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Environmental Protection Technology Series

IERL-RTP DATA QUALITY MANUAL

Industrial Environmental Research Laboratory
Office of Research and Development
U.S. Environmental Protection Agency
Research Triangle Park, North Carolina 27711

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IERL-RTP
DATA QUALITY
MANUAL

by

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SECTION I INTRODUCTION

1.1 DEFINITIONS

In order to facilitate the understanding of this manual, it is necessary to define three terms: quality, quality control, and quality assurance. It is sometimes difficult to distinguish quality control from quality assurance unless the proper definitions are kept in mind. The following definitions are based on those given by the American Society For Quality Control (ref. 1) and those given by the Environmental Protection Agency (ref. 2).

Quality

The totality of features and characteristics of a product or service that bear on its ability to satisfy a given purpose. For measurement systems, the product is measurement data and the characteristics of major importance are accuracy, precision, and completeness. For monitoring systems, completeness--or the amount of valid measurements obtained relative to the amount expected to have been obtained--is usually a very important measure of quality. The relative importance of accuracy, precision, and completeness depends upon the particular project requirements.

Quality control

The overall system of activities, the purpose of which is to provide a quality of product or service that meets the needs of users; also, the use of such a system. Maintaining a quality control program is the responsibility of the organization/individual implementing the project.

The aim of quality control is to provide quality that is adequate, dependable, and economical. The overall system involves integrating the quality aspects of several related steps, including the proper specification of what is wanted; production to meet the full intent of the specification; inspection to determine whether the resulting product or service is in accordance with the specification; and review of usage to provide for revision of specification.

Quality assurance

A system of activities, the purpose of which is to provide assurance that the overall quality control job is in fact being done effectively. The system involves a continuing evaluation of the adequacy and effectiveness of the overall quality control program with a view to having corrective measures initiated where necessary. For a specific product or service, this involves verifications, audits, and the evaluation of the quality factors that affect the specification, production, inspection, and use of the product or service. Maintaining an IERL-RTP quality assurance program is a function of the Process Measurements Branch.

1.2 BACKGROUND

The IERL-RTP has long recognized the importance of quality control as an integral part of its research and measurement activities. Heretofore, quality control has been practiced on a project-by-project basis, with the preparation and implementation of a quality control plan being the responsibility of the EPA project officer and the contractor. However, due to recent increased impetus in EPA energy and industrial processes programs and subsequent substantial increase in the number, scope, and importance of environmental assessment and technology development projects within IERL-RTP, the need for a formal, comprehensive, and integrated laboratorywide data quality program has become more critical. The development and implementation of a formal IERL-RTP data quality program was initiated in December 1974 by the preparation and distribution to senior staff members of the "Planning Document for an IERL-RTP Quality Assurance Program" (ref. 3). This planning document groups all IERL-RTP projects into five categories. Six categories are now existent, with the inclusion of environmental assessments. Further progress in developing and implementing an IERL-RTP data quality program has been realized through the preparation and on-site trial implementation of quality assurance procedures at IERL-RTP projects (refs. 4,5,6). Ultimately, quality assurance guideline documents will be generated for each project category.

SECTION II PURPOSE AND SCOPE OF DATA QUALITY MANUAL

2.1 PURPOSE

The purposes of this manual are:

1. To direct the establishment of and provide guidance for the implementation of an integrated data quality program for Industrial Environmental Research Laboratory - Research Triangle Park (IERL-RTP) projects.
2. To serve as a source of directive and instructive material for IERL-RTP project officers and contractors in the establishment and maintenance of project-specific quality control programs sufficient to insure that project data objectives are realized in the most economical manner (sections VI and VIII).
3. To serve as guidelines for the Process Measurements Branch within IERL-RTP in establishing and maintaining a quality assurance program to monitor, assess, and document the efficiency of the various project quality control programs (sections VII and VIII).

2.2 SCOPE

This manual describes the administrative systems pertaining to the establishment and maintenance of an IERL-RTP data quality program and presents guidelines for developing or designing quality control and quality assurance plans specific to given projects.

The administrative systems include: quality policies that provide both guidance for the establishment and implementation of a data quality program and quality objectives to guide in the designing of quality control and quality assurance plans (section III); organization, naming key quality personnel and groups (section IV); and a plan and schedule for implementing the quality program (section V).

Guidelines for developing project-specific quality control plans are given in sections VI and VIII and for quality assurance plans in sections VII and VIII.

SECTION III QUALITY POLICIES AND OBJECTIVES

This section contains the IERL-RTP policies to be followed in the establishment and maintenance of a data quality program. The objectives to be realized through a well-planned and conscientiously applied data quality program are also given here. A time schedule and details for implementation of these policies are given in section V. The organizational structure for establishing and maintaining the data quality program is given in section IV.

3.1 QUALITY POLICIES

IERL-RTP policies pertaining to the development, implementation, and maintenance of a data quality program are described by category below.

3.1.1 Coverage of the Data Quality Program

The IERL-RTP data quality program will have the following characteristics. It will be complete in nature, encompassing both in-house and contract experiments, tasks, and projects that either generate or use experimental data. It will be integrated, in that all experiments, tasks, and projects must have a quality control plan delineating the practices and procedures to be implemented at each level (e.g., operator, bench chemist, project leader, etc.) and each phase of the project. This plan will be evaluated and approved by the Process Measurements Branch. All experiments, tasks, and projects will also have a quality assurance plan for monitoring the effectiveness of the quality control program to be implemented by the Process Measurements Branch. Finally, the data quality program will be applied on a project-by-project basis according to project objectives and requirements.

3.1.2 Levels of Quality Application

Quality practices and procedures will be implemented at two levels.

1. Quality control The design and implementation of quality control practices and procedures required to assure that data quality is sufficient to meet project requirements are the responsibility of the individual or organization conducting the project. For example, on projects conducted under contract, the quality control plan will be prepared by the contractor, and reviewed and approved by the

EPA project officer with assistance from the Process Measurements Branch if desired. Inhouse projects will have quality control plans prepared by the responsible EPA staff member, with assistance from the Process Measurements Branch if desired.

2. Quality Assurance Quality assurance procedures for independently monitoring and assessing the efficiency and adequacy of individual quality control programs will be established and administered by the IERL-RTP director through the Process Measurements Branch. The quality assurance procedures shall be applied uniformly throughout the duration of the project. However, at any specific time during the project life, either at the request of the subject project officer or if deemed necessary by the Process Measurements Branch, the Process Measurements Branch may, using accepted quality assurance techniques, assess the IERL-RTP project's ongoing quality control program.

3.2 QUALITY OBJECTIVES

The primary objective of the IERL-RTP data quality program is to assure, assess, and document that the quality (i.e., precision, accuracy, and completeness) of measurements made by and/or experimental data used in IERL-RTP activities and publications is commensurate with the end use of the data. Management, administrative, statistical, investigative, preventive, and corrective techniques will be employed to maximize the end effectiveness of the data.

Specific data quality objectives are:

1. To establish acceptable limits on data quality as a function of project objectives, available resources, and measurement method capabilities;
2. To establish recommended procedures and require their use to insure the comparability of like data between projects;
3. To establish guidelines for the selection and use of additional measurement methods necessary to assure the collection of data of acceptable quality (i.e., of acceptable precision, accuracy and completeness) on a project-by-project basis;

4. To develop and implement quality control programs on each specific IERL-RTP project;
5. To develop and implement the quality assurance procedures necessary to independently monitor the efficiency of the individual project quality control programs;
6. To identify areas requiring new or improved measurement methods in order to achieve the level of quality required to satisfy project objectives.

SECTION IV ORGANIZATION FOR DATA QUALITY

The organizational structure, functional responsibilities, levels of authority, and lines of internal and external communication for management, direction, and execution of the quality program are given here. Individuals and groups or organizations discussed include the quality assurance manager, the quality assurance coordinator, the project officer, the Process Measurements Branch, and contractors.

4.1 ORGANIZATION STRUCTURE

IERL-RTP organizational structure is shown in figure 1. Figure 2 presents the laboratory's data quality program organization.

The chief of the Process Measurements Branch (PMB) is designated as the quality assurance manager and on data quality matters reports to the IERL-RTP director. The quality assurance coordinator directs the activities of the quality assurance group, which is composed of the Process Measurements Branch staff members and contract support. The coordinator is directly responsible to the quality assurance manager.

The quality control organizational hierarchy shows the control line moving from the appropriate division director, to branch chief, project officer, then contractor.

4.2 FUNCTIONAL RESPONSIBILITIES

The functional responsibility assignments for individuals and organizational components are given in this section.

4.2.1 Quality Assurance Manager

The chief of the Process Measurements Branch is the quality assurance manager. This person is responsible for the design development, implementation, and maintenance of the IERL-RTP data quality program. The chief directs the efforts of the quality assurance coordinator and thus the data quality activities of the Process Measurements Branch.

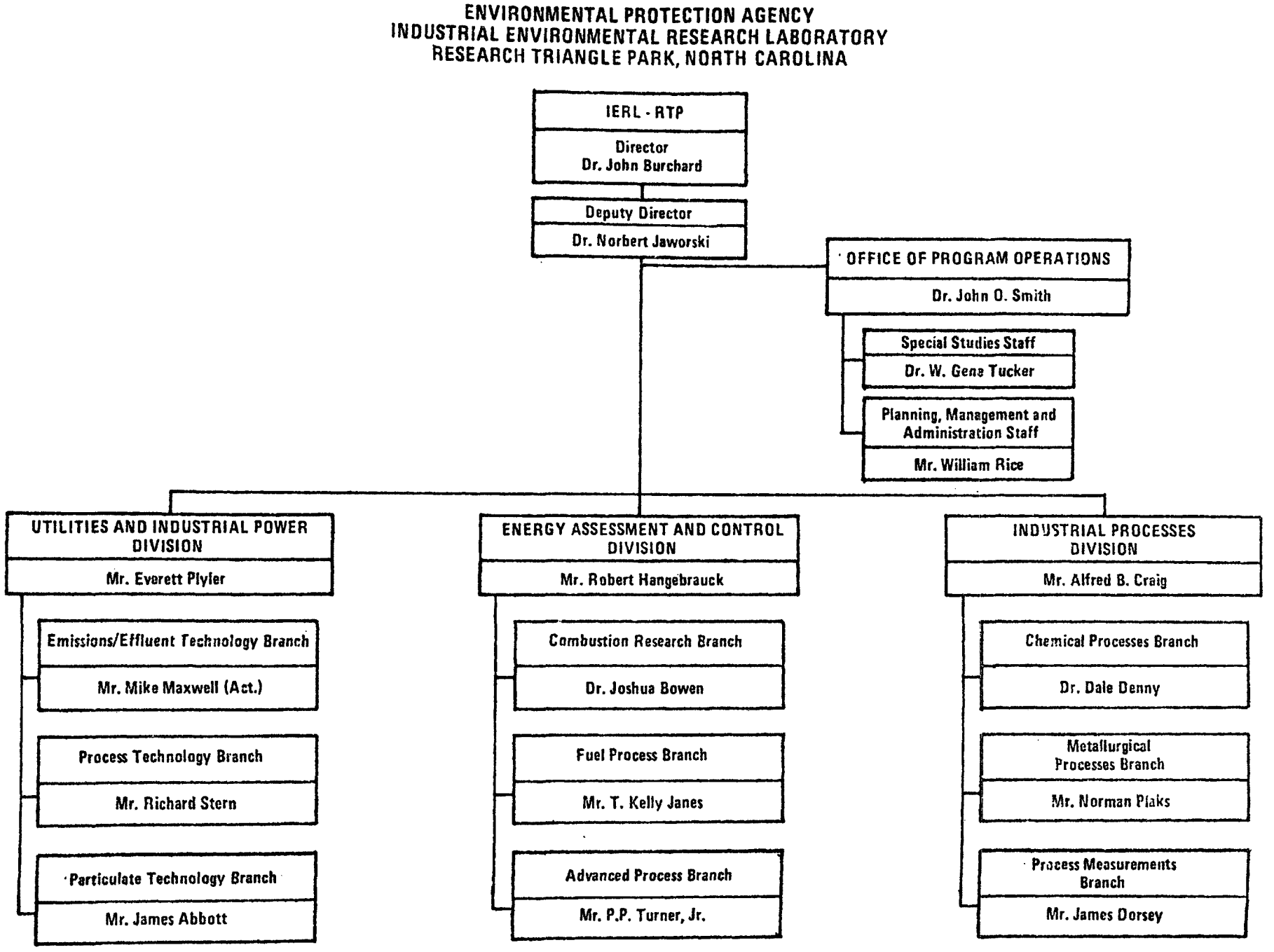

Figure 1. IERL-RTP organization chart.

