terms of the development of analytical procedures. For example, measurement methods for pesticides in water, air, and land, and in plant and animal tissues are now being developed jointly between methods development groups at NERC-RTP and NERC-Cincinnati.

These efforts are eliminating unnecessary duplication and serving to aggregate our limited personnel resource into "critical interdisciplinary arrays" which allow us to most effectively meet standardization goals. At the present time, the Office of Monitoring Systems has no programs for standardization of solid waste or noise measurement methodology. We expect to activate a noise program at NERC-Las Vegas at some future date.

2. Standardization activities not in the Office of Research and Development

Each Program Office has retained a final review over methods in its area of activity and promulgates these methods to support environmental standards.

The Office of Air and Water Programs is developing and testing methods for measuring emissions in the air from mobile and stationary sources. The Office of Noise Abatement and Control has contracted with the National Bureau of Standards (NBS) to develop and standardize methods for measuring the noise output of regulated items. The Office of Pesticides Programs (OPP) has an in-house quality assurance effort which includes development and standardization of methods and the distribution of standard reference materials. Methods are collaboratively tested by OPP and the Food and Drug Administration (FDA) laboratories. In some instances, the Regions have taken action to supply themselves with

standard reference materials and samples for methods standardization. An example is the Region IX reference sample of San Francisco Bay sediment. Work of this nature meets a legitimate need and will be recognized as we develop and implement the standardization protocol.

#### Gaps in the Standardization Program

1. At the present time, we are still two to three years behind in standardized methods needed for air and water standards.

2. There are not now available standardized methods for measuring specific radionuclides expected to be found in effluents from nuclear facilities.

3. Methods for measurement of pesticides in tissues and soils have not been validated by standardization procedures.

4. There are no standardized methods now available for the vast area of marine monitoring.

5. Until recently, the Office of Research and Development was conducting a small effort in the standardization of methodology for solid waste and solid waste processing characterization. This nucleus has been effectively terminated by recent budget cuts and redirections. Nevertheless, many measurements cannot be taken by simple adaptations of methods developed for air or water programs (e.g., the heat content of waste to be incinerated).

6. We also have no standardization resource commitments to meet the methods needs of the Office of Noise Abatement and Control.

7. Development of the equivalency protocols is lagging.

8. At the present time, mostly non-standardized measurement methods for research and trend monitoring are used to provide the data for criteria development. Data so generated have an unknown degree of uncertainty associated with them. Use of these data for criteria development introduces a like degree of uncertainty in the reliability of subsequent standards. This uncertainty can be avoided only through the use of standardized methods.

## Components of Measurement Methods and Standardization

Measurement, in general, can be regarded to be made up of a series of steps or modular functions. Sequentially, these functions are sampling, sample work-up, analysis, and data output. In some recent in situ measurement methods, these functions have been consolidated into a single instrumental method.

Sampling is the removal from the environmental continuum of a portion of the pollutant for detailed investigation. Sampling involves containerizing a discrete volume of polluted air, water, soil, or biological materials or it may involve partitioning the pollutant directly from these media into a filtering or absorbing device or into another fluid (e.g., the absorption of the sulfur dioxide pollutant in air into a solution of potassium tetrachloromercurate). Additionally, it includes those procedures necessary to preserve the sample. In all of these sampling methods, we must accurately know what fraction of the pollutant passes from the environmental continuum into the sample. Standardization of the sampling method establishes the reproducibility of this relationship. This relationship must be shown to be stable or to follow predictable changes from the time the sample is taken to the time the sample is worked up for analysis.

Sample work-up consists of the preparation of the sample by concentration of pollutant, removal of interfering substances, etc., for the analytical procedures to follow. It must be established that all pollutant losses during sample work-up can be quantitatively accounted for and are reproducible within statistically acceptable limits.

Analytical methods are designed to give accurate estimates of the true amount of pollutant remaining in the worked-up sample. The standardization procedure assures that these values are reproducible within statistically-acceptable limits. The value derived from the analytical method adjusted for predictable losses in sampling and sample work-up gives the estimation of the true concentration of the pollutant in the environmental continuum.

The analytical method is the last step in the measurement method that we must standardize to assure that data are of a consistently acceptable quality. However, it is

also highly desirable that compatible formats for automatic analytical data output be utilized to assure that our large and increasing data base can be adequately evaluated in a timely fashion.



## II. PHASES OF THE STANDARDIZATION PROGRAM

There are two major phases in the proposed standardization program: (a) establishing the elements of the standardization program; and, (b) implementing the standardization program (Table 1). A discussion of these two phases follows.

### A. Elements of the Standardization Program

The standardization program consists of three basic elements: (1) the standardization protocol (Figure 1); (2) equivalency guidelines; and, (3) instrumental data output formatting guidelines.

#### 1. Development and issuance of the standardization protocol

The standardization protocol consists of scientific and statistical procedures prescribed by EPA to evaluate and validate its analytical measurement methods. The protocol prescribes the criteria for initial reviews for methods selection, provides guidelines and details for initial testing, and finally, provides the guidelines and requirements for final validation and endorsement of the standardized method.

Minimally, the initial screening for acceptability of the method is determined by theoretical evaluations or cursory experimental analysis based on chemical, physical, or biological principles. The initial review is designed to provide a first approximation of the ultimate applicability and limitations of the method such as sensitivity and degree of susceptibility to interferences. In many instances, this initial review will have been completed by the methods research program. The protocol logically proceeds to further single laboratory or field testing, confirms or rejects the predictions based upon the theoretical review, and provides the criteria for designating the method as tentatively validated. The protocol then sets out the criteria for the subsequent controlled multi-laboratory collaborative testing of the method. And, finally, the protocol provides the statistical design criteria for analysis of the results of the collaborative test for either rejection or full validation of the method. Because the standardization protocol

TABLE 1Phases of the Standardization ProgramPHASE 1: Establishing the Elements of the Standardization Program

- Development and issuance of the standardization protocol
- Guidelines for determining equivalency
- Guidelines for designating reference methods
- Guidelines for instrumental data output formats

PHASE 2: Implementing the Standardization Program

- Establishment of the standardization program organizational and technical framework
- Implementation and operation under the standardization protocol and equivalency guidelines

will have impact throughout the Agency, it must be developed and approved in concert with all appropriate elements of the Agency.

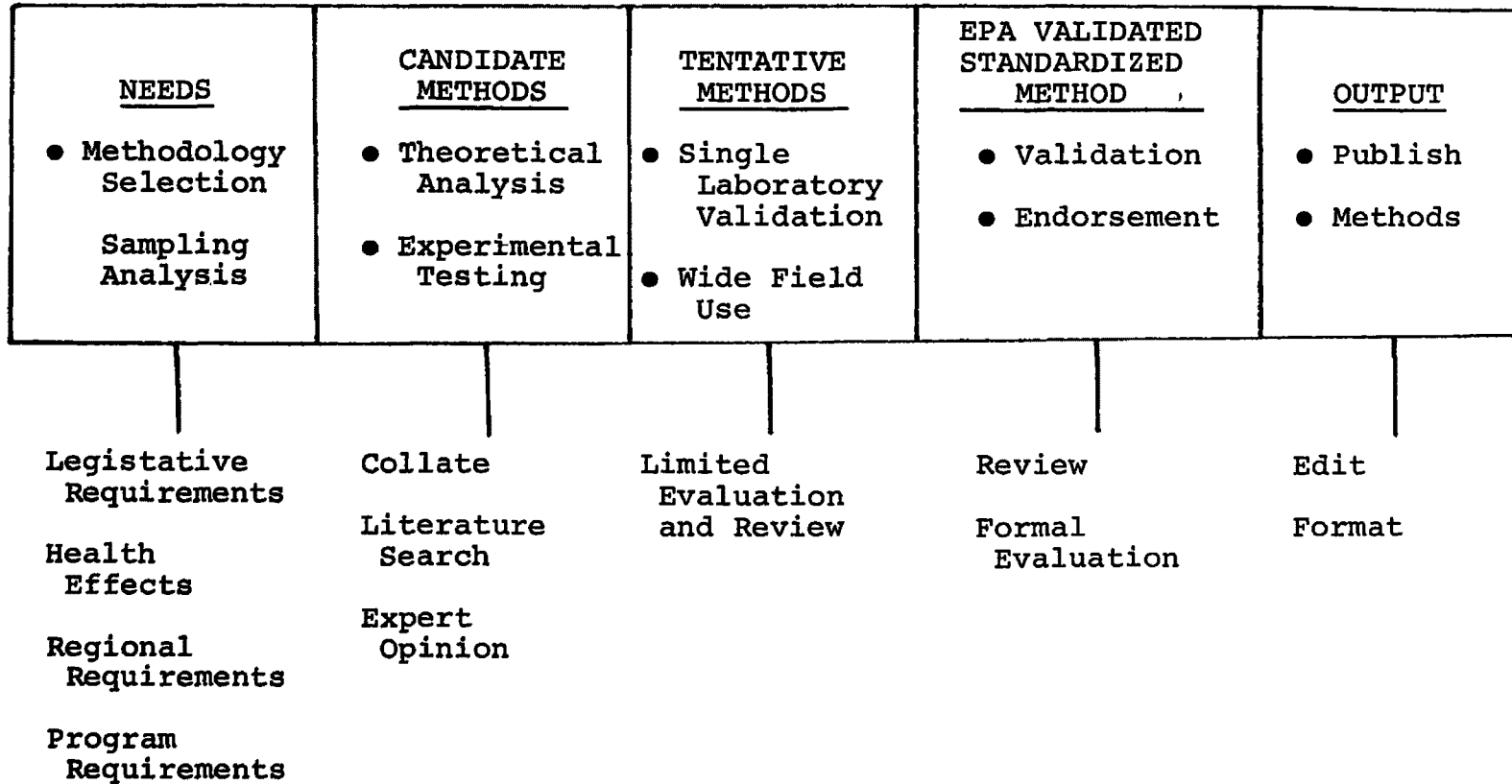
A diagram showing these relationships is illustrated in Figure 1. The initial draft of the standardization protocol is being prepared by the standardization activity. A first review for endorsement will be made by the quality assurance and related standardization activities at the National Environmental Research Centers. The draft protocol will be transmitted to the Office of Research and Development, the Office of Air and Water Programs, the Office of Hazardous Materials Control, and the Office of Enforcement and General Counsel for review and endorsement.