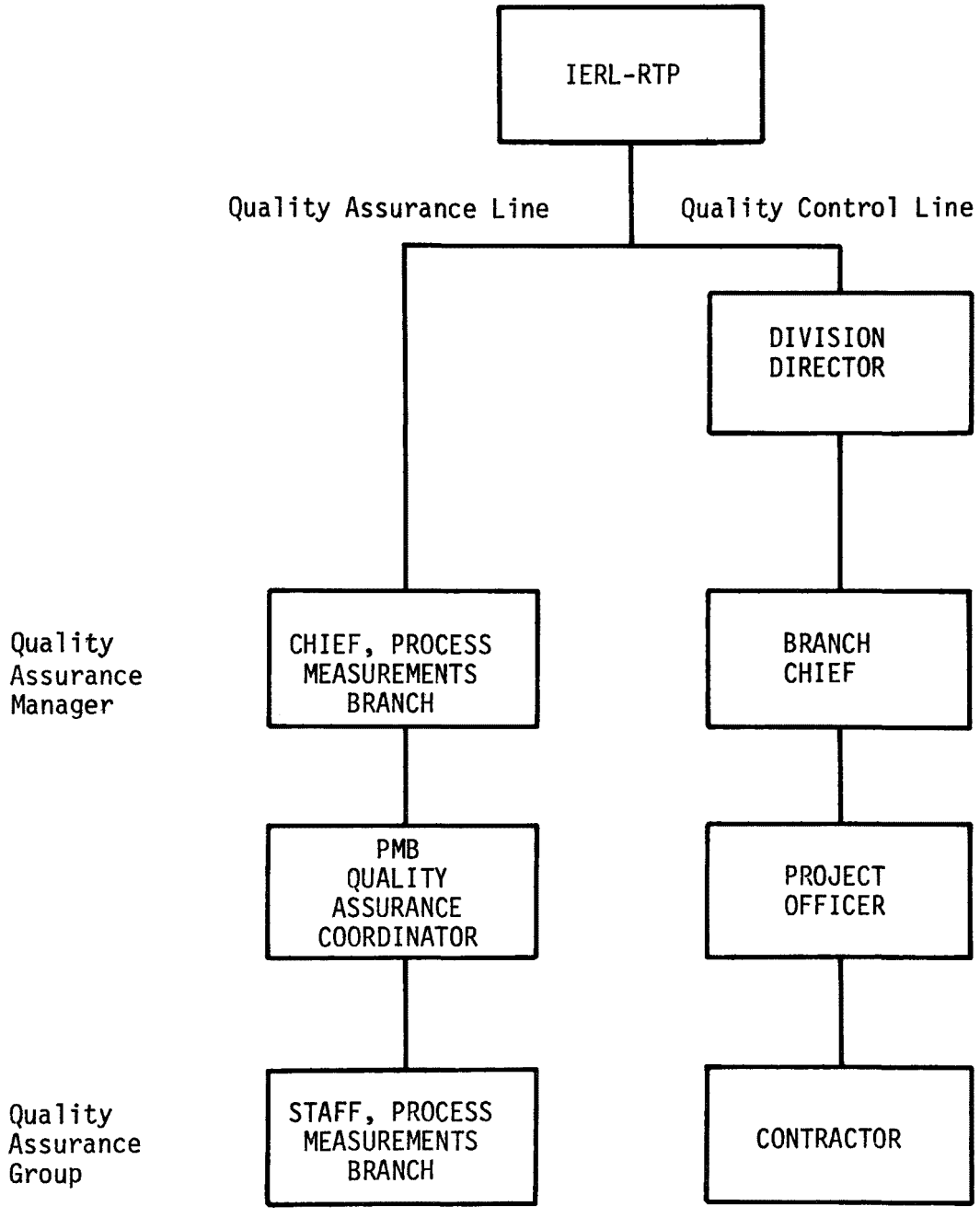

Figure 2. Data quality program organization.

4.2.2 Quality Assurance Coordinator

The quality assurance coordinator is responsible for overseeing all IERL-RTP data quality efforts. This person coordinates the activities of the Process Measurements Branch in the data quality program. He/she works with the appropriate project officers in designing and implementing project-specific quality control and quality assurance plans.

4.2.3 Process Measurements Branch

The Process Measurements Branch is responsible for coordinating all IERL-RTP quality activities. It initiates measures to insure the fulfillment of the overall quality objectives of the laboratory, and for carrying out the data quality policies in the most efficient and economical manner commensurate with insuring continuing acceptable levels of completeness, accuracy, and precision of experimental data produced. A summary of the data quality responsibilities and authority of the Process Measurements Branch is as follows:

1. It develops quality control guidelines and quality assurance programs, including statistical procedures and techniques, which will help the laboratory to meet desired quality standards at minimum cost; and coordinates the implementation of such programs with the appropriate project officer.
2. It reviews all measurement programs and insures that appropriate methods have been selected for data acquisitions.
3. It reviews quality control activities of the various projects and makes appropriate suggestions to the project officer regarding corrections and improvement.
4. It seeks out and evalutes new ideas and current developments in the field of quality assurance/control and recommends implementation wherever advisable.
5. It advises project officers in preparing and/or reviewing requests for proposals, work plans, project implementation, and reports of work with respect to quality aspects of technology, methods, and equipment.
6. It advises on packaging materials and procedures for sample handling and on requirements for maintaining sample integrity.
7. It advises project officers concerning schedules for system checks, calibrations, and other checking procedures.

8. It evaluates data quality statistically and maintains related quality assurance records and other pertinent information.
9. It coordinates the IERL-RTP program with the Environmental Monitoring and Support Laboratory/Quality Assurance Branch (EMSL/QAB) program.
10. It prepares and issues periodic quality assurance reports on specific projects to the project officer and the IERL-RTP director.
11. It prepares and issues periodic quality assurance summaries to the IERL-RTP director and to the EMSL-RTP director.

The quality assurance function is in the Process Measurements Branch and is under the direction of the quality assurance manager. The branch will have in-house and contract technical support as required to establish and maintain the data quality program.

4.2.4 Project Officer

The IERL-RTP project officer is ultimately responsible for the success or failure of the project. This person thus has the responsibility for determining the optimum level of quality control for the project and for seeing that the program is implemented and maintained. The project officer is responsible for quality control practices, beginning with the preparation of the request for proposal (RFP) and extending through the final report, as discussed in detail in section VIII.

4.2.5 IERL-RTP Contractors

For IERL-RTP projects conducted under contract, the contractor is responsible for designing, developing, implementing, and maintaining a quality control program to insure that the experimental data generated will be of suitable quality to satisfy the project requirements, and also for documenting that quality. The quality control plan must be approved by the IERL-RTP project officer.

4.2.6 Functional Relationships

Once a project has been defined or a contract negotiated the time sequence of events and interrelations between the Process Measurements Branch, the project officer, and contractor are illustrated in figure 3. The first column in the figure shows the data quality functions of the Process Measurements Branch. The second column gives the functions of the project officer (in-house project) or the project officer/contractor (contracts). The lines across columns show the points of interaction between different quality components of the data quality program.

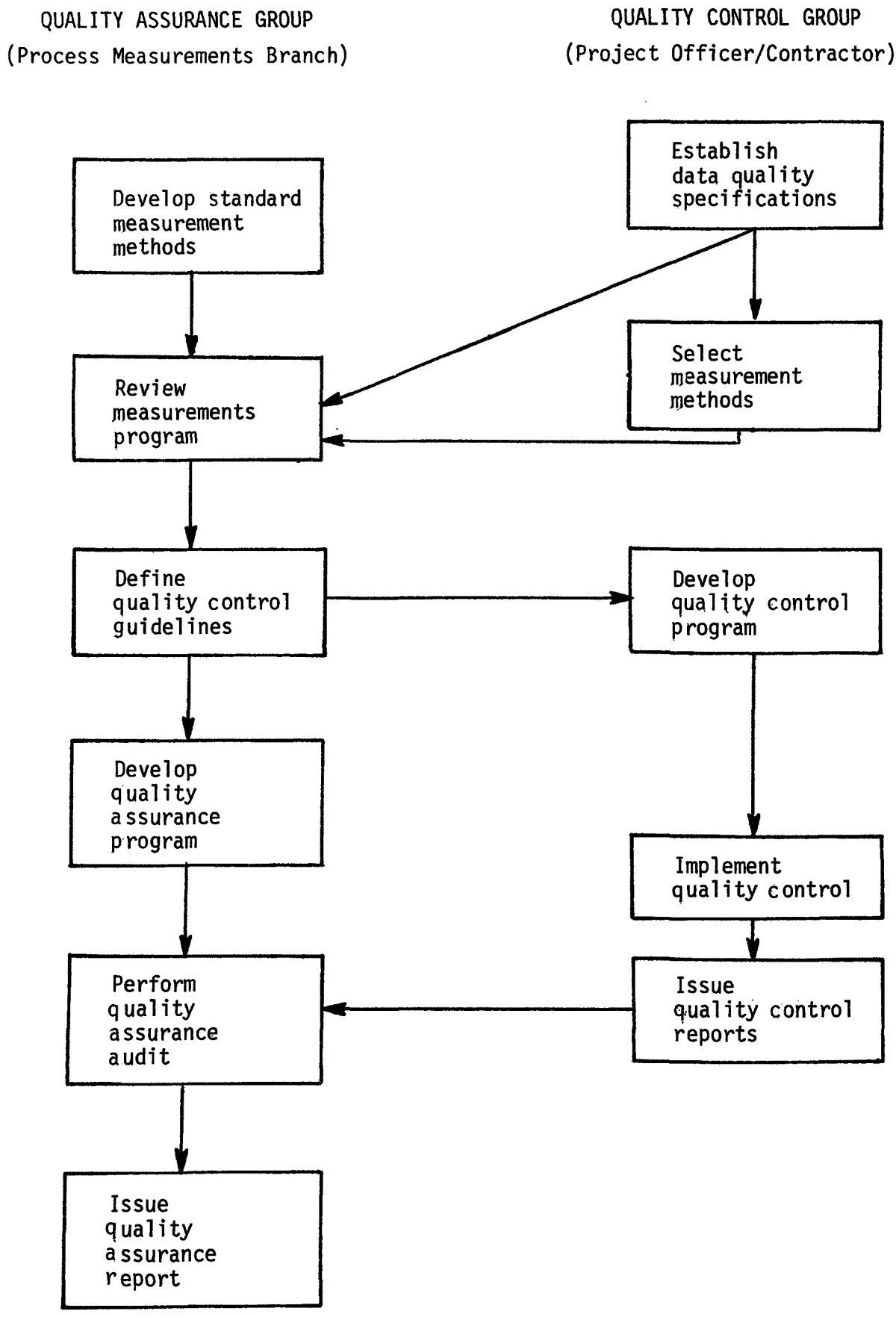

Figure 3. Flowchart of functional relationships.

SECTION V IMPLEMENTATION PLAN AND SCHEDULE

The plan for developing and implementing a comprehensive data quality program for IERL-RTP is predicated on the philosophy that a quality program should be implemented gradually and in phases such that the results from one phase can be used constructively in implementing the next phase. Also, the differences involved in implementing data quality programs to ongoing projects as compared to new projects must be considered.

The implementation plan requires that quality control and quality assurance procedures be applied to new projects, both in-house and contract, from the programs inception. That is, the Process Measurements Branch is presently available to assist the project officer (contract projects) in specifying quality control requirements for inclusion in the RFP and evaluating quality aspects of proposals and work plans. For new in-house projects, the Process Measurements Branch is available to help project officers prepare quality control plans for their projects.

The general plan and schedule for developing and implementing a laboratory-wide data quality program, starting with the preparation of a planning document, are given below.

5.1 IMPLEMENTATION SCHEDULE

A schedule for developing and implementing a laboratorywide data quality program is given in figure 4. In December 1974, a planning document for an IERL-RTP quality assurance program was prepared under the direction of the Process Measurements Branch and distributed to the laboratory's senior staff members. The date of the distribution of the plan-ning document is indicated as the first milestone on the implementation schedule.

Milestones 2, 3 and 4 in figure 4 show, respectively, the preparation of a general quality assurance plan for demonstration-size projects (EPA-600/2-76-081); making the plan specific for the EPA Wet-Limestone demonstration project at the Shawnee Steam-Electric Plant in Paducah, Kentucky (EPA-600/2-76-082); and on-site implementation of that plan for evaluation purposes (EPA-600/2-76-083). These three milestones occured in the last two quarters of 1975.

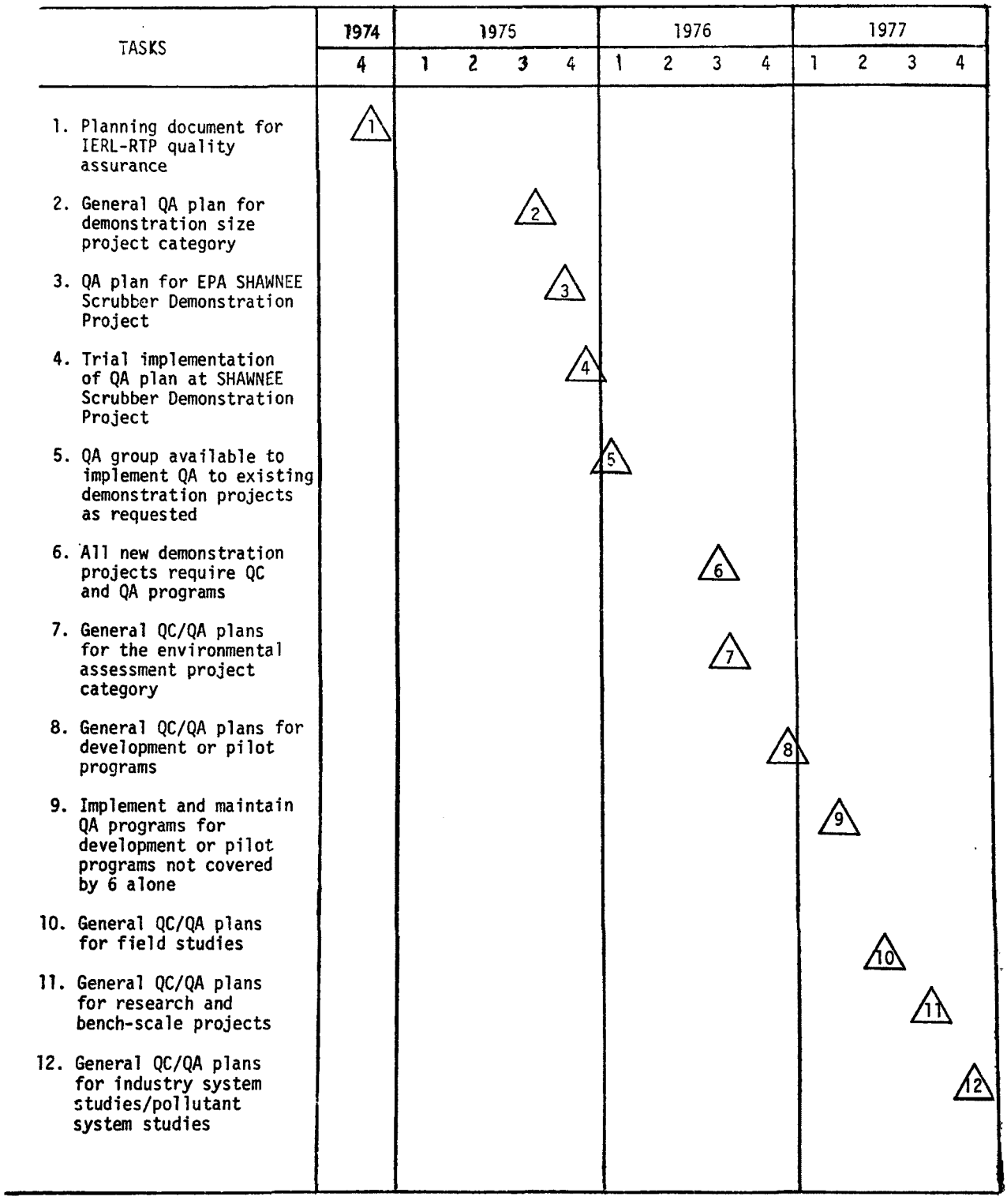

Figure 4. Data quality program implementation schedule.

Since completing the general quality assurance plan and testing it under field conditions, the primary effort has been directed toward implementing quality assurance procedures to other existing demonstration-size projects.

Effective September 1, 1976, all new demonstration projects and those existing demonstration projects having 1 year or longer to run must have quality control and quality assurance plans approved by the Process Measurements Branch (milestone 6). These plans include both quality control procedures to be carried out by the individual or organization conducting the project and quality assurance procedures to be administered through the Process Measurements Branch for monitoring the efficiency of the quality control procedures.

After September 1, 1976, general quality assurance plans will be prepared for the remaining five project categories, shown as milestones 7, 8, 10, 11, and 12 in figure 4. Because of the current interest in environmental assessments, the second general guideline document will be for this category. As figure 4 illustrates, a complete data quality program covering all IERL-RTP projects should be in effect by early 1978.

5.2 ESTIMATED COST OF IMPLEMENTATION

A definitive cost estimate for implementing and maintaining a data quality program cannot be made at this point in time. However, with the degree of importance placed on data quality by IERL-RTP, a realistic estimate of average costs per project are: (1) quality control costs in the range of 8 to 10 percent of the total project budget, and (2) quality assurance costs between 2 to 5 percent of the total project budget. From these estimates, then, the costs of the IERL-RTP data quality program as described in this manual when fully implemented should be in the range of 10 to 15 percent of the total laboratory project budget.

The above cost estimates apply to new projects. The net additional cost, if any, for implementing a data quality program to an ongoing project will depend upon the project's current level of quality control and quality assurance activities.

SECTION VI COMPONENTS OF A COMPREHENSIVE QUALITY CONTROL PROGRAM

6.1 GENERAL REMARKS

It is highly desirable that quality control and quality assurance programs be built into an IERL-RTP project from its inception; i.e., that quality control requirements be stated in the RFP, and that the contractor's provision for meeting those requirements be evaluated in the proposal and in the ensuing work plan. In this way, quality control is not treated as an extra-cost or add-on problem, but rather as an integral part of the total project.

Similarly, the project officer must be aware of the desirability of maintaining an adequate quality assurance program in order to insure the validity of the data from the project. Individual project categories, from environmental assessments through demonstration projects, have varying quality control and quality assurance requirements. Section VIII will treat some of these requirements individually, especially with regard to the RFP, proposal evaluation, and work plan review.

For efficiency of presentation, the major components of a quality control program are treated in a general way in the following subsections. Figure 5 is a matrix that attempts to show the applicability of each of these components to each project category. (A description of each category is given in section VIII.) The matrix is obviously arbitrary, and should serve as a general guide only, since individual projects will each have unique data requirements. The coding of the various quality control components is by the appropriate subsection number; e.g., component 6.2 in the matrix refers to subsection 6.2, Facilities and Equipment.

6.2 FACILITIES AND EQUIPMENT

A good beginning point in the assessment of an ongoing project is a general survey of the facilities and equipment available for day-to-day operation. Are they adequate for the job at hand? Do standards exist for evaluation of facilities, equipment, and materials?

The laboratories and data processing and other operational areas should be neat and orderly, within common-sense limits imposed by the nature of the

PROJECT CATEGORIES	FACILITIES AND EQUIPMENT	CONFIGURATION CONTROL	PERSONNEL TRAINING	DOCUMENTATION CONTROL	CONTROL CHARTS	IN-PROCESS QUALITY CONTROL	PROCUREMENT AND INVENTORY PROCEDURES	PREVENTIVE MAINTENANCE	RELIABILITY	DATA VALIDATION	FEEDBACK AND CORRECTIVE ACTION	CALIBRATION PROCEDURES
	QUALITY CONTROL PROGRAM COMPONENTS											
ENVIRONMENTAL* ASSESSMENTS										X		X
INDUSTRY/POLLUTANT SYSTEM STUDIES										X		
FIELD STUDIES	X									X		X
RESEARCH AND BENCH-SCALE PROJECTS	X	X								X		X
DEVELOPMENT OR PILOT-PLANT PROGRAMS	X	X		X	X			X		X	X	X
DEMONSTRATION PROJECTS	X	X	X	X	X	X	X	X	X	X	X	X

* Level I only; Levels II & III require more extensive QC programs, with Level III requiring all program components, as with demonstration projects.

Figure 5. Applicability of quality control program components to project categories.

operation. Laboratory benches, particularly areas where critical operations such as weighting are carried out, should be kept clear of all but necessary tools, glassware, etc. Personal items (coats, hats, lunch boxes) should not be left in the work area. Provision should be made for storage of these items in personal lockers. A neat, well-organized laboratory area serves to inspire neatness and organization among the laboratory workers.

Good laboratory maintenance, particularly for certain types of instrumentation, requires complete manuals that are kept in a convenient place so they are readily available to appropriate personnel. Responsibility for keeping up with any necessary manuals should be given to an individual, with the understanding that he/she must devise a system (check-in/checkout) for quick location of each document.

6.3 CONFIGURATION CONTROL

For IERL projects of moderate to long-term duration, the documentation of design changes in the system must be carried out unfailingly. Procedures for such documentation should be written and be accessible to any individual responsible for configuration control. It is all too easy, as the system is modified repeatedly, to allow one key person to hold, largely by memory, great amounts of vital information. Much of this information would be lost if this person were no longer available. Engineering schematics should be maintained current on both the system and subsystem level, and all computer programs should be listed and flow charted. Changes in computer hardware and software must be documented, even when such changes are apparently trivial. Significant design changes must be documented and forwarded to the EPA project officer by way of established procedure.

6.4 PERSONNEL TRAINING

For long-term projects, it is highly desirable that there be a programmed training system for new employees. This system should include motivation toward producing data of acceptable quality standards. A part of the program should involve "practice work" by the new employee. The quality of the work can be immediately verified and discussed with the supervisor, with appropriate corrective action taken. This system is to be preferred to on-the-job

training, which may be excellent or slipshod, depending upon a number of circumstances.

Key personnel (laboratory supervisors, senior engineers) should be required to document their specialized knowledge and techniques so far as possible. They should each be required to develop an assistant, if the program personnel situation allows, who could take responsibility when the senior person is unavailable. A most undesirable situation arises when replacement personnel must be brought in and forced to gain knowledge of the program through the experience of trial and error (see subsection 3.3 above). This is not an infrequent occurrence, however, when budgeting constraints override other priorities.

A thorough personnel training program should focus particular attention on those people whose work directly affects data quality (calibration personnel, bench chemists, etc.). These people must be cognizant of the quality standards fixed for the project and the reasons for those standards. They must be made aware of the various ways of achieving and maintaining quality data. As these people progress to higher degrees of proficiency, their accomplishments should be reviewed and then documented. A motivating factor for high performance could be direct and obvious rewards (monetary, status, or both), offered in a manner visible to other comparable personnel.

6.5 DOCUMENTATION CONTROL

If the project is of the type that generates a number of documents, procedures for making revisions to these documents must be clearly written out. The revisions themselves should be written and distributed to all affected parties, thus insuring that the change will be implemented and become permanent. If a technical document change pertains to an operational activity, that change should be analyzed for side effects. The change should not be rendered permanent until any harmful side effects have been controlled.

Revisions to computer software should be written with reasons for the changes clearly spelled out. The revisions should be distributed to all affected parties.

6.6 CONTROL CHARTS

For demonstration or pilot-plant programs, or any project where data is taken on a long-term basis, control charts are essential as a routine check on the consistency or "sameness" of the data precision. A control chart should be kept for each measurement that directly affects the quality of the data. Typically, control charts are maintained for duplicate analyses, percent isokinetic sampling rates, calibration constants, and the like. An example control chart is given as figure 6. The symbol σ (sigma) represents a difference, d, of one standard deviation unit in two duplicate measurements, one of which is taken as a standard or audit value. Two σ is taken as a warning limit and 3σ as a control limit. If a laboratory measurement differs from the audit value by more than 3σ, the technique is considered out of control. Control charts are dealt with in depth in a number of standard texts on quality control of engineering processes*.

6.7 IN-PROCESS QUALITY CONTROL

During routine operation, critical measurement methods should be checked for conformance to standard operating conditions (flow rates, reasonableness of data being produced, and the like). The capability of each method to produce data within specification limits should be ascertained by means of appropriate control charts. When a discrepancy appears in a measurement method, it should be analyzed and corrected as soon as possible.

For all standard methods, the operating conditions must be clearly defined in writing, with specific reference to each significant variable. Auxiliary measuring, gaging, and analytical instruments should be maintained operative, accurate, and precise by regular checks and calibrations against stable standards that are traceable to a primary standard, preferably furnished by the U.S. Bureau of Standards (if available).

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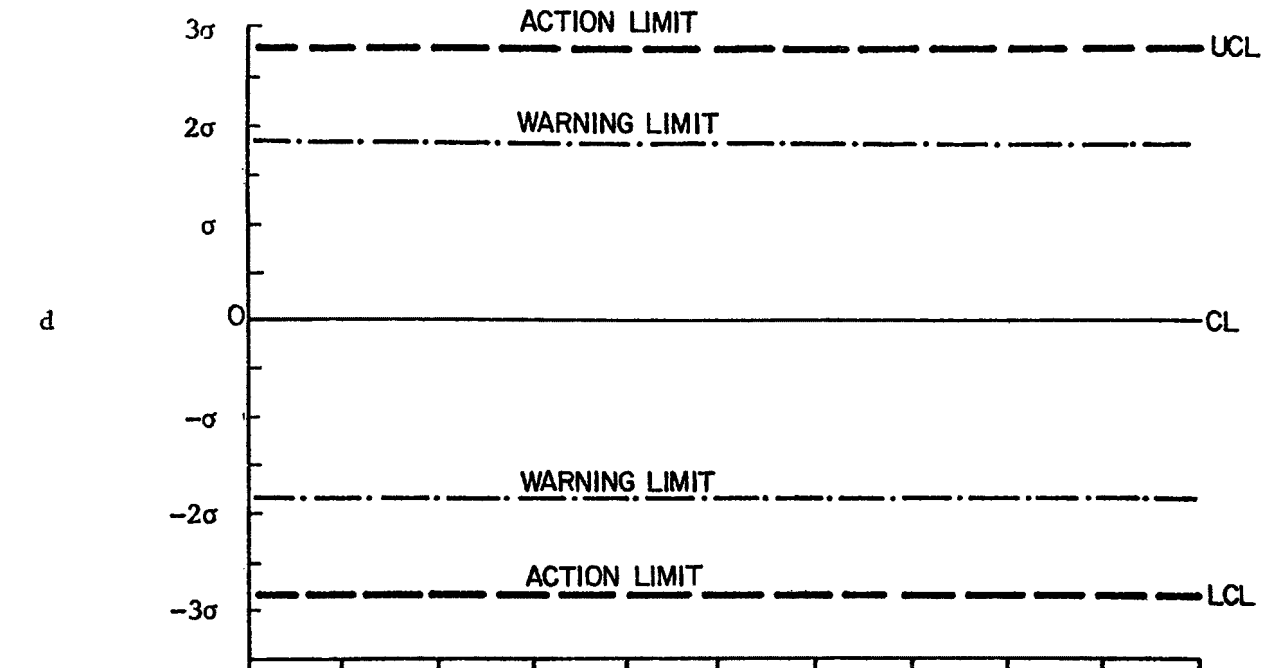
*Quality Assurance Handbook for Air Pollution Measurement Systems, Vol. 1, Principles, EPA-600/9-76-005.



CHECK NO.	1	2	3	4	5	6	7	8	9	10
DATE / TIME										
OPERATOR										
PROBLEM AND CORRECTIVE ACTION										

Figure 6. Standard quality control chart.

6.8 PROCUREMENT AND INVENTORY PROCEDURES

There should be well-defined and documented purchasing guidelines for all equipment and reagents having an effect on data quality. Performance specifications should be documented for all critical items of equipment. Chemical reagents considered critical to an analytical procedure are best procured from suppliers who agree to submit samples for testing and approval prior to initial shipment. In the case of incoming equipment, there should be an established and documented inspection procedure to determine if procurements meet the quality control and acceptance requirements. The results of this inspection procedure should be documented.