The steps in the standardization process are discussed more fully in the following sections:

a. Identification of methodology needs -- Methodology needs arise from considerations of statutory requirements, needs identified within the Agency, and needs identified outside the Agency. Needs for measurement methods must be identified to be responsive to the Agency's priority missions. The standardization process is lengthy and identification of needs well in advance of deadlines will allow coordination of the standardization process with the schedules of the activities requiring standardized measurement methods. The Office of Research and Development has institutionalized a need identification and reviewing system. Needs are solicited from the Program Offices and Regional Offices as well as from the Office of Research and Development elements. Methods standardization needs can be specifically identified as a single need or they can be highlighted in need statements pertaining to other areas such as criteria and standards development, as well as through projections relating to new priority pollutants from the experiences of field programs and from processes and effects and other research groups. Periodically, contracts and grants have been awarded to make five- to ten-year technology forecasts and predictions of related pollution loadings. These can also serve to identify measurement needs. All submitted needs will be subjected to preliminary reviews by the quality assurance program for first approximation priorities. Final prioritization will be made after review by all appropriate parties, work groups, or caucuses. These

Figure 1

ELEMENTS OF THE STANDARDIZATION PROTOCOL



reviews will determine if methods are available and will determine the relative needs for a method and pronouncement of final priorities. The final priority lists are made the subject of Environmental Research Objective Statements (EROS), Research Objective Achievement Plans (ROAP), and Tasks for funding considerations.

b. Selection of candidate methods\* --

Once a task for standardization of a method for measuring a pollutant has been approved and funded, the known methods applicable to the pollutant, the media, and the measurement purpose under consideration are subjected to theoretical analysis and limited laboratory and field testing for first approximations of applicability and limitations such as detection limitations, sensitivity, and susceptibility to interferences. Measurement methods from the literature or from any other source, within or without EPA, may be considered for inclusion on the list of candidate methods. When no satisfactory method can be identified which meets a particular need through this process, methodology research requirements will be identified and the standardization process will be delayed. Candidate methods are those which successfully pass this initial screening.

c. Evaluation and testing to select tentative methods -- Candidate methods which have been selected for further testing are then subjected to intensive single laboratory testing to verify predictions made by theoretical analysis. The best methods which meet minimum requirements will then be designated as tentative methods. Minimum requirements are those which will be defined by protocol for accuracy, precision, specificity, reliability, interferences, etc. Operational constraints such as cost, cycle time, and temperature limits will be based upon user requirements and state-of-the-art technology. This initial screening and testing may involve both research and program personnel. A tentative method is one which shows acceptable performance under a number of conditions but which has not been collaboratively tested.

d. Collaborative testing -- Collaborative testing is an important step in the validation of any

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

method of measurement to determine, on a statistical basis, the limits of error which can be expected when the method is used by a typical group of investigators. Collaborative testing is generally quite expensive. Accordingly, only those methods which are deemed to be particularly sensitive for the Agency's regulatory functions will be selected from the list of tentative methods for collaborative testing.

The collaborative testing, or inter-laboratory test, of a method is a vital part of the development and standardization of an analytical procedure to ensure that the procedure is clear and complete and to establish with confidence the limits of precision and accuracy which 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 method is fully characterized as to its sensitivity, accuracy, precision, reliability, range, and limits of detection. Additional requirements in terms of interferences, cost, cycle time, power source stability, reagents, operator training, physical environment, and maintenance may also be considered during method validation.

e. Endorsements and publication -- Once the method has been validated by collaborative testing or other procedures as may be deemed appropriate for the end use, 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 which are not part of regulations, this is the highest level of endorsement required before the method is declared a "standardized method" and is published by the quality assurance activity in the Environmental Monitoring Series or in other publications. For methods which support standards and are to be promulgated or cited in regulations, the method is transmitted through normal channels for approval, e.g., working groups and Steering Committee. Final endorsement is made by the Steering Committee before the method is then transmitted to the Administrator for approval as a "standardized reference method" and is published or cited in the Federal Register. Loose-leaf copies of reference methods will receive widespread distribution within EPA so that the method may be quickly and conveniently integrated

into the Agency's monitoring program. The concept of reference method is discussed in greater detail below. It should be noted that this concept is quite different from past uses in the Agency of this term.

Definition of the Term  
"Reference Method"

*As used in the Measurement Methods Standardization Strategy document, only a single method is to be selected by EPA and designated as its reference method for a single environmental pollutant or parameter under the range of conditions for which the method is applicable. The environmental pollutant or parameter measurement may be a chemical, physical, or biological quantity related to environmental quality. A method so designated must have acceptable accuracy and precision performance characteristics which have been scientifically and statistically validated by multiple laboratory collaborative tests under a variety of anticipated user conditions. The method must be readily available to a prospective user laboratory. This will preclude designation of very expensive, sophisticated methods as reference methods even though they may be the most accurate methods available because they would not be available to the large majority of prospective user laboratories. No method will be declared by the Agency as its reference method without full validation.*

*Under most conditions, only reference methods will be made part of the Agency's regulatory promulgations. In most instances, such promulgations should be delayed until applicable "reference methods" are available. Under very extenuating circumstances, use of "tentative methods" which have not been fully validated may be required by the Agency to support its regulatory promulgations. Such usage must clearly designate the interim status of such methods. Tentative methods will be replaced by fully-validated reference methods as soon as they become available.*

*Proper caveats must be included in promulgations which include "tentative methods" clearly explaining their limitations.*

*The reference method is the best, readily available method. Under most circumstances, it will be expected that the reference method will be the method of choice of most user laboratories. When other methods must be used for any reason, their equivalence to the performance characteristics of the reference method must be demonstrated to assure that data generated by their use is equivalent to that generated by the reference method and that statistically valid comparisons can be made between such data and that generated by use of the reference method.*

## 2. Equivalency determination

The concept that there can be only a single reference method in an environmental standard for a given pollutant requires that a provision be made for determining equivalency of alternate methods. The equivalency of a method to an official EPA reference method will be determined through the use of an official EPA test protocol which 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. The Environmental Protection Agency 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. Considering the large number of air, water, and categorical quality and 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. This activity must be given visibility by the quality assurance activities



either as individual tasks within Research Objective Achievement Plans, or better, as the main objective of such a plan.

### 3. Data formatting and instrument data systems compatibility guidelines

A final step in any determination is the recording of data in some form, generally obtained from an electrical signal (for example, a photometer reading). Common methods now in use are manual recording and strip charts; however, because of the continually increasing volume of data to be collected, there is a growing trend toward the use of more sophisticated data handling techniques with the electrical signal converted to a digital signal and recorded directly into a computer-compatible format. In order to encourage this desirable trend and meet increased Agency data handling requirements, the instruments which perform the final step in an analysis should be standardized in their mode of data presentation and manual data handling techniques should present data in a compatible form for entry into automated data handling systems. Therefore, data formatting and instrument data system compatibility are considered in the standardization process. The standardization program will assure coordination between designers of data collection and storage systems and designers of automated environmental monitoring instruments by publishing instrument data output guidelines.

#### B. Implementation of the Standardization Program

Implementation of the standardization program is concerned with two major types of activities: (1) the establishment of an organizational and technical framework for all Agency standardization activities; and, (2) the routine operation of the standardization program under the guidelines established by the protocol and related activities. Whereas the first activity is primarily concerned with management and policy responsibilities of the various organizational elements, the second activity is mainly concerned with the management of resources such as delineation of projects and tasks and the timetables that must be met. In this section of the report, these items are described and analyzed and the implementation plan is given.

# 1. Organization plan

a. Premises -- The organizational plan for the Agency's standardization program is based on the following premises:

- It is the responsibility of EPA to promulgate official reference methods in support of environmental pollution standards and to publish standardized methods for other widely used environmental measurements.
- The Environmental Protection Agency will not publish, as reference methods, any method that is unvalidated.
- Standardization of methods may be initiated by any laboratory under the approved Agency's protocol.
- Standardization activities are centrally coordinated to avoid unnecessary duplication.
- Standardization of methods follows an Agency-wide uniform and rigorous protocol of sound technical procedures for approving methods and techniques.
- There is close liaison with all functional elements and laboratories of the Agency.
- There is optimum interaction with all appropriate external organizations.

## b. Standardization program responsibilities

A number of laboratories now within EPA were set up by predecessor agencies for the sole purpose of testing and standardizing methods. Since incorporation into EPA, these laboratories have, in general, continued to perform the

same functions. There are also other laboratories, both within and outside EPA, engaged in standardization activities. Therefore, one of our high priority objectives is to coordinate standardization activities across the Agency. This will assure uniform quality of methods which have been standardized while meeting user needs completely and utilizing the available facilities, expertise, and resources in the most cost-effective manner. These objectives will be accomplished through rational assignment of methods standardization responsibilities coupled with a strong emphasis on the standardization protocol which encourages inter-laboratory communication and cooperation. The specific functions of the various organizational segments are given below.

(1) Office of Monitoring Systems -- The Office of Monitoring Systems has the primary responsibility for coordination and technical guidance in standardization activities. The Office of Monitoring Systems, in cooperation with the research activities and all other Program Offices and Regions, has the following responsibilities:

- Develops the necessary protocols, guidelines, and procedures for the standardization activity.
- Organizes and leads advisory committees for the development and/or review of guidelines and methods.
- Coordinates the implementation of an Agency-wide standardization program.
- Insures that the established guidelines are being followed.
- Collates and maintains a continually updated and prioritized list of monitoring methodology needs.
- Maintains information on all EPA standardization activities to minimize unnecessary duplication.

- Devises and implements a system for the evaluation and determination of manual and instrumented equivalent methods for sampling and analysis.
- Publishes approved analytical methods and sampling techniques and other guidelines as necessary.
- Provides for technical assistance when requested in the area of analytical methodology and sampling techniques.

(2) Standardization activities at NERC Laboratories -- Technical aspects of the standardization program will be implemented mainly by the standardization activities at the NERC's. These laboratories have, in addition to providing technical support to the Office of Monitoring Systems, the following major responsibilities: (1) designing and conducting collaborative testing programs; (2) evaluating test results; (3) determining method and instrument equivalence; and, (4) providing technical assistance.

Technical responsibilities within the Office of Research and Development for the various media and categories currently are as follows: standardization activities in air are conducted within the Quality Assurance and Environmental Monitoring Laboratory (QAEML) at NERC-RTP; those in water are conducted within the Analytical Quality Control Laboratory (AQCL) at NERC-Cincinnati; and pesticides activities are conducted within the Pesticide and Pesticides Effects Laboratory (PEEL) at NERC-RTP. NERC-Corvallis and NERC-Las Vegas are to be brought into the standardization program through assignments of tasks in standardization not being executed at the other NERC's, e.g., standardization of noise measurement methodology, standardization of data collection and formatting, and development of laboratory programs verifying instrumentation equivalency.

(3) Research activities -- Because of the close interface between methods research and methods standardization activities, the role of methods research programs in standardization activities cannot

be neglected. In many cases, the methods research groups will provide an essential function in assisting the quality assurance activities in the initial review of a method based on theoretical analysis of basic physical, chemical, and biological principles. The initial review may include experimental analysis of the method followed by evaluation of a working prototype of the instrument or procedure under a range of single laboratory conditions which could include field testing. The research activities will also provide valuable inputs by their participation in collaborative testing and methods endorsement required by the standardization protocol.

(4) Program Offices -- The Office of Air and Water Programs, the Office of Hazardous Materials Control, the Office of Planning and Management, and the Office of Enforcement and General Counsel, in addition to the other elements of the Office of Research and Development, assist the Office of Monitoring Systems in developing requirements, formulating the standardization protocol, establishing priorities, and conducting technical investigations. These are the organizational units that will specify needs and will be the users of the standardization product. Their participation in the program is essential. Assistance includes participation on advisory committees to deal with major policy issues and to coordinate program operations. To facilitate coordination, each Program Office will designate an advisory program coordinator who will provide continuing liaison with the Office of Monitoring Systems.

(5) Intra-agency Quality Assurance Coordinating Committee (IQACC) -- A formal mechanism to provide communication and coordination between the users and producers of the standardization product is essential. For this reason, a duly constituted intra-agency committee has been proposed. This committee is to be composed of the Director, Quality Assurance Division, one representative from each National Environmental Research Center, and representatives from the Office of Air and Water Programs, the Office of Enforcement and General Counsel, the Office of Hazardous Materials Control, and the Office of Planning and Management. Also, the Regions will have two representatives appointed by the Office of Regional Liaison. The committee's primary function will be to assist and advise the Office of Monitoring Systems

in fulfilling its coordination role and to serve as a forum for the resolution of major policy issues concerning quality assurance.

Specific advisory tasks which the committee may perform with respect to the standardization program include: (1) review of methods which are proposed for adoption as official EPA reference methods to ensure that the protocol for standardization has been followed; (2) evaluation of progress toward standardization goals; (3) identification of areas of duplication and suggestion of mechanisms to avoid duplication; and, (4) through its technical subcommittees, formulation and recommendation of protocols for standardization and other technical guidelines necessary for the implementation of an Agency quality assurance program,

(6) Steering Committee -- The role of the Steering Committee in the promulgation of environmental standards has been established by the Agency. Therefore, actions taken by the standardization program, such as the standardization protocol, reference methods, and equivalency determinations, must be routed through the Steering Committee for endorsement.

(7) Other Agency laboratories -- Any program or laboratory desiring the designation of a method as a standard method may perform the necessary tasks providing that they follow the protocol and submit information on their standardization efforts to the quality assurance activity for review for compliance with the protocol. If the information shows that the method has been properly evaluated according to the Agency's standardization protocol and if the method itself meets user needs in terms of accuracy, precision, and other considerations, then the method may be approved and published as a standard method. Endorsement by the Steering Committee and approval by the Administrator will be necessary if the method is to support regulations and be designated as a reference method.

An important and critical element of a standardization program is the collaborative testing and evaluation of tentative methods. Participants in these activities will include EPA laboratories as well as outside cooperating laboratories--other Federal, State, local, industrial, academic, usually on a voluntary basis (in certain instances, it becomes desirable to conduct such tests by contract). Where external laboratories participate

in the collaborative testing program, Regional Surveillance and Analysis Divisions will be used to coordinate such testing activities within their Regions. Also, where particular expertise resides in a Regional laboratory, that laboratory may actively participate in identification and evaluation of methods. Regional Surveillance and Analysis Divisions will have representation on all standardization coordinating committees through the Office of Regional Liaison.

(8) External standardization organizations -- Since the standardization program will have national impact, EPA will strive to utilize information from and cooperate with all outside interests, Federal, private, and international, in the development and establishment of approved analytical methods. The modes of involvement will be through encouraging cooperation or participation of key EPA personnel on a personal basis with established professional organizations such as:

- American Society for Testing and Materials (ASTM)
- American Public Health Association (APHA)
- Association of Official Analytical Chemists (AOAC)
- Air Pollution Control Association (APCA)

Methods standardized by such organizations will be considered for adoption as reference methods by EPA.

## 2. Projects and schedules

This section on projects and schedules deals only with the near-term portion of the program. Scheduling for actual standardization of methods is dealt with in the section on resources which follows this section.

A methods standardization program requires a twofold effort. The first is the establishment of the organizational framework and procedures, or protocol, under which the EPA standardization program will operate.

The second is the actual implementation of this program which includes testing, evaluating, and publishing standard methods and official EPA reference methods. Projects and milestones have been identified for both and are presented in this section of the report.

Although ideally the implementation follows the establishment of the framework and protocols, legislative mandates demand that existing programs not be interrupted or delayed. These existing programs are attempting to meet mandated needs on a crash basis. There is an urgent and continuing need to compile candidate and tentative methods for immediate use to form a base line until fully-evaluated methods become available.

Overall, five major tasks have been delineated. These are briefly described below and milestones for each are shown in Table 2.

a. Protocol for standardization --

In developing the protocol, the document will be concerned with more than just technical considerations. Certain legal and administrative issues will require interactions for resolution between the quality assurance activities and elements from the Office of Enforcement and General Counsel and other Program and Regional Offices. The basic protocol will be developed by the Office of Monitoring Systems with the assistance of the standardization activities at the NERC's. The milestones for preparing the final protocol document are shown in Table 2. The final document will be submitted for review and endorsement to all offices concerned with monitoring.

b. Compilations of sampling procedures --

In some cases, the requirement for uniformity in sampling is so pressing that the immediate circulation of reasonably well-characterized candidate sampling methods throughout the Agency is preferable to waiting for the results of thorough collaborative testing programs. This is particularly true where legal requirements exist but resources for standardization are not adequate to conduct evaluation and collaborative testing on several different methods at once. In order to meet these needs with minimum delay, the Office of Monitoring Systems and the standardization groups at the NERC's will assemble compendia of sampling methods. These compendia will not have the status of official EPA reference methods, but will be candidate



Table 2

MILESTONES FOR PREPARING FINAL STANDARDIZATION PROTOCOL

Activity	FY 1974											
	1st Quarter			2nd Quarter			3rd Quarter			4th Quarter		
	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
Protocol for Standardiza- tion	▲ <sup>O</sup>					▲ <sup>D</sup>			▲ <sup>P</sup>			
Compilations of Sampling Procedures	▲ <sup>O</sup>		▲ <sup>R</sup>						▲ <sup>C</sup>			
Update for Compilation of Abstracts of Analytical Methods (air, pesticides, radiation, solid waste, water)				▲ <sup>D</sup>					▲ <sup>P</sup>			
Equivalency Air*			▲ <sup>S</sup>									
Water			▲ <sup>D</sup>			▲ <sup>S</sup>						
Instrument Data System Compatibility Guidelines												
Standardization of units		▲ <sup>O</sup>					▲ <sup>D</sup>					▲ <sup>R</sup>

\*Currently being considered by the Steering Committee.

NOTE: This chart is based on the assumption that the strategy is approved prior to October 1, 1973.