Whenever discrepant materials are detected, the materials are either returned or disposed of, at the discretion of the quality control supervisor.

Once an item has been received and accepted, it should be documented in a receiving record log giving a description of the material, the date of the receipt, results of the acceptance test, and the signature of the responsible individual. It is then placed in inventory, which should be maintained on a first-in, first-out basis. It should be identified as to type, age, and acceptance status. In particular, reagents and chemicals that have limited shelf life should be identified as to shelf expiration date and issued from stock only if they are still within that date.

6.9 PREVENTIVE MAINTENANCE

For long-term projects, it is important that preventive maintenance procedures be clearly defined and written for each measurement system and its support equipment. When maintenance activity is necessary, it should be documented on standard forms maintained in logbooks. A history of the maintenance record of each system serves to throw light on the adequacy of its maintenance schedule and parts inventory.

6.10 RELIABILITY

The reliability of each component of a measurement system relates directly to the probability of obtaining valid data from that system. It follows that procedures for reliability data collection, processing, and reporting should be clearly defined and in written form for each system component. Reliability

data should be recorded on standard forms and kept in a logbook. If this procedure is followed, the data can be utilized in revising maintenance and/or replacement schedules.

6.11 DATA VALIDATION

Data validation procedures must be defined for each project. An environmental assessment and a demonstration project will have entirely different procedures, since in one case the data are taken on a "one-point" basis and in the other a great quantity of data is accumulated over a long period of time, usually years. Whatever the nature of the project, it is important that the criteria for data validation be documented. Whenever practical, acceptance limits should be established, these limits being subject to modification as the program continues. Any required data validation activities should be recorded in standard form in a logbook. Where possible (as in most demonstration projects), validation criteria should be programmed, so that routine data-taking will include automatic flagging of invalid data.

Most projects should, on a random but regular basis, be subjected to quality audits. These audits must be independent of normal project operations, preferably performed by an independent organization. Such audits should include both systems reviews and independent measurement checks. Section 4.0 will discuss these elements of a quality assurance program.

6.12 FEEDBACK AND CORRECTIVE ACTION

Closely tied to the detection of invalid data is the problem of establishment of a closed loop mechanism for problem detection, reporting, and correction. Here it is important that the problems are reported to those personnel who can take appropriate action. For most projects, a feedback and corrective action mechanism should be written out, with individuals assigned specific areas of responsibility. Again, documentation of problems encountered and actions taken is most important. Standard forms, kept in a logbook, are recommended. If appropriate, a periodic summary report on problems and corrective action should be prepared and distributed to the appropriate levels of management. This report should include: a listing of major problems for the reporting period; names of persons responsible for corrective action;

criticality of problems; due dates; present status; trend of quality performance (i.e., response time, etc.); and a listing of items still open from previous reports.

6.13 CALIBRATION PROCEDURES

All IERL-RTP project categories except paper studies involve the taking of experimental data. The quality of these data relates directly to the care with which calibration procedures are carried out. It is not an exaggeration to say that calibration procedures are the crux of any attempt to produce quality data from a measurement system. For this reason it is extremely important that the procedures be technically sound and consistent with whatever data quality requirements exist for that system. Calibration standards must be specified for all systems and measurement devices, with written procedures for assuring, on a continuing basis, traceability to primary standards. Since calibration personnel may change from time to time, the procedures must be in each instance clearly written in step-by-step fashion. Frequency of calibration should be set and documented, subject to rescheduling as the data are reviewed. Full documentation of each calibration and a complete history of calibrations performed on each system are absolutely essential. This permits a systematic review of each system's reliability.

Good calibration techniques and procedures are also vital to short-term experimental projects, since data taken from these studies may be used as justification for expanded efforts in certain directions.

SECTION VII GUIDELINES FOR QUALITY ASSURANCE PROGRAMS

7.1 GENERAL STATEMENT

The objective of a quality assurance program is to independently evaluate the quality control program of a project. The quality assurance program must be appropriate to the work being done and to the quality control program for the project data. As mentioned earlier, it is most important that each project have provision for an adequate quality control program. Section 7.2 will give appropriate quality control statements for the RFP, while sections 7.3 and 7.4 will deal with the evaluation of quality control in the proposal and the work plan. The initial stage of a quality assurance program should be assistance in planning and development of the project data quality control program.

Short-term experimental projects must have rigorous quality control of the ensuing data. Quality assurance on such projects may consist of "one-shot" audits, or there may be no formal quality assurance because of time constraints. A minimum quality assurance approach would involve sampling a percentage of the raw data collected and verifying the calculations. The techniques used and general approach could also be reviewed for appropriateness, and an attempt made at comparing the work being done with that of other investigators. This can be done off-site, if necessary, and at minimal expense.

For IERL projects of moderate to long duration, the assessment of quality control should normally consist of a series of systems and performance audits. The frequency of such audits obviously should be dictated by the specific project. It is recommended that a minimum frequency be once each calendar year. The initial systems and performance audit should take place within the first quarter of the first project year. Subsequent scheduling should be dependent on the requirements of management and the apparent quality of the day-to-day data being obtained. More frequent auditing may be necessary in the initial stages of the project.

7.2 THE REQUEST FOR PROPOSAL - QUALITY CONTROL ASPECTS

The design of the RFP is predicated on stating as clearly as possible what the objectives of the project are; e.g., to design, construct, and maintain a given control system, systematically examining the interaction of appropriate

system parameters. The quality of the data obtained from the project will depend upon numerous factors--instrumentation, personnel, sampling technique, sample size, statistical expertise. It is therefore critical that the RFP be as explicit as possible in delineating two things--what quality of data is expected, and how that quality is to be insured.

Generally speaking, the RFP should require that the bidding organizations address each of the major areas of quality control discussed in sections 6.2 through 6.13 of this manual. Reference to figure 3 gives those areas of quality control considered particularly appropriate for each project category.

Since most RFP's are limited in length, it would in most cases be inappropriate to include more than a brief (one- or two-paragraph) statement of quality control requirements. Nevertheless, it is most important that the bid solicitation be as explicit as possible concerning quality control. In those cases where an RFP is quite lengthy, the quality control statement may be several pages long.

7.3 EVALUATION OF QUALITY CONTROL IN THE PROPOSAL

The proposal should contain a statement as to the precise position the bidder's company takes regarding quality control programs. This should include past projects and the quality control program effectiveness in that project. In particular, there should be a clear and explicit response to the quality control requirements stated in the RFP. This response must be compared directly, item-by-item, with other proposals submitted against the RFP. The evaluation should result in a determination of a "figure of merit" for the bidder's quality control organization and the competence of the staff.

There should be provision for changes in procedures when it is evident that data being obtained are not sufficiently accurate or appropriate for the intent of the project as outlined by the project officer.

If a contractor has a good proposal but is unclear on some phases of data quality, it would seem worthwhile to have him clarify his proposal by asking him to answer specific questions. If the answers to these questions are still vague, it is a good indication that the quality for these phases of the project may be questionable if this contractor carries out the project.

7.4 EVALUATION OF QUALITY CONTROL IN THE WORK PLAN

The work plan should be a detailed accounting of the actual steps to be taken to complete the work delineated in the proposal and should be in direct accord with the requirements of the RFP and other agreements with the project officer. Particular attention should be placed on the areas considered critical with respect to quality control, in order to realize the collection of data having acceptable precision, accuracy, representativeness, and completeness.

In cases where the submitted proposal has been accepted but lacks the completeness required by the project officer, the problem areas should be directly addressed in the work plan, showing the details of the work to be done.

The work plan must be submitted to the project officer before any work is begun by the contractor. The plan can be accepted in draft form, which will allow for minor changes prior to the final plan's acceptance and approval.

7.5 THE ON-SITE QUALITATIVE SYSTEMS AUDIT

The objective of the on-site qualitative systems audit is to assess and document (1) facilities; (2) equipment; (3) systems; (4) recordkeeping; (5) data validation; (6) operation, maintenance, and calibration procedures; and (7) reporting aspects of the total quality control program for a project. The review should accomplish the following:

1. Identify existing system documentation; i.e., maintenance manuals, organizational structure, operating procedures, etc;
2. Evaluate the adequacy of the procedures as documented; and
3. Evaluate the degree of use of and adherence to the documented procedures in day-to-day operations, based on observed conditions and a review of applicable records on file.

To aid the auditor in performing the review, a checklist is included as appendix A. This checklist should be modified, as appropriate, for various projects.

7.6 THE PERFORMANCE AUDIT

In addition to a thorough on-site systems review, quantitative performance audits should be periodically undertaken. The objective of these audits is to evaluate the validity of project data by independent measurement techniques. It is convenient to classify the major measurement methods into three areas: physical measurements, gas stream measurements, and liquid stream measurements (the latter including analysis of any suspended solids). Appendix B lists in table form a number of standard techniques for auditing in the three major areas just mentioned. Table 1 (of appendix B) is a compilation of commonly measured physical properties, with a selection of possible measurement, calibration, and audit techniques. Table 2, concentrating on analysis of gas effluent streams, lists the material to be analyzed, and measurement, calibration, and audit techniques for that material. Finally, table 3 very briefly and generally deals with measurement methods appropriate to liquids and solids. The specific techniques vary widely from project to project, but for the analytical phase the audit technique generally involves use of reference samples of known composition and/or splitting a sample among several laboratories for independent analyses. It is desirable to perform calibration checks on individual system components, and/or do side-by-side sampling runs to compare both sampling and analysis technique precision and accuracy.

7.7 DATA QUALITY ASSESSMENT

Standard methods exist for estimation of the precision and accuracy of measurement data. Efficient usage of the audit data requires that a rationale be followed which gives the best possible estimates of precision and accuracy within the limits imposed by timing, number of samples taken, and the general situation at the project site.

Appendix C lists statistical definitions and techniques often used in quality assurance work. Other statistical techniques exist which may apply to specific projects (or to highly specialized areas of a given project). For projects of sufficient duration, it is usually worthwhile to acquire the services of a statistical consultant to most effectively treat the available data.

As a general guide to expected data quality for a number of reference methods, appendix D lists in table form both ambient air and source sampling methods. An estimate of the method bias and precision with comments on major error sources is given, and the appropriate EPA quality assurance guideline document for each method is referenced.

SECTION VIII DEVELOPMENT OF QUALITY CONTROL AND QUALITY ASSURANCE PLANS FOR IERL PROJECT CATEGORIES

8.0 GENERAL

One approach to developing quality control and quality assurance plans within IERL is to divide all projects into six categories, with projects within a given category having common characteristics as to size, duration, objectives, and data quality requirements. This makes them amenable to the same general set of quality control and quality assurance practices and procedures. Suggestions as to applicable practices and procedures are given for each of the project categories in the following subsections.

The primary characteristics and objectives of projects within each project category are given, followed by a discussion of quality control and quality assurance applications to the different phases of a project cycle. These phases, when the project is performed by a contractor, include (1) request for proposal, (2) proposal evaluation, (3) work plan review, (4) project implementation, and (5) final report. Quality control practices for in-house projects could begin with the work plan review. The categories 1 through 6 are:

1. Environmental assessments,
2. Industry system studies/pollutant system studies,
3. Field studies,
4. Research and bench-scale projects,
5. Development or pilot programs, and
6. Demonstration projects.

8.1 ENVIRONMENTAL ASSESSMENTS

8.1.1 Description of Project Category

An environmental assessment involves "(1) a systematic evaluation of the physical, chemical, and biological characteristics of the streams associated with a process; (2) predictions of the probable effects of the streams on the environment; (3) the prioritization of the streams; and (4) identification of

any necessary control technology programs."* The objectives of an assessment include identification and measurement of pollutants for which specific standards have been set, and also those suspected to have harmful effects on the environment. The ultimate goal of environmental assessments is insurance that the effluent streams from a process are within current environmental standards of acceptability.

Sampling and analysis programs for environmental assessments are extensive, and presently are conducted in three distinct phases or levels. Level I involves a broad survey of all process streams. Level II concentrates on those streams identified in Level I as "high priority," i.e., having significant amounts of harmful materials present. These prioritized streams are subjected to more quantitative studies, for the purpose of establishing the appropriate control technology. Level III is a long-term, continuous monitoring program for selected "indicator" materials.

8.1.2 Applicability of Quality Control and Quality Assurance Procedures

Request for Proposal

The RFP must specify the data quality requirements† for each level of the assessment. For purposes of process stream prioritization, the RFP for a given industrial or energy process should indicate, if possible, the "threshold" concentrations of specified suspected or known pollutants. These concentrations would be the minimum for designating those pollutants for more quantitative study in Level II. It should be stated that such designated concentrations are subject to modification in light of the results of Level I studies.

Because of the completeness and comprehensiveness of the sampling and analysis programs in an environmental assessment, the RFP will not generally be able to anticipate the data quality requirements for each measurement. Nevertheless, every attempt should be made to specify the quality control and quality assurance requirements as completely as possible, so that prospective contractors

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*Taken from a draft copy of "Guidelines for Environmental Sampling and Analysis Programs - Historical Development and Strategy of a Phased Approach," by Dorsey, Lochmüller, Johnson and Statnick, IERL-EPA-RTP, 1976.

†As quantitatively as possible.

will be realistic in their estimations of the cost of quality control for the assessment.

Proposal Evaluation

Environmental assessments generally require extensive sampling and analytical capability. Each proposal must be evaluated on the known personnel and equipment inventory of the bidding organization. Instrumentation requirements may be large, and there must be experienced technical and professional personnel to carry out each level of the assessment. The ability to produce high-quality data, within whatever specifications were made in the RFP, should enter heavily into the overall evaluation of each proposal.