Key: O = Conceptualization Study  
D = Draft  
R = RFP  
C = Contract Awarded  
P = Publish  
S = Submit to Administrator  
for Approval

sampling methods for use by Agency laboratories subject to restrictions and caveats on the use of data.

c. Compilations of available analytical methods -- As with sampling, there is a continuing need in the Agency for up-to-date information on available analytical methodology. There is also a long-term need for a unified set of approved Agency reference/standardized methods; however, in some cases, the advantages of using a reasonably well-characterized candidate or tentative reference method outweigh the benefits of waiting for the fully-evaluated and tested method particularly in cases where the candidate or tentative method appears to have good potential for eventual publication as an official EPA reference method. To meet the short-term need, the Office of Monitoring Systems, in concert with the NERC's, will prepare compendia of candidate and tentative methods. In fact, the first edition of a compendia of abstracts of over 400 methods has just been published by the Office of Monitoring Systems.

d. Equivalency -- The Environmental Protection Agency has adopted a policy to permit the use of measurement methods equivalent to the official methods adopted by the Agency. The activities described in this section are intended to give the user of an alternate method an opportunity to demonstrate equivalency under a fair and impartial procedure which will encourage innovation and advancement of the state-of-the-art while maintaining high standards of quality and assure the intercomparability of data.

(1) Equivalency of air methodology -- A draft equivalency document for measurements required by the National Ambient Air Quality Standards (NAAQS) has been prepared by NERC-RTP and is currently awaiting Agency approval. The document covers instrumentation and methodology and includes details on test procedures and performance specifications. Similar guidelines will need to be required for measurements called for in the New Source Performance Standards (NSPS) and the National Emissions Standards for Hazardous Air Pollutants (NESHAP).

(2) Equivalency of water methodology -- NERC-Cincinnati has developed interim equivalency guidelines for water methodology required by Section 304(g) of the Federal Water Pollution Control Act amendments of 1972.

This includes information on test procedures, standard reference materials, referee methods, and statistical handling of data to verify results. Permanent guidelines must still be developed.

(3) Other measurements -- Eventually, we will need equivalency guidelines covering other measurements such as pesticides, radiation, noise, and solid waste. Since there are no EPA promulgated standards requiring reference methods in these areas, the need for equivalency guidelines for these is less urgent.

e. Data output -- Guidelines must be prepared which will enable the standardization process to extend to the output terminal of electronic instruments to enable direct digital input to computerized data banks. This activity, to be undertaken by the Office of Monitoring Systems, will require close cooperation with the organizational elements responsible for the Agency's data systems. Without their participation, such guidelines cannot be prepared.

### III. METHODS STANDARDIZATION PROGRAMMING

#### Introduction

The first portion of this document has discussed our strategies, protocols, and guidelines to organize and implement the Agency-wide standardization program. In reality, the ultimate product of the standardization effort is not strategies, protocols, or guidelines, but the standardized method whose validity has been established to high degrees of scientific and statistical certainties and a series of reports that makes these validated methods available to the monitoring community. Again, confronted with realities, our output of standardized methods is directly related to the resources in terms of funds and manpower which the Agency deems appropriate for this effort. We have, therefore, included in this chapter on Methods Standardization Programming, options at four successive programming levels describing what standardization outputs the Agency can realize with its commitment of resources.

In our first option, we describe our present resource commitments for standardization. We are lagging seriously in providing standardized methods for air standards which were promulgated in 1971. We are now confronted with needs for standardized methods for water standards which will not be fulfilled in a timely manner. To date, we have not been confronted with standards for pesticides, radiation, or other categorical standards. We are initiating standardization in some of these areas on a very modest scale in anticipation of future needs.

At the second programming level which we discuss, we will be able to make positive headway in closing the gap in our standardized methods needs for past environmental standard promulgations.

At the third programming level, we could keep abreast of our needs for standard methods support of environmental standards in a timely manner.

And, finally, at the fourth programming level, we could start to standardize some of the more widely used research methods. Much of the data generated by the use of such methods will be used to develop the criteria for

eventual environmental standards. Standardization of such methods will assure continuity of data reliability and intercomparability with data that will eventually be generated by monitoring activities from reference methods.

We have also included in this chapter a representative example of necessary lead times to have a standardized method available at the time an environmental standard is promulgated, and a brief example of the expected costs for standardization of a measurement method.

### Lead-time Requirements

The schedules for the standardization of individual methods are closely linked to the needs of the Program Offices and Regions, statutory requirements, anticipated legislation, research results, and the Office of Research and Development's need statements submitted through cognizant authority. A case in point is the requirement for validated methodology for air quality measurements levied upon the Office of Research and Development by the Office of Air and Water Programs. In this request, this office established a "control schedule" for approximately 30 pollutants which imposed a timetable for providing official EPA reference methods. These requirements included both techniques for ambient as well as source measurements. In order to meet this "control schedule," the measurement methods must be available well in advance of the actual environmental standard promulgation schedule. The requisite lead times are shown below:

	<u>Lead time in months</u>
National Ambient Air Quality Standards	15
New Source Performance Standards	12
National Emissions Standards for Hazardous Air Pollutants	12
Mobile Source Emissions Standards	24-36
Fuel and Fuel Additives Regulations	18

In addition to these lead times, we must also add up to approximately one year which is the time required for the actual methods standardization process. Thus, ideally, standardization of a method must begin two to three years prior to the promulgation of the standard. Until now, this type of advance notice and planning has not been possible and, for this reason, we are now playing "catch up."

### Standardization Costs

It is estimated on the basis of past experience that the cost to standardize a measurement method can be as high as \$100,000 and require four man years of effort. This estimate was made on the following assumptions:

- Several existing methods are available in the scientific literature, but the specific procedure suitable for EPA requirements has not been identified.
- A thorough screening effort is required to identify the best methods and to evaluate their applicability.
- The selected procedures must be collaboratively tested under actual laboratory operating conditions.

The individual tasks leading to a fully-standardized method are itemized below with associated required resources.

<u>Task</u>	<u>MY</u>	<u>Dollars</u>
Literature search	0.1	2,500
Preliminary laboratory examination of alternative methods	0.4	10,000
Selection of best approach	0.1	2,500

<u>Task</u>	<u>MY</u>	<u>Dollars</u>
Preparation of preliminary method description and procedure	0.1	2,500
Testing method at various concentrations of pollutant	0.3	7,500
Testing method in actual samples	1.0	25,000
Identifying interferences	0.1	2,500
Modify procedure to eliminate interferences and retest	0.4	10,000
Determine single laboratory precision and accuracy	0.4	10,000
Determine multi-laboratory precision and accuracy	1.0	25,000
Publish and distribute	0.1	2,500

Using an actual case, the cost breakdown on the three collaborative tests which were performed on ambient air methods for sulfur dioxide, particulates, and carbon monoxide follows:

Contract Cost:

<u>Item</u>	<u>Cost</u>
Direct materials	\$ 19,600
Direct labor (staff & shop)	107,960
Overhead	104,264
Travel	12,436
Other direct charges	30,652
Fixed fee	18,909
Total	<u>\$293,821</u>

In-house Support:    0.5MY (est.) or \$14,000

Estimated standardization cost per pollutant:

Contract cost	\$293,821
In-house cost	14,000
Total	<u>\$307,821</u>

Cost per pollutant  $\$307,821 \div 3 = \$102,607$

It must be recognized that for these methods there was no corroborative data from other sources and, thus, the high cost.

In some cases, a method may have been already fully evaluated and validated by a recognized standards-setting organization such as ASTM or APHA. In these cases, EPA may only need to conduct a very limited review and the cost of obtaining an EPA approved standardized method would be considerably reduced.

Programming Level 1--Present Resource Allocations1. Standardization of air methodology

A large portion of the current program consists of completion of projects that were started in 1972 and 1973. These projects, totalling \$1,377,000, are listed below:

- Collaborative testing of methods for nitrogen oxides, sulfur dioxide, and sulfuric acid mists from sulfuric acid plants, particulates from power plants, and visible emissions from several stationary sources (Group I).
- Collaborative testing of methods for carbon monoxide from petroleum fluid catalytic cracking units, sulfur dioxide from refinery gas burning, and hydrogen sulfide from fuel gas reprocessing (Group II).
- Sulfur dioxide and sulfuric acid mists from copper, lead, and zinc smelters (Group IIA).



- Methods for mercury and beryllium for the National Emissions Standards for Hazardous Air Pollutants.
- Collaborative testing of the chemiluminescent method for ozone, several methods for nitrogen oxides, and the 24-hour sampling procedures for sulfur dioxide, collaborative test for the hydrocarbon method, and verification of the guidelines for determining equivalency for the National Ambient Air Quality Standards.
- Development of new and improved materials and techniques for calibrating air pollution devices.

New starts in FY 1974 include:

- Standardizing a particulate method for a selected Group II or III industry.
- Evaluating and collaborative testing of methods for total respirable solids from Kraft paper mills, fluorides from aluminum reduction plants, nitrogen oxides and sulfur oxides from gas turbines, and fluorides and phosphates from fertilizer plants (Group III).
- Evaluating collaborative testing results for three ambient methods.
- Testing of a permeation device for nitrogen dioxide.
- Developing standards for ozone, carbon monoxide, zero air, and sulfate for ambient measurements and reference standards for sulfur dioxide, nitrogen oxides, and hydrogen sulfide from stationary sources.

These additional efforts approved for FY 1974 will cost \$753,000 and require 7.7 man years.

At our present programming level in FY 1974, we have not been able to initiate any new starts for anticipated new ambient air methods. We are also lagging in our efforts to catch up with our source measurement methods requirements. Our efforts to produce standardized reference materials for methods standardization are also lagging behind our requirements.

## 2. Standardization of water methodology

In response to the requirements of the new Water Bill, 72 parameters were identified for control under the effluent permit program. In fulfillment of Section 304(g), validated measurement methods have been issued for 30 of these parameters. Forty-two methods must still be validated for accuracy, precision, and reliability before the totality of the immediate requirements can be met. There are also no validated methods to support the ocean dumping permit program. In this area, adaptation of methods developed for fresh waters to marine waters will require considerable effort. We are equally hard pressed for validated methods for the measurement of some of the pollutants that are being declared as toxic pollutants in fulfillment of Section 307(a) of PL 92-500.

The programming level for FY 1974 will allow for completing the report of a joint preliminary study on comparative methods for the analysis of mercury which was conducted with the American Society for Testing and Materials (ASTM), analyzing the results of the collaborative test for 10 trace metals, completing the report for the collaborative test for 10 pesticides in water, collaboratively testing the spectrophotometric and fluorimetric methods for chlorophyll analysis, and preparing a manual of biological methods. These efforts will cost \$50K and require 2.5 man years.

Continuous monitors for influent and effluent streams are being evaluated and design and performance specifications for single parameter monitors are being prepared. Similarly, effluent and intake stream automatic sampling devices and specifications for data output, handling, and transmission systems are being developed and evaluated. These efforts will cost \$105K and require 4.5 man years.

The total standardization effort for water will cost \$155K and require 7.0 man years.

At this programming level, very little work can be undertaken to fulfill the methods requirements of the effluent discharge and ocean dumping permit program or the toxic materials standards. In addition, the much needed standardization for biological, microbiological, and viral measurement methods will be indefinitely delayed.

### 3. Standardization of radiation methodology

For radiation measurement requirements, a compendium of 38 single laboratory-tested methods to measure radionuclides associated with aqueous wastes from nuclear facilities has been published. These methods have not been validated by collaborative tests. Analytical methods are also being developed and evaluated for radioactive gases in in-plant waste streams, radioactive effluents discharged in marine environments, and long-lived radioactive materials from reprocessing plants. Single laboratory tests are also being made on the performance of thermoluminescent detectors for radionuclides.

Some standardization of sampling techniques for radionuclides in soil, biota, and air is also being conducted.

The total radiation standardization effort will cost \$292K and require 12.8 man years.

The present program will not include any collaborative testing for measurement methods for environmental ionizing or non-ionizing radiation nor will it allow adequate standardization of sampling techniques for radionuclide content of plants, animals, soil, and air in the environment of nuclear facilities and fuel reprocessing plants.

### 4. Standardization of pesticides methodology

Present activities include field testing of a system to measure pesticides in air, economic evaluation of a completely automated system for analysis of pesticides, collaborative testing of a method for alkyl phosphate pesticides in association with the re-entry problem, and evaluation of the electrolytic conductivity detector for

chlorinated pesticides. The program is strongly oriented toward methods for pesticides in food and animal tissues. This effort will cost \$50K and require 1.5 man years. Methods currently being developed for sampling pesticides in air and water will need to be standardized.

#### 5. Standardization of noise methodology

No standardization activities for noise measurement methodology exists within ORD. The National Bureau of Standards is conducting some methods standardization for EPA's Office of Noise Abatement and Control.

#### 6. Standardization of solid waste methodology

The solid waste standardization activity was discontinued pending review of the entire program. Some measurement methods such as heat content are unique to solid waste management and will need to be standardized.

Resource Summary--Programming Level 1: The current standardization effort costs \$1250K and requires 29.0 man years of effort. Additionally, carry-over funds totalling \$1377K represent contractual obligations that will be completed in FY 1974. At this level, we have made standardized methods available for about 55 pollutants over a period of three years and are in the process of standardizing about 26 additional methods. Some of the additional methods are alternative methods for pollutants for which collaboratively tested methods are already available, for example, sulfur dioxide, nitrogen dioxide, and ozone.

#### Programming Level 2--Critical Needs

Critical needs identified at this programming level are the requirements for standardized methods imposed by promulgated environmental standards.

#### 1. Standardization of air methodology

At this level, the standardization of source measurement methods will be accelerated, whereby, the methods requirement for sources through Group III industries would be met by the end of FY 1974 or early FY 1975. This schedule would, of course, be highly dependent on the easy adaptability of Group I industry methods to the

succeeding groups. In the event that interferences preclude each adaptability, completely new methods would be required at considerably higher costs and require more time. This level of effort would also expand the capability to evaluate equivalency guidelines and methods.

The new activities would cost \$200K and require 2.3 man years for a total program cost of \$953K and 10 man years.

## 2. Standardization of water methodology

The increased efforts would be used to accelerate the efforts to meet the requirements of the effluent discharge and ocean dumping permit programs and the toxic substances standards. The acute limitation on funds and manpower will make it very difficult to fulfill all of these requirements in less than two to three years. The new activities would cost \$200K and require 2.2 man years for a total program cost of \$355K and 9.2 man years.

## 3. Standardization of radiation methodology

We will, as in Level 1, fulfill single laboratory testing requirements for the most important radionuclide measurements from nuclear devices and facilities. In addition, a program of collaboratively testing of these methods will be started. These methods will be needed for the EPA nuclear facility radiation inspection program. Level 2 incremental costs would be \$40K and require 0 man years for a total program cost of \$334K and 12.8 man years.

## 4. Standardization of pesticides methodology

Analytical methods which have been standardized in the past will be published. Increased emphasis will be placed on sampling methodology for water and air samples. Level 2 incremental costs would be \$70K and require 1.5 man years for a total program cost of \$120K and 3.0 man years.

## 5. Standardization of noise methodology

A base program will be started by developing a framework for standardization of noise methodology. Actual collaborative testing would be started in the succeeding year. Level 2 incremental costs would be \$30K and 2 man years for a total program cost of \$30K and 2 man years.

## 6. Standardization of solid waste methodology

At this level, most of the measurement methodology requirements of solid waste programs would be met through simple adaptations of methods known to be acceptable in other areas (such as New Source Performance Standards for incinerator emissions). The most critical methodology needs which are unique to solid waste would be fulfilled by a dedicated effort of \$30K and 1 man year (compared with no effort under Level 1).

Resource Summary--Programming Level 2: To meet the most critical needs for standardized methods would require \$650K and 9 man years over the current resource allocations for a total program cost of \$1900K and 38 man years. This would permit us to initiate standardization of 27 critically required additional methods which still leaves many water and radiation methods unstandardized.

### Programming Level 3--Meeting Environmental Standards Needs for Methods

At the third programming level, needs for standards methods support of environmental standards could be met in a much more timely manner.

#### 1. Standardization of air methodology

In addition to the activities at Levels 1 and 2, the program to validate methods proposed as equivalent to EPA reference methods would be expanded. Also, at this level, some standardization activities and development of related standard reference materials could be undertaken in anticipation of new regulations. Level 3 incremental costs would be \$237K and require 1 man year for a total program cost of \$1190K and 11.0 man years.

#### 2. Standardization of water methodology

In addition to activities at Levels 1 and 2, the program would be accelerated to allow standardization of methods required by the permit program in a much more timely and responsive manner. Level 3 incremental costs would be \$170K and require 1 man year for a total program cost of \$525K and 10 man years.

### 3. Standardization of radiation methodology

There is no proposed increase over the critical level for the radiation measurements standardization program. Level 3 incremental costs would be \$0 and require 0 man years for a total program cost of \$325K and 12.8 man years.

### 4. Standardization of pesticides methodology

In addition to activities at Levels 1 and 2, we will initiate a continuing program for validating equivalent methods. Level 3 incremental costs would be \$70K and require 1 man year for a total program cost of \$190K and 4 man years.

### 5. Standardization of noise methodology

In addition to our activities in Level 2, we will initiate a standardization effort for measurement methodologies. This effort would need to be closely related with the acoustic's group at NBS. Level 3 incremental costs would be \$70K and require 1 man year for a total program cost of \$100K and 3.0 man years.

### 6. Standardization of solid waste methodology

There is no proposed increase over the critical level. Level 3 incremental costs would be \$0 and require 0 man years for a total program cost of \$30K and 1 man year.

Resource Summary--Programming Level 3: We could meet most of our higher priority needs above the critical level with an incremental resource increase of \$550K and 4 man years for a total program cost of \$2440K and 42 man years.

### Programming Level 4--Most Standardization Needs

At programming level 4, most standardized methods requirements for environmental standards could be met in a responsive and timely manner. In addition, other commonly-used methods could also be standardized.

#### 1. Standardization of air methodology

At this level of effort, standardized methods could be provided eventually (once we are caught up) for

virtually all commonly-used measurements within the Agency whether they are directly in support of environmental standards or simply used for routine trend monitoring or research. In addition, we would be able to evaluate a substantial number of "equivalent methods" each year within our own laboratories greatly increasing the confidence associated with their use. This provides a useful mechanism for EPA's monitoring activities to keep abreast of the state-of-the-art. Level 4 incremental costs would be \$200K and require 3 man years for a total program cost of \$1390K and 14 man years.

## 2. Standardization of water methodology

Reference methods would be validated for most routinely-used physical, chemical, microbiological, and biological methods. Sampling procedures would be developed and evaluated for both ambient and effluent measurements. Equivalency guidelines would be published and candidate methods evaluated for equivalency. Specifications for instrumentation and instrument data output would be developed. Level 4 incremental costs would be \$300K and require 3 man years for a total program cost of \$825K and 13.0 man years.