Work Plan Review

The work plan affords the contractor the opportunity to demonstrate in some detail how the assessment will be carried out, and in particular how the data quality will be assured. The project officer, after reviewing the work plan with the Quality Assurance Group representative, may wish to negotiate more or less time or resources to various phases of the assessment, in line with EPA's conception of the program's priorities and data quality requirements. The work plan should be as definite as possible with respect to how the data will be acquired and what quality control procedures will be employed.

Project Implementation

Periodic reports to the project officer should contain appropriate sample data, statistical treatments, and contractor judgments as to the quality of data being currently obtained. These reports should be carefully read and analyzed by the project officer and Quality Assurance Group representative, since these reports serve as the primary means of communication from the contractor. If inadequate data quality procedures are being used, the project officer should immediately make arrangements to improve quality control at the project, and perhaps should modify the nature and/or frequency of systems reviews and performance audits.* These quality assurance programs can, if

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*The assumption here is that the reviews and audits can be carried out by an audit team which visits the industrial or energy site and makes comparable measurements, as well as observing the contractor team in operation. This may not be practical in some situations.

correctly timed, point out contractor quality control deficiencies and make for minimum data loss.

Final Report

Quality control and quality assurance procedures must be included in the final report of an environmental assessment, since the assessment is a phased operation, and decisions as to priority will be made after each phase is completed. Quality control and quality assurance must be documented such that sufficient confidence may be placed in the data to justify the decisions made.

8.2 INDUSTRY SYSTEM STUDIES/POLLUTANT SYSTEM STUDIES

8.2.1 Description of Project Category

This category includes projects that are paper studies involving the collection and analysis of air pollution measurement data from the literature or personal contacts.

An industry system study as performed in-house or by a contractor for the IERL Laboratory is of short to medium duration (normally 3 to 6 months). Typical objectives of an industry system study are the following:

1. To characterize an industry with respect to the type and magnitude of air pollutant emissions;
2. To assess the present degree of control of these emissions; and
3. To evaluate the technical feasibility and the economic and environmental costs and benefits of improved control methods.

Pollutant system studies are also usually of short duration. The purpose of these studies is to identify the sources and to estimate the concentration of a particular pollutant.

The data reported in a paper study must be of sufficient quality to allow IERL to determine the appropriate followup action. Quality requirements will depend upon the financial implications of the decisions to be made on the basis of the data. The quantitative confidence level exhibiting these characteristics varies with the type of pollutant. For example, an industry system study reporting of a nitrogen oxide emission level as 50 ppm $\pm$ 30 ppm would probably provide an adequate basis from which to determine that the emissions were of little consequence, whereas reporting the emission of vinyl chloride to 50 ppm

± 30 ppm would most likely spur an immediate followup for additional information. In general, the accuracy and precision of data reported in a paper study is not as critical as the data quality from, for example, a specific pilot plant study, since the paper study will be for general program development decisions and will be followed by more detailed and specific projects when necessary.

8.2.2 Application of Quality Control and Quality Assurance Procedures

Request for Proposal

Quality assurance for a study begins with preparation of the RFP. The project officer should consult with the Quality Assurance Group to insure that proposals can be evaluated on an equivalent basis. The RFP should include the specific type of data to be obtained and an indication of the type of precision and accuracy statements to be attached to the reported data. For example, in a pollutant system study (or industry system study), it may be stated that:

1. "All pollutant sources should be identified for which the concentration of NO_x exceeds 50 ppm;"

or

2. "Concentration of NO_x is to be given for identified sources with estimates of the precision of the reported levels, e.g., ± 20 percent of the reported value."

The RFP should specify or request the bidder to estimate the sample size necessary to insure that the sample is representative of the population of interest. General requirements for statistical evaluation of the data obtained as well as guidelines for referencing and assignment of confidence levels to the data should be given in the RFP.

Proposal Evaluation

A representative from the Quality Assurance Group should evaluate the proposals and prepare a report to the project officer describing the ability of each contractor to accomplish the above requirements. The contractor's proposal rationale for analyzing the data and making inferences and conclusions also provides a preview of quality control for the project. For example, the means by which a contractor may propose to estimate the data quality if 2. above is the suggested objective might be: (1) to use the Federal Register guidelines on precision and accuracy for standard reference methods when the information

is not presented in a report, (2) to compare to the reference methods if the results are quoted with precision statements, or (3) to call the author of the report/data tabulations if neither of the above is applicable.

Work Plan Review

When the contract is awarded, preparation and review of the work plan allows refinement of the quality control procedures outlined in the proposal. The project officer in conjunction with the Quality Assurance Group representative can ascertain if the contractor has allowed sufficient time and resources to develop a reasonable data base from which statistical correlations can be developed. The proposed methodology of analyzing and drawing conclusions from the data can also be reviewed at this time for adequacy and completeness. The work plan is expected to be more definitive than the proposal and should address the data quality aspects, when required, even if the proposal did not respond to those.

Project Implementation

During the course of the project, monthly reports from the contractor to the project officer provide the opportunity for continuing quality assurance. Review of monthly reports provides the project officer the opportunity to detect quality problems by comparing the interim results against acceptance criteria established in the work plan. Early detection of problems can lead to correction in a timely manner to avoid the use of questionable data or the loss of time occasioned by correcting deficiencies late in the program. Correction of the problem may consist of modification of the information collection or correlation procedure or perhaps a redefinition of the project objectives in light of the accumulated experiences.

Final Report

The results of the study should be evaluated in view of several points of consideration. The degree of depth of the evaluation clearly depends on the data quality objectives. Some of the points to be considered are:

1. Data sources;
2. Inferences from data on:
    a. the effect of data precision and accuracy on conclusions,
    b. the appropriateness of the analysis procedure (engineering and statistics);

3. Comparison with comparable studies/research that are considered to be of good quality;
4. Limitations of data; and
5. The need to make measurements.

A summary of the applicability of the reported data along with the appropriate comments on their quality should be included in the final report when requested. This information should be reviewed by the Quality Assurance Group and reported in abbreviated form to the laboratory director with a copy to the project officer. These statements provide a source of information on the adherence of the contractor to the data quality criteria as described in the request for proposal, proposal, and/or work plan. This report by the Quality Assurance Group serves as a project evaluation file and a source of quality assurance information.

8.3 FIELD STUDIES

8.3.1 Description of Project Category

Projects in this category are usually of short duration, i.e., less than 2 or 3 months. There will be a great variation in data quality requirements depending on the project objectives. A field study may, for example, be for evaluation of a new device for sizing submicron particles.

The conduct of such studies will typically require a contractor familiar with the industry, control system, or device to be assessed or evaluated. The quality control techniques for the pertinent measurement systems will need to be supplied by the project officer and Quality Assurance Group. The contractor should be required to use standard reference methods or an equivalent method, if possible. The burden of proof of using another equivalent method would be upon the contractor. The justification for using nonreference methods should be clearly stated.

8.3.2 Application of Quality Control and Quality Assurance Procedures

The degree of precision and accuracy requested in the reported results of field studies may vary considerably from one study to another, and consequently it is necessary to specify as carefully as possible the requirements of the prospective contractor in the RFP. For example, measurement methods may be

specified, the desired precision of the results given, and the responder asked to indicate in the proposal how the desired data quality levels can be attained through proper measurement methods and appropriate quality control procedures. The Quality Assurance Group can provide advice as to what levels of precision are attainable, based on past experience.

Proposal Evaluation

The proposals submitted can be reviewed and rated as to their responses to the data quality aspects and the quality assurance methods. The Quality Assurance Group would utilize its file of past experience on contractors to aid in this evaluation.

Work Plan Review

After contract award, the work plan becomes one of the most effective means for assurance of data quality through the use of appropriate measurement methods and quality control techniques, and the use of suggested standards for checking on the precision and accuracy of the method. The Quality Assurance Group will review the work plan in detail for its inclusion of applicable quality control techniques.

Project Implementation

During the project implementation phase, the Quality Assurance Group will be kept informed through periodic reports from the contractor to the project officer and from the project officer concerning adherence to the work plan, any problems in doing so, and suggested corrections to problems. If the Quality Assurance Group can advise as to the means for assuring data quality, it should indicate this to the project officer for consideration/use by the contractor. The contractor's proficiency in making the measurements can be evaluated and estimates of the precision and accuracy of the measurements made by the use of on-site system reviews and audits, conducted at the beginning and periodically throughout the project life.

Final Report

At the termination of the contract and upon submittal of the final report, the Quality Assurance Group should file an evaluation report on the study briefly summarizing the pertinent data quality information, the capability of the contractor to produce high-quality data, and general comments on the

contractor's quality assurance procedures as appropriate. This file of evaluative information provides a ready source of data for future contractor evaluation and data quality improvement techniques. The good techniques are just as important to include in the evaluation as the deficient ones.

8.4 RESEARCH AND BENCH-SCALE PROJECTS

8.4.1 Description of Project Category

Research and bench-scale projects are exploratory studies of a pollutant measurement or control method, with the primary objectives of developing and evaluating a successful process or device. The duration of this type of project is variable and may continue concurrently with pilot plant or prototype studies.

Research projects are defined here as primarily paper studies consisting of the theoretical development of a new technology. The bench-scale project is the first experimental attempt to demonstrate the postulated results. The data quality requirements of a bench-scale study are dependent on the nature of the particular project. For example, documentation of the precision and accuracy of measurements would be critical when bench-scale project results support pilot plant studies, whereas qualitative measurements with an accuracy of $\pm$ 20 percent may be adequate for a preliminary demonstration of the feasibility of a new pollutant control device.

8.4.2 Application of Quality Control and Quality Assurance Procedures

Request for Proposal

An RFP leading to research and bench-scale studies may of necessity be general since IERL cannot always anticipate the characteristics of novel devices and innovative techniques proposed by contractors. However, the RFP and proposal evaluation should require a discussion of measurement systems and basis for selection.

Work Plan Review

When the contract is awarded, more specific guidelines can be laid out in the preparation and review of the work plan, although a stringently defined test plan is not always applicable to a bench-scale study. The project may be

conducted in a more cost-effective manner by allowing the researcher to make exploratory studies with inexact measurements in the early stages of the project and then to concentrate on additional measurement development specific to the most promising directions.

Project Implementation

During the course of the project, frequent communication between the contractor, the project officer, and the Quality Assurance Group is essential for quality assurance. Written monthly reports are useful, but frequently more cost-effective project management and quality assurance can be ascertained through personal conferences to review the progress of the work and the intended direction for continuation. If the project is of such a nature that measurements of high precision and accuracy are required, the project officer should require documentation of the procedure for operations, calibrations, quality checks, and validation of data. Data quality may be assessed by means of performance audits using duplicate, control, and/or blind samples. These methods may detect quality problems and allow for their correction early in the program.

Final Report

Quality assurance in the final report of a research or bench-scale project is of critical importance, since the study may lead to additional funding of the process or equipment development at a more sophisticated level. The methods used for sampling and measurement of data, for analysis, and for correlation must be rigorously presented so that the results could be duplicated in an independent study if desired.

8.5 DEVELOPMENT OR PILOT PROGRAM

8.5.1 Description of Project Category

This program has as one of its major objectives the development and refinement of theoretical and empirical models relating the process variables and system parameters to the response variables of interest, e.g., concentration of particulate matter. Hence, this is the stage of development in which an experiment consisting of a series of runs is planned for deriving the relationships of interest. In some cases the determination will be made of "optimum" values of control system parameters for various plant parameters. Data quality

aspects are described in the steps of the contract procurement and implementation cycle.

8.5.2 Application of Quality Control and Quality Assurance Procedures

Request for Proposal

In this stage of control equipment development, the objectives of the program should be clearly indicated as to data quality. The statement of work should include the request that the contractor suggest an experimental plan that will assure the attainment of the quality objectives (assuming these objectives to be compatible with the existing or developed technology). The RFP should give relatively high priority to the data quality control plan as an evaluation criterion of the proposal. Types of statements which might be employed in the RFP are:

> "Submit a proposed experimental plan to relate variables X, Y, Z, and W to concentration of the pollutant in the effluent stream and indicate how the precision of the relationship will be checked by the use of the design plan and the associated analysis."
>
> "Indicate the methods of measurement of critical variables and the expected precision and accuracy of these methods."

Proposal Evaluation

At this stage, the project officer and Quality Assurance Group should review the data quality aspects of the proposals for the purpose of rating the prospective contractors on their apparent ability to provide data of good quality. At this point it should be noted that past records of contractor performance will be very helpful. Judgment of new prospective contractors must be made on the basis of a careful evaluation of their discussion. Absence of any details on data quality aspects, even though the discussion may have very good general ideas, would be a signal for concern and lower ratings.

Work Plan Review

Shortly after the award of the contract to a company, the Quality Assurance Group should assist the project officer in the role of evaluating the adequacy of the quality control aspects of the work plan. The plan should have considerably more detail concerning data quality than the proposal. Also it is possible that the selected contractor was strong on several other rating

criteria in the proposal evaluation but lower in the quality control aspects. This would be the appropriate time to request that the contractor strengthen the data quality program, in particular the experimental plan. At this point, in order to insure good quality data that will meet the needs of IERL, the following factors should be considered:

1. The experimental plan to attain objectives;
2. The means for adherence to the plan--control of system parameters;
3. Measurement methods of sufficient precision and accuracy for meeting the project needs, and use of standards in checking the data quality;
4. Appropriate checks of measurements under specified conditions/ control system parameters (i.e., independent or repeat runs should be included in the experimental plan, and duplicate measurements should be made for those results with large variation; for example, if the coefficient of variation [100 x standard deviation/mean] is greater than 5 percent).
5. Data reporting and quality checks included in plan;
6. Analysis methods with indicated checks, if necessary, to insure valid results.