## 3. Standardization of radiation methodology

No change from Level 2.

## 4. Standardization of pesticides methodology

No change from Level 3.

## 5. Standardization of noise methodology

No change from Level 3.

## 6. Standardization of solid waste methodology

No change from Level 2.

Resource Summary--Programming Level 4: At this level of resource availability, we could start to standardize some of the methods we more routinely use for research and trend monitoring. This would lead to an improvement in the quality of data from which effects criteria are developed. We could initiate this expanded standardization



activity with an incremental resource increase of \$500K and 6.0 man years for a total program cost of \$2865K and 48 man years.

Comments on "Measurement Methods Standardization  
Strategy" Document

INTRODUCTION

In August 1972, the Office of Monitoring Systems distributed a draft standardization strategy for Agency-wide review and comment. The responses were nearly unanimous in endorsing the concept of an Agency-wide standardization program. Many comments indicated a need for clarification of the roles to be played by various components, particularly Regional Surveillance and Analysis Divisions and the National Environmental Research Centers. Some objections were raised with respect to the appraisal of current status and capabilities of ongoing programs. The major issues raised by the review are given below.

(1) Degree of centralization: While the majority of reviewers approved of the concept of a centrally-directed standardization program, a few with existing in-house programs felt they should retain their responsibilities. On the basis of the majority of reviewers and the mandate of EPA Order No. 1110.22B, the revised strategy calls for at least the coordination and review of all standardization activities by the Office of Monitoring Systems with one option being complete transfer of all standardization resources to the Office of Monitoring Systems.

(2) Use of the Federal Register: Most, but not all, of the reviewers felt that EPA should be able to publish official reference methods without using the Federal Register. The revised draft allows for publication in an appropriate form depending upon requirements.

(3) Coordination: Several comments reflected great interest in the establishment of formal and informal means of communication and coordination, in fact, some used the reply as a vehicle to communicate their immediate needs for standardized methods. The need for effective communication has been recognized in the strategy and efforts are underway to establish an Intra-agency Quality Assurance Coordinating Committee.

Many other minor revisions have been incorporated directly into the revised strategy document.

SUMMARY OF COMMENTSREGION I

- (1) The plan is well conceived and represents a sound and realistic approach to meet a fundamental need.
- (2) The EPA Regional Offices should fully participate in collaborative testing and act as a focal point for such testing with non-EPA offices in the Regions.
- (3) Assure adequate provisions for updating methods.

REGION IV

- (1) The Analytical Quality Control Laboratory in Cincinnati has had an excellent program for water methods evaluation and standardization for over four years.
- (2) Existing system should be strengthened particularly in the program areas with weak standardization methods.
- (3) Need for more reference samples and collaborative testing.
- (4) Methods should be published in a manual rather than in the Federal Register. This would allow both "official EPA standards" and "provisional EPA standards."
- (5) Collaborative testing should be in-house. External laboratories should be encouraged to participate through Regional framework.
- (6) Collaborative testing should be directed by the NERC's. All EPA laboratories should participate.

- (7) The Surveillance and Analysis Divisions should have explicitly recognized input into identification and prioritization of measurement needs.

REGION VI

- (1) Strategy document does not adequately tell how standardization programs will be implemented. Does not show how Regional Surveillance and Analysis Divisions will be involved.
- (2) Resource allocations show no monies or positions allocated to Regions.
- (3) Feels standard methods development is one of the most critical areas for future EPA activities, particularly in relationship to States and localities.
- (4) Regions should coordinate interactions with States/localities starting from beginning of standardization process.

REGION VII

- (1) The proposal adequately expresses needs for development of a program of this scope and magnitude.
- (2) Need for publishing standard methods in the Federal Register.
- (3) Resource allotments and emphasis accorded to microbiological methods is not sufficient. Need for dramatic increase here dictated by recent instrumented methods.
- (4) More emphasis should be placed on Regional Surveillance and Analysis Divisions rather than NERC's "ivory towers."

REGION VIII

- (1) Proposals in general well construed and presented.

- (2) Standardization of environmental monitoring methods and procedures urgently needed within the Agency.
- (3) Status of old FWPCA-U.S. Geological Survey (USGS) Memorandum of Agreement should be resolved. This assigned ambient water quality data gathering to USGS.
- (4) Draft gives impression that existing water methodology standardization is non-existent which is definitely not the case.
- (5) Sampling and sample preparation procedures should receive greater emphasis.
- (6) Indicate how other Federal agencies will interface with this program.

#### REGION IX

- (1) Office of Enforcement and General Counsel should be involved in methods review. This is especially important for sampling procedures particularly with regard to chain of custody.
- (2) Overall treatment of data handling seems inadequate. Feels existing systems, e.g., SAROAD, NEDS, and SOTDAT, should be amalgamated.
- (3) Too little emphasis on organic chemical techniques.
- (4) Inadequate treatment of bacteriological methods.
- (5) Some emphasis should be given to encouraging outside collaboration, e.g., through program grants.
- (6) Consideration should be given to equivalency testing for water sampling and testing instruments.

- (7) No resources are identified for Regional participation.
- (8) Alternatives at different levels of resources should be identified.
- (9) Sampling techniques should be given more emphasis.
- (10) Regional participation should be given greater emphasis.

REGION X

- (1) The report is comprehensive and well presented.
- (2) Publication of a method in the Federal Register does not assure its credibility with the scientific community. ASTM methods are of value because they have been thoroughly tested.
- (3) Duties of the policy and advisory committees are not well defined.
- (4) Cost and time schedule to implement the proposed program are ambiguous.

Office of  
Hazardous  
Materials  
Control

- (1) Not clear if comments made on revision of EPA Order No. 1110.22A were taken into account in this draft.

Office of  
Radiation  
Programs

- (1) Draft comprehensive in most respects. Excellent working paper on which to build.
- (2) Advisory committee should be immediately activated.
- (3) Standardization activities of other agencies, e.g., AEC, national societies, such as ASTM, ANSI, ANS, should be given more emphasis.
- (4) Industry standards should be accepted if they are consistent with EPA program requirements.

- (5) Not convinced that program direction and management should be centralized in one office.
- (6) The draft ignores the Office of Radiation Programs' non-ionizing radiation program.
- (7) Dose concept is very important for radiation methods and should be recognized in the draft. Pathway media are important here. (Subsequent discussions with the Office of Radiation Programs have resolved this question.)
- (8) Existing Office of Radiation Programs' activities should be recognized.

Office of  
Solid Waste  
Management  
Programs

- (1) Standardization of sampling and analytical methods vitally needed and essential to EPA.
- (2) Need for avenues of communication between Office of Monitoring Systems and operating programs. Standardizing must respond rapidly to needs of operating programs.
- (3) Provision of technical assistance to outside world is function and responsibility of operating programs.
- (4) Identifies specific areas where standardized methods are needed.

Office of  
Toxic  
Substances

- (1) Well thought out proposal. Proposal appears to be fundamentally sound.
- (2) Why should EPA have its own standard methods instead of quasi-official compendia?
- (3) Federal Register is a cumbersome route to promulgate standard methods; should be through EPA Order mechanism.

- (4) Does not feel standard analytical procedures should apply to biological properties or engineering performance.
- (5) Insufficient effort given to feedback from persons in the field.
- (6) Make up of the advisory committee too vague. Operations program should be represented directly not through the Assistant Administrators.
- (7) While the Office of Monitoring Systems has the lead role, the activity is of pronounced interest to all segments of the Agency.

Office of  
Pesticides  
Programs

- (1) In favor of participating in such a program. It would have value to the current operational monitoring programs.
- (2) The Office of Pesticides Programs should be utilized in development of standardization procedures.
- (3) The National Pesticides Monitoring Panel has a task force to write a manual on field sampling techniques and data analysis methods for pesticides monitoring.
- (4) The Office of Pesticides Programs is currently standardizing the computer codes and processing of all types of information; this effort should be coordinated with the Office of Research and Development.

Office of  
Air and Water  
Programs

- (1) Need for monitoring standardization is critical.
- (2) Need plan to assure quality control associated with monitoring data.



- (3) Draft does not discuss adequately the standardization of sampling procedures or data handling.
- (4) Fails to provide recognition of requirements to attach quality control confidence to all data available to analysts. To accomplish this, there is a pressing need for ORD to provide analytical laboratory identification, published laboratory methods, and grades for each laboratory and its techniques.

NERC-RTP  
Office of  
Director

- (1) Real need for a unified position in several areas of standardization. Draft serves quite well to bring together a logical statement of EPA's overall standardization policy.
- (2) Conflict regarding who is responsible for preparing methods for promulgation with regulatory standards: Office of Air and Water Programs or Office of Research and Development?
- (3) A possible conflict on policy with respect to where the responsibility for equivalency protocol lies.
- (4) There has not been effective involvement by the NERC-RTP standardization program in the activities of standards development of the Office of Air and Water Programs. Strategy document seems like good vehicle to propose policy in this area.
- (5) No serious problems with funding levels. Role of standardization activities outside EPA must be considered, e.g., ASTM.

- (6) Specific factors to be considered in accepting a method as reference should be carefully considered, possibly expanding list.

NERC-RTP  
Emission  
Standards and  
Engineering  
Division

- (1) Comments on lead times for methods associated with New Source Performance Standards and National Emissions Standards for Hazardous Air Pollutants. Standardization data lags standard developments program.

NERC-RTP  
Quality  
Assurance and  
Environmental  
Monitoring  
Laboratory

- (1) Basically a good document.
- (2) Feels "standardized methods" should be "reference methods" for comparison. Concept of "candidate methods" for comparison with "reference method" and designation of these as "equivalent methods" when they meet certain requirements in comparison with the "reference method." This will assure that best scientific technology is employed in critical areas.
- (3) Does not feel that all "official reference methods" should be promulgated in the Federal Register but should be in manuals instead.
- (4) Feels that telemetering activities have limited use in Agency and should be restricted primarily to specific research projects.
- (5) Does not agree that Regional Surveillance and Analysis Divisions should do collaborative testing, but should be included as a collaborative laboratory.
- (6) Responsibility of Headquarter's Standardization Branch is to provide overall policy guidance and coordination in standardization

areas across all media. NERC operating laboratories have responsibility for standardization activities for methods evaluation, tentative methods, recognizing candidate methods, etc.

- (7) Feels we should prepare "reference methods" and not "standard methods."
- (8) Most important requirements of a reference method are accuracy and precision which are usually established by collaborative testing.
- (9) What should be the involvement of outside organizations such as NBS, ISC, etc., in EPA's standardization strategy?
- (10) What specific things must be determined when a method is under development?
- (11) Interferences and costs generally not determined in collaborative testing.
- (12) Federal Register should be used with discretion for promulgating a method. It should not be used in all cases.
- (13) Does not feel that the Regional Surveillance and Analysis Divisions have capability to conduct a collaborative test in air methods.
- (14) Wants some policy on what EPA's relationship with other "standard methods" organizations should be.
- (15) Feels there should be more communication between the Office of Air and Water Programs and NERC-RTP so that each can be aware of the others needs in the standards-setting program.

NERC-  
Las Vegas

- (1) Document is well written and should be given total support throughout the Agency.
- (2) Supports EPA quality assurance strategy.
- (3) Brings up possible duplication of activity in radiation with NERC-Cincinnati.

NERC-Cin  
Office of  
Director

- (1) Ultimately support for standardization can be related to long-term economic and environmental dividends greatly exceeding the cost of standardization.
- (2) Methods standardization is an expensive, tedious, laboratory task which will require a significant chunk of resources.
- (3) Methods defensibility lies in the exhaustive, collaborative, replicative, and statistically-significant studies of its performance in any analyst's hands under a variety of conditions.

NERC-Cin  
Analytical  
Quality  
Control  
Laboratory

- (1) Suggests improved terms or definitions for "candidate method," "tentative method," and "standard method."
- (2) Does not believe establishment of equivalency can be left solely to the proposer in the private sector, but that some EPA collaborative testing is required for this evaluation.
- (3) Responsibility for selection of an EPA method cannot be transferred to an outside group.
- (4) Asks for careful selection of factors to be weighed in selecting a reference method.

- |  |   |
|--|---|
| NERC-Cin<br>Radiochemistry<br>& Nuclear<br>Engineering<br>Laboratory | (1) Draft provides a good overview of<br>ORD programs and planning in<br>standardization.   |
|  | (2) Variety of media may necessitate<br>several methods for same<br>radionuclide.   |
|  | (3) Participation of external groups<br>should be given added emphasis.   |
| NERC-Cin<br>Solid Waste<br>Research<br>Laboratory                    | (1) The Solid Waste Research Laboratory<br>feels it urgent that solid waste<br>tested methods be available as<br>quickly as possible. |

The above comments were submitted by the following individuals:

<u>REGION I</u>	Edward V. Fitzpatrick, Director Surveillance and Analysis Division
<u>REGION IV</u>	John A. Little, Director Surveillance and Analysis Division
<u>REGION VI</u>	Eloy R. Lozano, Director Surveillance and Analysis Division
<u>REGION VII</u>	Garry L. Fisk, Director Surveillance and Analysis Division
<u>REGION VIII</u>	Keith O. Schwab, Director Surveillance and Analysis Division
<u>REGION IX</u>	Paul DeFalco, Jr., Regional Administrator
<u>REGION X</u>	Gary L. O'Neal, Director Surveillance and Analysis Division
Office of Hazardous Materials Control	G. R. Comstock, Director Management and Program Evaluation

Office of Radiation Programs	William A. Mills, Director Criteria and Standards Division
Office of Solid Waste Management Programs	H. Lainer Hickman, Jr., Director of Operations for Solid Waste
Office of Toxic Substances	Farley Fisher, Chemist
Office of Pesticides Programs	L. E. Miller Pesticides Programs Manager
Office of Air and Water Programs	Robert L. Sansom Assistant Administrator  R. R. Goodwin, Director Emission Standards and Engineering Division Office of Air Quality Planning and Standards
NERC-RTP	Paul A. Kenline, Director Program Coordination Staff  S. David Shearer, Director Quality Assurance and Environmental Monitoring Laboratory  John B. Clements, Chief Methods Standardization Branch Quality Assurance and Environmental Monitoring Laboratory
NERC-LV	J. R. McBride, Deputy Director National Environmental Research Center
NERC-Cin	Andrew W. Breidenbach, Director National Environmental Research Center  Dwight G. Ballinger, Director Analytical Quality Control Laboratory

NERC-Cin  
(Cont)

Bernd Kahn, Director  
Radiochemistry and Nuclear  
Engineering Laboratory

D. F. Bender, Project Manager  
Support Services Branch  
Solid Waste Research Laboratory



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

SEP 20 1973

OFFICE OF  
RESEARCH AND DEVELOPMENT

SUBJECT: Measurement Methods Standardization  
Strategy Document -- ACTION MEMORANDUM

FROM: Assistant Administrator for  
Research and Development

TO: The Acting Deputy Administrator

THRU: AX *Stan, I know that a great deal  
of thought and effort has gone into this  
package. It is a major step forward. Than*

ISSUE

How should the measurement methods standardization activity be structured in order to meet the Environmental Protection Agency's goals with respect to the selection and promulgation of measurement methods to be used in pollution monitoring? *to you  
and you  
staff wt  
develop*

DISCUSSION

Background - The availability and selection of scientifically proven, appropriate, and cost-effective measurement methods very often impinge on a variety of EPA decisions and actions--the setting of standards, the 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 method may delay our 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; these methods must be routinely applicable at a reasonable cost. Our 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

*John 2  
12/24*



could successfully attack and discredit our environmental data measurement methodology. For this reason, we must verify our measurement methodology through a laboratory-oriented scientific standardization which cannot be successfully challenged. Our methods defensibility lies in the proper application of a standardization protocol--the exhaustive, collaborative, replicative, inter-laboratory testing of the method for accuracy and precision under the conditions required by environmental standards or other requirements of our Agency, 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.

In this sense, standardization stands intermediate between research and quality control. Our research program conceptualizes and creates measurement methodology based upon state-of-the-art scientific and engineering knowledge, together with the skillful application of currently accepted scientific principles. Standardization operates independently of research and is closely related to quality control, providing maximum credibility to the methods validation procedure by minimizing the research or operational laboratory biases associated with either an extremely high level of competence and familiarity with the method or an average level of competence and total unfamiliarity with the method. Our quality control program complements standardization and completes the Agency's quality assurance program by assuring that validated methods are used in the production of environmental data and that laboratories maintain the validated, legally-acceptable levels of performance which have been established for methods by the standardization program.

Present Status - Current Agency standardization activities have been thoroughly reviewed and a comprehensive plan for an EPA standardization program developed setting forth organizational strategy, delineating technical projects and tasks, and briefly discussing resource requirements for this program. Present activities in standardization are inadequate to provide the unchallengeable methods which we need to support our programs. Some of our problems are technical in nature; others which are addressed here are organizational and procedural. In short, the basic problem is the lack of a coordinated and logical approach to standardization which has resulted

in the proliferation and use of methods of questionable reliability and utility. In fact, EPA has been criticized for its inability to provide adequately tested methods and give uniform and credible guidance to the various internal and external monitoring programs. The major causes are:

1. Many EPA programs and laboratories are involved in selection of methods and unilateral standardization efforts. This frequently results in the selection and use of statistically unreliable methods.

2. In many areas, competing methods for measuring specific pollutants have been made available from different components of EPA.

3. The available lead times and funding in many cases do not allow satisfactory standardization effort prior to required methods designation and promulgation.

4. The involvement of many laboratories in "standardization" of similar methods leads to unnecessary duplication of effort.

It is in search of a solution to these problems that we propose the implementation of an Agency-wide standardization program.

The need for a central management and coordination of the Agency's activities in quality assurance was recognized in the Deputy Administrator's April 18, 1972 memorandum on monitoring where the Office of Monitoring Systems was charged with this responsibility. In response to this directive, a comprehensive plan for an EPA quality control program was developed which received Agency approval on February 13, 1973. This present memorandum and the enclosed documents complement the quality control program and complete the strategy for a balanced quality assurance program. Since the implementation of this program requires the full cooperation of all components of EPA involved with monitoring, the adopted strategy must be formally recognized. This issue deals only with the basic questions of operation and responsibility in the attainment of the Agency's standardization goals.

In all, three options are presented for consideration. The basic question is the degree of central authority that is required to implement an adequate program.

The Standardization Plan - The first draft of the standardization plan was developed and distributed for Agency-wide review late 1972. The majority of reviewers agreed with the need for a clear, Agency-wide standardization capability. Two separate sub-issues relating to: (1) reference methods versus standard methods; and, (2) methods promulgation are presented as Tab A. In Tab B, we present the revised standardization strategy plan which reflects the comments (Tab C) of the reviewers of the first draft.

### ALTERNATIVES

Three options are presented for consideration to correct present weaknesses in EPA's standardization activities. These range from status quo to a level which would provide a maximum confidence in the reliability of all methods being used.