The ultimate benefits of a well-designed experimental program should be the provision of the greatest information per unit cost of the experiment. Because the cost of a single run of an experiment of the type required at this stage of development is high, it places the greatest importance on making the best possible use of the data, e.g., utilizing the preferred analysis methods resulting in valid interpretations with attached measures of confidence/precision.

Project Implementation

Throughout the conduct of the project work, the Quality Assurance Group should be made aware of any quality control problems through appropriate reports, e.g., monthly progress reports and quarterly reports. The project officer should provide for on-site checks of the quality control procedures. This may be performed by personnel of the Quality Assurance Group or a contractor so designated by the Group, with a written report provided to the Quality Assurance Group. The Quality Assurance Group should advise the project officer and project contractor on such matters of quality control as:

1. use of specific standards for checking pollutant measurement methods,
2. how often checks should be made,
3. calibration frequency,
4. use of quality control techniques as required, and
5. interlaboratory programs for pollutant measurement methods.

Final Report

The final report on the project should include the necessary information on data quality. Raw data should be provided as an appendix to the report. Only in circumstances of unusually large amounts of data should they be separated from the report, e.g., provided in one copy by computer printout. The analysis of the data should be illustrated by example, the statement of precision and accuracy of the data included, with method of computation, particularly when different from well-documented methods. If relationships are presented (e.g., concentration of SO_2 vs. selected control system parameters) raw data should be shown on the figures, if two-dimensional. Otherwise, the raw data and corresponding predicted mean given by the relationship are to be given in tabulated form. This allows more ready interpretation by IERL. The raw data should be given by order of the experimental run along with remarks or conditions surrounding the run which may be pertinent in some later evaluation or analysis. The inability to obtain data for certain parameter values should be noted. Pertinent raw data on the instrument checks should also be included in the report with supporting data maintained in the lab notebooks, should any questions arise. A statement of limitations and applicability of the data should be included in the final report.

Based on the final report, the Quality Assurance Group should provide a summary report to the director of IERL with a copy to the project officer indicating the pertinent data aspects of the project. A checklist of considerations should be employed for convenience in such evaluations.

8.6 DEMONSTRATION PROJECTS

8.6.1 Description of Project Category

These projects have as their goal the demonstration of control systems, models, and methods in full-scale systems, i.e., under plant operational

conditions. The control systems methods and models will have been developed under previous research and pilot-scale operations. The demonstration projects usually will be of at least 1-year duration. The values of the control system parameters and plant operation variables will be changed very little, offering little opportunity for experimental research. There will be the opportunity for the use of both quality control and quality assurance techniques. The data quality will be an important aspect of this type of study. For example, quality control chart data should be maintained on the critical parameters and response measurements and these data provided with the final report in an appropriate summary form. There will be the need for using well-documented measurement methods of desired precision/accuracy. Standards should be used to calibrate and maintain control of quality of the measurement methods. The data quality aspects should be described in reference to the steps of the procurement and project implementation stages of the control system demonstration and evaluation.

8.6.2 Application of Quality Control and Quality Assurance Procedures

Request for Proposal

The objectives of the demonstration program for the specified control system and its associated models and methods of analysis should be clearly indicated in the RFP. The contractor should be requested to give relatively high priority to data quality, quality control and assessment techniques, maintenance and calibration of pollutant measurement instruments, use of appropriate standards, and other general quality control capabilities in the proposal.

The Quality Assurance Group should provide inputs to the RFP based on the previous studies of the control system and the requirements of data precision and accuracy. An example of such a statement would be:

> "Methods used for measuring the emissions of the pollutant must include the standard reference methods of the Federal Register--or an equivalent method, provided proof is given that the method employed is equally precise and accurate."

Proposal Evaluation

The proposals should be reviewed and rated as to the discussion of the data quality aspects of the demonstration study. This rating should be based on the prospective contractor's familiarity with quality control procedures,

his current quality control activities, performance on previous studies if available from the Quality Assurance Group files, and other general laboratory practices, such as preventive maintenance of equipment. The Quality Assurance Group should be responsible for review of this aspect of the proposals.

Work Plan Review

The selected contractor should prepare a work plan shortly after contract award, detailing the project demonstration plan, which includes the quality control aspects of the study. The work plan should contain much more detail concerning quality control than the proposal. In cases where quality control may have been a weak point of the selected contractor's proposal, this aspect of the work plan will need to be reviewed carefully to assure that:

1. The measurement program will meet the objectives of the study if properly implemented;
2. Means are presented for controlling and monitoring the plant and control system parameters;
3. Measurement methods are sufficiently precise and accurate for meeting the project needs; that standards will be used to calibrate and maintain instruments, and interlaboratory and intralaboratory measurements will be used to assure data quality;
4. Quality control charts will be maintained on selected parameters deemed to be important;
5. Data reporting and quality checks will be included in the plan and data quality will be assessed;
6. Problem identification, e.g., out-of-control operations, will be indicated, with progress reports that give the problem and its effect on data quality.

Project Implementation

During the implementation stage, the Quality Assurance Group should be provided a copy of all progress reports that relate to any aspect of data quality. At certain indicated milestones in the project work, the group should check to see that the contractor is adhering to the work plan (data quality aspects), and should advise the project officer and contractor of the availability of certain standards, estimated precisions of specific methods

(if available and unknown to them), and uses of quality control charts. The Quality Assurance Group is to serve for the duration of the project both as a resource group, because of its records of similar information from several projects that may use the same methods, and as an advisory source of information on general aspects of quality assurance. The Quality Assurance Group should design and coordinate through the project officer a program of performance audits and on-site system inspections sufficient to assure, assess, and document the data quality throughout the project's duration.

Final Report

The final report serves as a means of reporting and properly summarizing the raw data, data quality, the precision and accuracy of measurement methods, the methods of engineering and statistical analysis, and quality control chart information. All raw data should be included in the final report, to the extent possible. If it is excessive, then one computer printout might be filed with IERL to back up the laboratory notebook maintained by the contractor, should any problems arise in interpretation and analysis at a later date.

Methods of analysis of data quality should be provided unless they are well-documented in the literature, in which case they may be referenced.

A statement of limitation, if any, and applicability of the results should be given in the report. This may be part of an executive summary or in a section entitled "Data Quality -- Applicability of Methods and Results."

The results of the project demonstration as reported in the final report should be assessed by the Quality Assurance Group, against both the data quality objectives set forth in the RFP and the details provided in the work plan. The contractor should be rated according to a checklist of items to be used in such studies. A copy of this evaluation should be given to the director of IERL, to the project officer, and perhaps to QAB. This file of project evaluation closes the loop and provides useful information for future projects, proposal evaluations, RFP statements, and alternate improvements of data quality in all IERL-RTP projects in the area of activity.

SECTION IX REFERENCES

1. Glossary and Tables for Statistical Quality Control, the American Society for Quality Control, Milwaukee, Wisconsin, 1973.

2. Quality Assurance Handbook for Air Pollution Measurement Systems, Volume 1, Principles, EPA-600/9-76-005.

3. "Planning Document for a Control Systems Laboratory Quality Assurance Program," Final Report for EPA Contract No. 68-02-1398, Task 8, December 1974.

4. "Guidelines for Demonstration Project Quality Assurance Programs," Final Report for EPA Contract No. 68-02-1398, Task 20, January 1976.

5. "A Quality Assurance Program for the EPA Wet Limestone Scrubber Demonstration Project, Shawnee Steam-Electric Plant, Paducah, Kentucky," Final Report for EPA Contract No. 68-02-1398, Task 20, January 1976.

6. "Development and Trial Field Application of a Quality Assurance Program for IERL Projects," Final Report for EPA Contract No. 68-02-1398, Task 20, January 1976.

APPENDIX A QUALITATIVE ON-SITE SYSTEMS AUDIT CHECKLIST

This checklist gives three descriptions to each facet of a typical quality control system. In all cases, the "5" choice indicates the most desirable and effective mode of operation; "3" is marginal and tolerable; "1" is definitely unacceptable and ineffective as a mode of operation.

It is not always possible to describe accurately all options with only three choices. Therefore, a "2" or "4" rating may be selected if the evaluator feels that an in-between score is more descriptive of the actual situation.

After all the applicable questions are answered, an average is computed to give an overall indication of the quality control system effectiveness.

Generally, a rating of 3.8 or better is considered acceptable.

A rating between 2.5 and 3.8 indicates a need for improvement but no imminent threat to current project performance.

A.1 QUALITY ORGANIZATION

		SCORE
(1.1)	Overall responsibility for quality assurance (or quality control) for the organization is:	
	(a) Assigned to one individual by title (e.g., Quality Control Coordinator).	5
	(b) Assigned to a specific group within the organization.	3
	(c) Not specifically assigned but left to the discretion of the various operational, analytical, inspection, and testing personnel.	1
(1.2)	The Quality Control Coordinator is located in the organization such that:	
	(a) He has direct access to the top management level for the total operation, independent of others involved in operational activities.	5
	(b) He performs as a peer with others involved in operational activities, with access to top management through the normal chain of command.	3
	(c) His primary responsibility is in operational activities, with quality assurance as an extra or part-time effort.	1
(1.3)	Data reports on quality are distributed by the Quality Control Coordinator to:	
	(a) All levels of management.*	5
	(b) One level of management only.	3
	(c) The quality control group only.	1
(1.4)	Data Quality Reports contain:	
	(a) Information on operational trends, required actions, and danger spots.	5
	(b) Information on suspected data/analyses and their causes.	3
	(c) Percent of valid data per month.	1

*Management at appropriate levels in all applicable organizations such as subcontractors, prime contractor, EPA.

A.2 THE QUALITY SYSTEM

SCORE

(2.1) The quality control system is:

(a) Formalized and documented by a set of procedures which clearly describe the activities necessary and sufficient to achieve desired quality objectives, from procurement through to reporting data to the EPA/RTP. 5

(b) Contained in methods procedures or is implicit in those procedures. Experience with the materials, product, and equipment is needed for continuity of control. 3

(c) Undefined in any procedures and is left to the current managers or supervisors to determine as the situation dictates. 1

(2.2) Support for quality goals and results is indicated by:

(a) A clear statement of quality objectives by the top executive, with continuing visible evidence of its sincerity, to all levels of the organization. 5

(b) Periodic meetings among operations personnel and the individual(s) responsible for quality assurance, on quality objectives and progress toward their achievement. 3

(c) A "one-shot" statement of the desire for product quality by the top executive, after which the quality assurance staff is on its own. 1

(2.3) Accountability for quality is:

(a) Clearly defined for all sections and operators/analysts where their actions have an impact on quality. 5

(b) Vested with the Quality Control Coordinator who must use whatever means possible to achieve quality goals. 3

(c) Not defined. 1

A.2 THE QUALITY SYSTEM (continued)

SCORE

(2.4) The acceptance criteria for the level of quality of the demonstration projects routine performance are:

(a) Clearly defined in writing for all characteristics. 5

(b) Defined in writing for some characteristics and some are dependent on experience, memory and/or verbal communication. 3

(c) Only defined by experience and verbal communication. 1

(2.5) Acceptance criteria for the level of quality of the project's routine performance are determined by:

(a) Monitoring the performance in a structured program of inter- and intralaboratory evaluations. 5

(b) Scientific determination of what is technically feasible. 3

(c) Laboratory determination of what can be done using currently available equipment, techniques, and manpower. 1

(2.6) Decisions on acceptability of questionable results are made by:

(a) A review group consisting of the chief chemist or engineer, quality control, and others who can render expert judgment. 5

(b) An informal assessment by quality control. 3

(c) The operator/chemist. 1

A.2 THE QUALITY SYSTEM (continued)

SCORE

(2.7) The quality control coordinator has the authority to:

(a) Affect the quality of analytical results by inserting controls to assure that the methods meet the requirements for *precision*, *accuracy*, *sensitivity*, and specificity. 5

(b) Reject suspected results and stop any method that projects high levels of discrepancies. 3

(c) Submit suspected results to management for a decision on disposition. 1

A.3 IN-PROCESS QUALITY ASSURANCE

(3.1) Measurement methods are checked:

(a) During operation for conformance to operating conditions and to specifications, e.g., flow rates, reasonableness of data, etc. 5

(b) During calibration to determine acceptability of the results. 3

(c) Only when malfunctions are reported. 1

(3.2) The capability of the method to produce within specification limit is:

(a) Known through method capability analysis ($\bar{X}$-R Charts) to be able to produce consistently acceptable results. 5

(b) Assumed to be able to produce a reasonably acceptable result. 3

(c) Unknown. 1

(3.3) Method determination discrepancies are:

(a) Analyzed immediately to seek out the causes and apply corrective action. 5

(b) Checked out when time permits. 3

(c) Not detectable with present controls and procedures. 1

A.3 IN-PROCESS QUALITY ASSURANCE (continued)

SCORE

(3.4) The operating conditions (e.g., flow rate, range, temperature, etc.) of the methods are:

(a) Clearly defined in writing in the method for each significant variable. 5

(b) Controlled by supervision based on general guidelines. 3

(c) Left up to the operator/analyst. 1

(3.5) Auxiliary measuring, gaging, and analytical instruments are:

(a) Maintained operative, accurate, and precise by regular checks and calibrations against stable standards which are traceable to the U.S. Bureau of Standards. 5

(b) Periodically checked against a zero point or other reference and examined for evidence of physical damage, wear or inadequate maintenance. 3

(c) Checked only when they stop working or when excessive defects are experienced which can be traced to inadequate instrumentation. 1

A.4 CONFIGURATION CONTROL

(4.1) Procedures for documenting, for the record, any design change in the system are:

(a) Written down and readily accessible to those individuals responsible for configuration control. 5

(b) Written down but not in detail. 3

(c) Not documented. 1

A.4 CONFIGURATION CONTROL (continued)

SCORE

(4.2) Engineering schematics are:

(a) Maintained current on the system and subsystem levels. 5

(b) Maintained current on certain subsystems only. 3

(c) Not maintained current. 1

(4.3) All computer programs are:

(a) Documented and flow charted. 5

(b) Flow charted. 3

(c) Summarized. 1

(4.4) Procedures for transmitting significant design changes in hardware and/or software to the EPA project officer are:

(a) Documented in detail sufficient for implementation. 5

(b) Documented too briefly for implementation. 3

(c) Not documented. 1

A.5 DOCUMENTATION CONTROL

(5.1) Procedures for making revisions to technical documents are:

(a) Clearly spelled out in written form with the line of authority indicated and available to all involved personnel. 5

(b) Recorded but not readily available to all personnel. 3

(c) Left to the discretion of present supervisors/managers. 1

A.5 DOCUMENTATION CONTROL (continued)

SCORE

(5.2) In revising technical documents, the revisions are:

(a) Clearly spelled out in written form and distributed to all parties affected, on a controlled basis which assures that the change will be implemented and permanent. 5

(b) Communicated through memoranda to key people who are responsible for effecting the change through whatever method they choose. 3

(c) Communicated verbally to operating personnel who then depend on experience to maintain continuity of the change. 1

(5.3) Changes to technical documents pertaining to operational activities are:

(a) Analyzed to make sure that any harmful side effects are known and controlled prior to revision effectivity. 5

(b) Installed on a trial or gradual basis, monitoring the product to see if the revision has a net beneficial effect. 3

(c) Installed immediately with action for correcting side effects taken if they show up in the final results. 1

(5.4) Revisions to technical documents are:

(a) Recorded as to date, serial number, etc. when the revision becomes effective. 5

(b) Recorded as to the date the revision was made on written specifications. 3

(c) Not recorded with any degree of precision. 1

A.5 DOCUMENTATION CONTROL (continued)

SCORE

(5.5) Procedures for making revisions to computer software programs are:

(a) Clearly spelled out in written form with the line of authority indicated. 5

(b) Not recorded but changes must be approved by the present supervisor/manager. 3

(c) Not recorded and left to the discretion of the programmer. 1

(5.6) In revising software program documentation, the revisions are:

(a) Clearly spelled out in written form, with reasons for the change and the authority for making the change distributed to all parties affected by the change. 5

(b) Incorporated by the programmer and communicated through memoranda to key people. 3

(c) Incorporated by the programmer at his will. 1

(5.7) Changes to software program documentation are:

(a) Analyzed to make sure that any harmful side effects are known and controlled prior to revision effectivity. 5

(b) Incorporated on a trial basis, monitoring the results to see if the revision has a net beneficial effect. 3

(c) Incorporated immediately with action for detecting and correcting side effects taken as necessary. 1

A.5 DOCUMENTATION CONTROL (continued)

SCORE

(5.8) Revisions to software program documentation are:

(a) Recorded as to date, program name or number, etc., when the revision becomes effective. 5

(b) Recorded as to the date the revision was made. 3

(c) Not recorded with any degree of precision. 1

A.6 PREVENTIVE MAINTENANCE

(6.1) Preventive maintenance procedures are:

(a) Clearly defined and written for all measurement systems and support equipment. 5

(b) Clearly defined and written for most of the measurement systems and support equipment. 3

(c) Defined and written for only a small fraction of the total number of systems. 1

(6.2) Preventive maintenance activities are documented:

(a) On standard forms in station log books. 5

(b) Operator/analyst summary in log book. 3

(c) As operator/analyst notes. 1

(6.3) Preventive maintenance procedures as written appear adequate to insure proper equipment operation for:

(a) All measurement systems and support equipment. 5

(b) Most of the measurement systems and support equipment. 3

(c) Less than half of the measurement systems and support equipment. 1

A.6 PREVENTIVE MAINTENANCE (continued)

SCORE

(6.4) A review of the preventive maintenance records indicates that:

(a) Preventive maintenance procedures have been carried out on schedule and completely documented. 5

(b) The procedures were carried out on schedule but not completely documented. 3

(c) The procedures were not carried out on schedule all the time and not always documented. 1

(6.5) Preventive maintenance records (histories) are:

(a) Utilized in revising maintenance schedules, developing an optimum parts/reagents inventory and development of scheduled replacements to minimize wear-out failures. 5

(b) Utilized when specific questions arise and for estimating future work loads. 3

(c) Utilized only when unusual problems occur. 1

A.7 DATA VALIDATION PROCEDURES

(7.1) Data validation procedures are:

(a) Clearly defined in writing for all measurement systems. 5

(b) Defined in writing for some measurement systems, some dependent on experience, memory, and/or verbal communication. 3

(c) Only defined by experience and verbal communication. 1

A.7 DATA VALIDATION PROCEDURES (continued)

SCORE

(7.2) Data validation procedures are:

(a) A coordinated combination of computerized and manual checks applied at different levels in the measurement process. 5

(b) Applied with a degree of completeness at no more than two levels of the measurement process. 3

(c) Applied at only one level of the measurement process. 1

(7.3) Data validation criteria are documented and include:

(a) Limits on: (1) operational parameters such as flow rates; (2) calibration data, (3) special checks unique to each measurement; e.g., successive values/averages; (4) statistical tests; e.g., outliers; (5) manual checks such as hand calculations. 5

(b) Limits on the above type checks for most of the measurement systems. 3

(c) Limits on some of the above type checks for only the high-priority measurements. 1

(7.4) Acceptable limits as set are reasonable and adequate to insure the detection of invalid data with a high probability for:

(a) All measurement systems. 5

(b) At least 3/4 of the measurement systems. 3

(c) No more than 1/2 of the measurement systems. 1

A.7 DATA VALIDATION PROCEDURES (continued)

SCORE

(7.5) Data validation activities are:

(a) Recorded on standard forms at all levels of the measurement process. 5

(b) Recorded in the operator's/analyst's log book. 3

(c) Not recorded in any prescribed manner. 1

(7.6) Examination of data validation records indicates that:

(a) Data validation activities have been carried out as specified and completely documented. 5

(b) Data validation activities appear to have been performed but not completely documented. 3

(c) Data validation activities, if performed, are not formally documented. 1

(7.7) Data validation summaries are:

(a) Prepared at each level or critical point in the measurement process and forwarded to the next level with the applicable block of data. 5

(b) Prepared by and retained at each level. 3

(c) Not prepared at each level nor communicated between levels. 1

(7.8) Procedures for deleting invalidated data are:

(a) Clearly defined in writing for all levels of the measurement process, and invalid data are automatically deleted when one of the computerized validation criteria is exceeded. 5

(b) Programmed for automatic deletion when computerized validation criteria are exceeded but procedures not defined when manual checks detect invalid data. 3

(c) Not defined for all levels of the measurement process. 1

A.7 DATA VALIDATION PROCEDURES (continued)

SCORE

(7.9) Quality audits (i.e., both on-site system reviews and/or quantitative performance audits) independent of the normal operations are:

(a) Performed on a random but regular basis to ensure and quantify data quality. 5

(b) Performed whenever a suspicion arises that there are areas of ineffective performance. 3

(c) Never performed. 1

A.8 PROCUREMENT AND INVENTORY PROCEDURES

(8.1) Purchasing guidelines are established and documented for:

(a) All equipment and reagents having an effect on data quality. 5

(b) Major items of equipment and critical reagents. 3

(c) A very few items of equipment and reagents. 1

(8.2) Performance specifications are:

(a) Documented for all items of equipment which have an effect on data quality. 5

(b) Documented for the most critical items only. 3

(c) Taken from the presently used items of equipment. 1

(8.3) Reagents and chemicals (critical items) are:

(a) Procured from suppliers who must submit samples for test and approval prior to initial shipment. 5

(b) Procured from suppliers who certify they can meet all applicable specifications. 3

(c) Procured from suppliers on the basis of price and delivery only. 1

A.8 PROCUREMENT AND INVENTORY PROCEDURES (continued)

SCORE

(8.4) Acceptance testing for incoming equipment is:

(a) An established and documented inspection procedure to determine if procurements meet the quality assurance and acceptance requirements. Results are documented. 5

(b) A series of undocumented performance tests performed by the operator before using the equipment. 3

(c) The receiving document is signed by the responsible individual indicating either acceptance or rejection. 1

(8.5) Reagents and chemicals are:

(a) Checked 100% against specification, quantity, and for certification where required and accepted only if they conform to all specifications. 5

(b) Spot-checked for proper quantity and for shipping damage. 3

(c) Released to analyst by the receiving clerk without being checked as above. 1

(8.6) Information on discrepant purchased materials is:

(a) Transmitted to the supplier with a request for corrective action. 5

(b) Filed for future use. 3

(c) Not maintained. 1

(8.7) Discrepant purchased materials are:

(a) Submitted to a review by Quality Control and Chief Chemist for disposition. 5

(b) Submitted to Service Section for determination on acceptability. 3

(c) Used because of scheduling requirements. 1

A.8 PROCUREMENT AND INVENTORY PROCEDURES (continued)

SCORE

(8.8) Inventories are maintained on:

(a) First-in, first-out basis. 5

(b) Random selection in stock room. 3

(c) Last-in, first-out basis. 1

(8.9) Receiving of materials is:

(a) Documented in a receiving record log, giving a description of the material, the date of receipt, results of acceptance test, and the signature of the responsible individual. 5

(b) Documented in a receiving record log with material title, receipt date, and initials of the individual logging the material in. 3

(c) Documented by filing a signed copy of the requisition. 1

(8.10) Inventories are:

(a) Identified as to type, age, and acceptance status. 5

(b) Identified as to material only. 3

(c) Not identified in writing. 1

(8.11) Reagents and chemicals which have limited shelf life are:

(a) Identified as to shelf life expiration data and systematically issued from stock only if they are still within that date. 5

(b) Issued on a first-in, first-out basis, expecting that there is enough safety factor so that the expiration date is rarely exceeded. 3

(c) Issued at random from stock. 1

A.9 PERSONNEL TRAINING PROCEDURES

SCORE

(9.1) Training of new employees is accomplished by:

(a) A programmed system of training where elements of training, including quality standards, are included in a training checklist. The employee's work is immediately rechecked by supervisors for errors or defects and the information is fed back instantaneously for corrective action. 5

(b) On-the-job training by the supervisor who gives an overview of quality standards. Details of quality standards are learned as normal results are fed back to the chemist. 3

(c) On-the-job learning with training on the rudiments of the job by senior coworkers. 1

(9.2) When key personnel changes occur:

(a) Specialized knowledge and skills are retained in the form of documented methods and descriptions. 5

(b) Replacement people can acquire the knowledge of their predecessors from coworkers, supervisors, and detailed study of the specifications and memoranda. 3

(c) Knowledge is lost and must be regained through long experience or trial-and-error. 1

(9.3) The people who have an impact on quality, e.g., calibration personnel, maintenance personnel, bench chemists, supervisors, etc., are:

(a) Trained in the reasons for and the benefits of standards of quality and the methods by which high quality can be achieved. 5

(b) Told about quality only when their work falls below acceptable levels. 3

(c) Are reprimanded when quality deficiencies are directly traceable to their work. 1

A.9 PERSONNEL TRAINING PROCEDURES (continued)

SCORE

(9.4) The employee's history of training accomplishments is maintained through:

(a) A written record maintained and periodically reviewed by the supervisor. 5

(b) A written record maintained by the employee. 3

(c) The memory of the supervisor/employee. 1

(9.5) Employee proficiency is evaluated on a continuing basis by:

(a) Periodic testing in some planned manner with the results of such tests recorded. 5

(b) Testing when felt necessary by the supervisor. 3

(c) Observation of performance by the supervisor. 1

(9.6) Results of employee proficiency tests are:

(a) Used by management to establish the need for and type of special training. 5

(b) Used by the employee for self-evaluation of needs. 3

(c) Used mostly during salary reviews. 1

A.10 FEEDBACK AND CORRECTIVE ACTION

(10.1) A feedback and corrective action mechanism to assure that problems are reported to those who can correct them and that a closed loop mechanism is established to assure that appropriate corrective actions have been taken is:

(a) Clearly defined in writing with individuals assigned specific areas of responsibility. 5

(b) Written in general terms with no assignment of responsibilities. 3

(c) Not formalized but left to the present supervisors/managers. 1

A.10 FEEDBACK AND CORRECTIVE ACTION (continued)

SCORE

(10.2) Feedback and corrective action activities are:

(a) Documented on standard forms. 5

(b) Documented in the station log book. 3

(c) Documented in the operator's/analyst's notebook. 1

(10.3) A review of corrective action records indicates that:

(a) Corrective actions were systematic, timely, and fully documented. 5

(b) Corrective actions were not always systematic, timely, or fully documented. 3

(c) A closed loop mechanism did not exist. 1

(10.4) Periodic summary reports on the status of corrective action are distributed by the responsible individual to:

(a) All levels of management. 5

(b) One level of management only. 3

(c) The group generating the report only. 1

(10.5) The reports include:

(a) A listing of major problems for the reporting period; names of persons responsible for corrective actions; criticality of problems; due dates; present status; trend of quality performance (i.e., response time, etc.); listing of items still open from previous reports. 5

(b) Most of the above items. 3

(c) Present status of problems and corrective actions. 1

A.11 CALIBRATION PROCEDURES

SCORES

(11.1) Calibration procedures are:

(a) Clearly defined and written out in step-by-step fashion for each measurement system and support device. 5