Option A: All standardization activities (all collaborative testing and final technical approval) are centralized within one program element-- Monitoring Quality Assurance. Methods are standardized as required for operating programs.

- pro: 1. A central focal point is readily available for guidance on methodology.
- 2. Best possible mechanism is established for timely development of uniform standard methods.
- 3. Centralized standardization may permit more economical use of resources.
- con: 1. Loss of individual program capability (where it now exists) to respond to their own priority (and unique) needs.
- 2. Some reassignment of functions and reprogramming of resources are necessary.

3. Does not encourage method user to work on modifying or improving existing methods.

Option B: A basic standardization protocol is developed and followed in all EPA methods testing activities. Under this option, the quality assurance program, as at present, would conduct the bulk of standardization, provide technical guidance, and, in addition, coordinate all standardization activities and serve as the EPA clearinghouse for methods of measurement. Individual laboratories could still conduct their own standardization activities, if necessary, within the provisions of the standardization protocol.

- pro:
1. Transfer of funds and functions is not necessary.
  2. A central focal point is readily available for guidance on methodology.
  3. Increased uniformity in method quality is effected through a common standardization protocol.
  4. Permits a better use of existing resources.

- con:
1. Some loss in flexibility of individual programs.
  2. An added administrative burden to provide maximum coordination in keeping close track of all methods standardization.

Option C: Status quo. The quality assurance program continues to conduct a major portion of the standardization activities (as it now does) and coordinates, inasmuch as possible, the ongoing standardization activities. Each program is free to conduct their own methods evaluation program.

- pro: 1. No transfer of resources or changes in existing lines of authority.
2. Allows maximum flexibility for each program.
- con: 1. Overall, the least efficient use of limited resources is likely, due to fragmented effort.
2. Proliferation of questionable "standard methods" is continued.
3. Conflicting guidance regarding measurements is still provided.

#### RECOMMENDATION

That Option B be approved for immediate implementation. This will assure availability to the Agency and other user groups of the most reliable, cost-effective measurement methodology.

Approve: John Zwarler

Disapprove: \_\_\_\_\_

Date: 12/28/73

#### CONCURRENCES

AM, Alm	Concur <u>1/1/74</u>	Nonconcur _____	Date <u>1/1/74</u>
AG, Kirk	Concur <u>1/1/74</u>	See Tab _____	Date <u>10-30-73</u>
AF, Sansom	Concur <u>1/1/74</u>	Nonconcur _____	Date <u>NOV 7 1973</u>
AB, Dominick	Concur <u>1/1/74</u>	See Tab <u>D</u>	Date <u>11/5/73</u>
AO, Marienthal	Concur <u>1/1/74</u>	Nonconcur _____	Date <u>12/18/73</u>
		See Tab <u>E</u>	
		See Tab <u>F</u>	

Prepared by: ARMQ:RBMedz and GOzolins:jl:WSM:x50660:8/13/73

3 Enclosures (listed on next page)

*\*See request*

3 Enclosures:

Tab A: Issues I and II

Tab B: The Plan for the "Measurement  
Methods Standardization Strategy"  
Document

Tab C: Comments on the Plan by Headquarters,  
Regions, and NERC's

## ISSUE I

Should EPA require the use of Agency-wide "standard measurement methods" or establish "reference methods" and permit the use of equivalent methods?

## DISCUSSION

Mandatory use of standard measurement methods would assure that every analyst would use exactly the same methodology and procedures of known accuracy and precision to measure a given pollutant in a given media. On the other hand, endorsement of standardized reference methods would establish required performance levels for accuracy and precision while allowing the analyst to select or modify any suitable method to measure a given pollutant. In both cases, the performance of the laboratories would be maintained at acceptable levels by our quality control program.

Development and use of methods by past Agency practices have been a mix of the two approaches. Environmental quality standards promulgated under the Clean Air Act were supported by "reference methods." Because of time limitations, these methods were not validated prior to their promulgation. The use of methods equivalent to the reference methods was specifically permitted. This pattern of usage is now occurring in the water effluent permit program, e.g., reference methods and equivalency provisions.

As the standardization program becomes more centralized and incorporates an accepted standardization protocol, a decision must be made between two alternatives:

## ALTERNATIVES

Option A: EPA develops and requires the use of "standard methods."

- pro:
1. Assures the comparability and compatibility of environmental data irrespective of source.
  2. Allows standardization of equipment and instruments and simplifies and allows economics of scale in their purchase.
  3. Brings about the greatest uniformity in monitoring for monitoring systems and environmental data.

- con:
1. Rigid adherence to the use of a standard method frequently serves only to codify obsolete methods.
  2. Some methods now in use and not complying to the standard method would have to be discarded, sometimes at great expense.
  3. Would tend to stifle competitive research to develop newer measurement concepts that could provide better quality data faster and more cheaply.
  4. Prevents modifications of methods or use of alternate methods when conditions require such modifications and changes.
  5. This option would be inconsistent with promulgated guidelines which permit the use of "equivalent methods" by non-EPA monitoring activities.

Option B: EPA develops and endorses standardized "reference methods" and provides for the use of equivalent methods when appropriate.

- pro:
1. Does not stifle competitive incentives to develop better methodology.
  2. Can be implemented to assure a uniform, high quality, Agency-wide standardization program with a minimum of expense and disruption of existing programs.
  3. Does not administratively "lock in" on obsolete methods.
  4. Is consistent with existing promulgations concerning methodology.



- con: 1. Complicates instrumental and procedural arrays due to methods proliferation.
2. Makes task of quality control more difficult.

#### RECOMMENDATION

Option B for developing and endorsing "reference methods" is recommended for approval. The risk of extending official sanction to obsolete methodology is too great to lock ourselves into a "standard methods trap." However, it must be emphasized that for any enforcement application when an official standardized reference method is available and applicable, it must be used with no deviations.

Approve: \_\_\_\_\_

Disapprove: \_\_\_\_\_

Date: \_\_\_\_\_

*John Zearley*

*12/28/73*

## ISSUE II

Should it be Agency policy to promulgate only fully-validated "reference methods" with environmental standards?

## DISCUSSION

It has been Agency practice to publish a measurement method by which a pollutant is to be measured together with the environmental standard. Lead times for providing these methods were so short that many unvalidated methods have been promulgated with environmental standards. These methods were designated in the regulations as "EPA reference methods." Regulations also include a provision for equivalency.

This practice has proven to be unsatisfactory. In the case of Ambient Air Quality Standards, one of the methods selected was found to be inaccurate under most environmental monitoring conditions. For another method, subsequent investigation showed that the level for which the standard was set fell near the limits of detection of the reference method. For this reason, only an extremely skilled analyst can make measurements in the critical concentration region. Several other methods which were selected in this manner are still being tested for reliability. For these reasons, it has been deemed necessary to tighten the requirements for reference methods.

Several conditions are being proposed in the strategy document which must be met before a measurement method can be designated a "reference method." These are: (1) the method must be part of an environmental standard; (2) there can be only one reference method applicable in a particular concentration range for any given pollutant in an environmental standard; (3) the reference method must be fully validated by collaborative tests for accuracy, precision, and concentration range of pollutant for which it is applicable; and, (4) the reference method must be readily available to the majority of the regulated user groups. The provision for the use of equivalent methods would still apply. These considerations lead to three major options which must be evaluated for decision and policy determination.

## ALTERNATIVES

Option A: Only fully-validated reference methods shall be promulgated with environmental standards.

- pro: 1. The best scientific support is provided for monitoring support of the standard.
2. The probability of retraction of the method and/or the standard due to poor methodology and questionable data is materially lessened.
3. The comparability of the data from measurements taken at different times and in different places is assured.
4. The probability of successful challenge of the data and method is remote.
- con: 1. Promulgation of the standard may be delayed due to the lack of a fully-validated measurement method.

Option B: Any method regardless of degree of validation may be promulgated with an environmental standard. This is the status quo.

- pro: 1. There is no delay in the promulgation of standards because any available method can be used to support the promulgation.
2. Allows fulfillment of legislative mandates for standards within the prescribed time frames.
- con: 1. The method may be of questionable accuracy and precision and monitoring data might be too unreliable to support regulatory actions.
2. Both the method and the standard may have to be retracted because of successful challenge by the regulated user community.

Option C: It is the policy of the Agency to promulgate only fully-validated reference methods with its standards. Under very extenuating circumstances, when methods which are not fully validated must be used, they must be designated as "tentative methods" and caveats pertaining to the limitations of their use must be included in the regulation.

- pro:
1. Allows fulfillment of the legislative mandates for standards within the prescribed time frames.
  2. The regulated user community is alerted to the tenuous nature of the "tentative method" promulgation and will expect its replacement by a fully-validated "reference method" when one is available.
  3. The need to retract a reference method is practically eliminated; the retraction of a tentative method is far less embarrassing.
- con:
1. The tentative method may be of questionable accuracy and precision and the monitoring data may be too unreliable to support regulatory actions.
  2. Both the tentative method and the standard may be subjected to successful challenge by the regulated user community and have to be retracted.
  3. Data taken at different times and at different places with the tentative method may not be intercomparable.

#### RECOMMENDATION

From a purely scientific point of view, Option A would be recommended. However, EPA must be pragmatic, and there

will be requirements for environmental standards and regulatory actions that must be supported by best available methodology regardless of validation. For this reason, Option C is recommended for approval.

Approve: John Zeebles  
Disapprove: \_\_\_\_\_  
Date: 12/28/73