(b) Defined and summarized for each system and device. 3

(c) Defined but operational procedures developed by the individual. 1

(11.2) Calibration procedures as written are:

(a) Judged to be technically sound and consistent with data quality requirements. 5

(b) Technically sound but lacking in detail. 3

(c) Technically questionable and lacking in detail. 1

(11.3) Calibration standards are:

(a) Specified for all systems and measurement devices with written procedures for assuring, on a continuing basis, traceability to primary standards. 5

(b) Specified for all major systems with written procedures for assuring traceability to primary standards. 3

(c) Specified for all major systems but no procedures for assuring traceability to primary standards. 1

(11.4) Calibration standards and traceability procedures as specified and written are:

(a) Judged to be technically sound and consistent with data quality requirements. 5

(b) Standards are satisfactory but traceability is not verified frequently enough. 3

(c) Standards are questionable. 1

A.11 CALIBRATION PROCEDURES (continued)

SCORE

(11.5) Frequency of calibration is:

(a) Established and documented for each measurement system and support measurement device. 5

(b) Established and documented for each major measurement system. 3

(c) Established and documented for only certain measurement systems. 1

(11.6) A review of calibration data indicates that the frequency of calibration as implemented:

(a) Is adequate and consistent with data quality requirements. 5

(b) Results in limits being exceeded a small fraction of the time. 3

(c) Results in limits being exceeded frequently. 1

(11.7) A review of calibration history indicates that:

(a) Calibration schedules are adhered to and results fully documented. 5

(b) Schedules are adhered to most of the time. 3

(c) Schedules are frequently not adhered to. 1

(11.8) A review of calibration history and data validation records indicates that:

(a) Data are always invalidated and deleted when calibration criteria are exceeded. 5

(b) Data are not always invalidated and/or deleted when criteria are exceeded. 3

(c) Data are frequently not invalidated and/or deleted when criteria are exceeded. 1

A.11 CALIBRATION PROCEDURES (continued)

SCORE

(11.9) Acceptability requirements for calibration results are:

(a) Defined for each system and/or device requiring calibration including elapsed time since the last calibration as well as maximum allowable change from the previous calibration. 5

(b) Defined for all major measurement systems. 3

(c) Defined for some major measurements systems only. 1

(11.10) Acceptability requirements for calibration results as written are:

(a) Adequate and consistent with data quality requirements: 5

(b) Adequate but others should be added. 3

(c) Inadequate to ensure data of acceptable quality. 1

(11.11) Calibration records (histories) are:

(a) Utilized in revising calibration schedules (i.e., frequency). 5

(b) Utilized when specific questions arise and reviewed periodically for trends, completeness, etc. 3

(c) Utilized only when unusual problems occur. 1

A.12 FACILITIES/EQUIPMENT

(12.1) Facilities/Equipment are:

(a) Adequate to obtain acceptable results. 5

(b) Adequate to obtain acceptable results most of the time. 3

(c) Additional facilities and space are needed. 1

A.12 FACILITIES/EQUIPMENT (continued)

SCORE

(12.2) Facilities, equipment, and materials are:

(a) As specified in appropriate documentation and/or standards. 5

(b) Generally as specified in appropriate standards. 3

(c) Frequently different from specifications. 1

(12.3) Housekeeping reflects an orderly, neat, and effective attitude of attention to detail in:

(a) All of the facilities. 5

(b) Most of the facilities. 3

(c) Some of the facilities. 1

(12.4) Maintenance Manuals are:

(a) Complete and readily accessible to maintenance personnel for all systems, components, and devices. 5

(b) Complete and readily accessible to maintenance personnel for all major systems, components, and devices. 3

(c) Complete and accessible for only a few of the systems. 1

A.13 RELIABILITY

(13.1) Procedures for reliability data collection, processing, and reporting are:

(a) Clearly defined and written for all system components. 5

(b) Clearly defined and written for major components of the system. 3

(c) Not defined. 1

A.13 RELIABILITY (continued)

		SCORE
(13.2)	Reliability data are:	
	(a) Recorded on standard forms.	5
	(b) Recorded as operator/analyst notes.	3
	(c) Not recorded.	1
(13.3)	Reliability data are:	
	(a) Utilized in revising maintenance and/or replacement schedules.	5
	(b) Utilized to determine optimum parts inventory.	3
	(c) Not utilized in any organized fashion.	1

APPENDIX B STANDARD TECHNIQUES USED IN QUANTITATIVE PERFORMANCE AUDITS

Table 1. Physical measurements

Property	Measurement Methods	Calibration Methods	Audit Techniques
Density	a. Vibrating U-tube b. Mass/flow meter c. Bubble tube	Take sample, get weight and volume at process temperature and calculate density.	Frequency: Before start and at end of demonstration, monthly in between. Technique: Use of appropriate laboratory weight and volume measures.
Flow	a. Orifice meter i. manometer ii. differential pressure cell iii. mechanical gauges iv. electrical cells b. Pitot tube i. manometer ii. mechanical gauges iii. electrical cells iv. differential pressure cell c. Venturi meter d. Magnetic flow meter e. Ultrasonic flow meter	Primary method is to remove meter from process and calibrate on test stand. Secondary method is calibration of elements following sensor.	Frequency: Before start and at end of demonstration, monthly in between. Remove sensor element and inspect for corrosion or fouling. Carry out manufacturer recommended calibration procedure. For transducer and output, apply substitute signal and calibrate.
Humidity	a. Wet bulb/dry bulb thermometers b. Dewpoint meters c. Electronic humidity cells d. Fluidic	Calculation of humidity from wet and dry bulb measurements and psychrometric relations.	Frequency: Before start and at end of demonstration, weekly for wet/dry bulb, monthly for others. Technique: Remove sensor and subject to air stream having wet/dry apparatus for comparison.

Table 1. Physical measurements (con.)

Property	Measurement Methods	Calibration Methods	Audit Techniques
Level	a. Bubble tube b. Float c. Conductivity cell d. Capacitance cell e. Differential pressure cell f. Ultrasonic g. Sight glass	Measure level with sight glass or dip stick.	Frequency: Before start and at end of demonstration, monthly in between. Technique: Measure level at several points in range and compare to readout.
Pressure, differential pressure	a. Mechanical gauge b. Manometer c. Electrical pressure cell d. Differential pressure cell	Use of dead weight tester is primary standard. Secondary standards are a. Manometer with known fluid b. Precision mechanical gauges c. Standard electrical pressure cells	Frequency: Before start and at end of demonstration, monthly in between. Technique: Pressure sensors to be provided with test taps and valves, also tap for secondary source for d/p or electrical cells. Manometer is preferred for calibration in field where possible
Temperature	a. Thermocouple b. Resistance Temperature Detector c. Thermistor d. Filled bulb e. Mercury thermometer	Comparison to reference point a. Ice point H_2O b. Boiling point H_2O c. Standard thermometer d. Electronic standard	Frequency: Before start and at end of demonstration, monthly in between. Technique: Remove sensor, insert in reference temperature. For non-removable sensor, measure output of sensor, and insert substitute signal into instrument input and check calibration.

Table 2. Gas effluent streams

Material	Measurement Method	Calibration Method	Audit Techniques
Carbon Monoxide	Method 10 (Continuous)	Standard calibration gas.	Provide SRM* for measurement.
Nitrogen Oxide	Method 7 (Grab)	Calibrate Sampling Train components and use control samples for analysis phase.	1. Independent duplicate sampling and analysis. 2. Review and observe operating procedures, check calibration of train components, and prepare blind samples for field team to measure.
	Continuous	1. Use standard calibration gases plus 2. Compare results to Method 7.	1. Provide NO/NO_2 calibration gas: NBS-SRM (analysis phase). 2. Compare to Method 7 (total measurement method).
Particulates	Method 5 (Sampling Train)	Calibrate components of sampling train: pitot tube, dry gas meter, orifice meter, temperature measurement devices, probe heater, filter holder, temperature system	1. Audit of total method by independent, simultaneous measurement from sampling through analysis. 2. Calibration check on sample train components per cent isokinetic rate, and visual observation of operating procedures.
	Optical (transmissometer)	Filters	Calibration check with independent set of NBS filters.

* Standard Reference Material, from the National Bureau of Standards.

Table 2. Gas effluent streams (con.)

Material	Measurement Method	Calibration Method	Audit Techniques
Sulfur Dioxide	Method 6 (Batch)	Calibrate sampling train components and use standards samples for analysis phase.	1. Independent duplicate sampling and analysis. 2. Review/observe operating procedures, check calibration of train components, and analyze split samples and/or prepare blind samples for field team to measure.
	Method 12 (Continuous)	1. Use standard calibration gases plus 2. Use calibrated absorbance filter furnished by instrument manufacturer.	1. Compare to Method 6. 2. Provide SRS for measurements.

Table 3. Liquid streams, suspended solids

Material	Measurement Method	Calibration Method	Audit Techniques
Liquid Stream Samples- per cent solids, ionic species	Standard chemical and instrumental techniques (atomic absorption spectrometry, potentiometry, amperometry, etc.)	Calibrate glassware, balances, instruments.	Control samples, split samples.
Effluent solids; e.g., per cent water, CaO, SO_3^{-2}, SO_4^{-2}, CO_2, inerts, etc.*	Standard gravimetric, volumetric, instrumental techniques (such as x-ray fluorescence).	Calibrate volumetric, gravimetric, instrumental measurement devices (glassware, balances, meters, etc.)	Control samples, split samples.
pH	a. pH cell b. Indicators (test papers) c. Wet chemical	a. Subject to known pH buffer solution b. Sample stream and measure pH with independent method/instrument.	Frequency: Daily to weekly Technique: Remove pH cell from process and insert in buffered solutions in range of process pH.

* typical of solids composition in the effluent of a wet limestone SO_2 scrubber.

APPENDIX C DEFINITIONS AND STATISTICAL TECHNIQUES USEFUL IN QUALITY ASSURANCE PROGRAMS

I. CENTRAL TENDENCY AND DISPERSION

A. The Arithmetic Mean.

The sum of all values in a measurement set, divided by the number of values summed. Commonly called the "average." Often denoted symbolically by a bar over the variable symbol, as "X".

$$\bar{X} = \sum_{i=1}^{n} X_i \Big/ n$$

B. Range.

The difference between the maximum and minimum values of a set of values.

$$R = X_{max} - X_{min}$$

A rough indication of variability, particularly when the set of values is small (<10).

C. Standard Deviation.

An indication of the dispersion of a set of numbers about the mean value. Normal (and other) distributions are expressed as a function of the standard deviation.

For a given set of values, the defining equation is:

$$s = \left[\frac{\sum_{i=1}^{n} (X_i - \bar{X})^2}{n-1} \right]^{1/2}$$

For computational purposes, it is convenient to use:

$$s = \left[\frac{\sum_{i=1}^{n} X_i^2}{n} - \bar{X}^2 \right]^{1/2}$$

D. Relative Standard Deviation, or Coefficient of Variation.

The dispersion of a set of values, expressed as a percentage of the mean.

$$CV = (s/\bar{X}) \times 100$$

II. MEASURES OF VARIABILITY

A. Accuracy.

The difference (either on an absolute or percentage basis) between a measured value and an assumed "true" value. The larger the difference, the lower the accuracy.

$$B = X - T, \quad \text{or}$$

$$\%B = \frac{(X-T) \times 100}{T}$$

(see "Bias")

B. Bias.

A nonrandom measurement error; a consistent difference either between sets of results or between a measured value and a "true" value. If the latter, the bias or percent bias is measured by the relationships in A above. (See III. SIGNIFICANCE TESTS, A. t-test)

C. Precision.

A measure of agreement among individual measurements of a variable, under identical or similar conditions. Precision may be expressed in several ways, and care must be exercised in the definition and use of precision measures.

One set of such measures* follows:

1. Within-laboratory: The within-laboratory standard deviation, s, measures the dispersion in replicate single determinations made by one laboratory team (same field operators,

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* These definitions are taken from EPA collaborative test result publications, and are applied to the various federal reference sampling and analysis techniques. Since these techniques are frequently used in evaluating emissions from IERL projects, they are particularly appropriate for this guidelines document.

laboratory analyst, and equipment) sampling the same true concentration.

2. Between-laboratory: The between-laboratory standard deviation, s_b, measures the total variability in a concentration determination due to determinations by different laboratories sampling the same true stack concentration. The between laboratory variance, s_b^2, may be expressed as

$$s_b^2 = s_L^2 + s^2$$

and consists of a within-laboratory variance plus a laboratory bias variance, s_L^2.

3. Laboratory bias: The laboratory bias standard deviation, $s_L = \sqrt{s_b^2 - s^2}$, is that portion of the total variability that can be ascribed to differences in the field operators, analysts and instrumentation, and due to different manners of performance of procedural details left unspecified in a technique. This term measures that part of the total variability in a determination which results from the use of a technique by different laboratories, as well as from modifications in usage by a single laboratory over a period of time. The laboratory bias standard deviation is estimated from the within-and between-laboratory estimates previously obtained.

A corresponding set of coefficients of variation would be CV, CV_b, and CV_L. These are convenient to use if the precision is proportional to the mean value of the variable.

III. SIGNIFICANCE TESTS

A. t-test.

If one has an assumed "true" value, however obtained, the existence of a significant bias in other measurements of this value can be defined by a t-test:

$$t = \frac{\bar{d} - 0}{s_d/\sqrt{n}}$$

where t = a parameter, the magnitude of which is referenced to tabulated values. A t-value which exceeds the tabulated value for given specifications of probability and number of degrees of freedom indicates the existence (within the definition of probability specified) of a significant bias. The more stringent the probability requirement; i.e., the smaller the probability chosen, the larger the tabulated t-value.

$\bar{d}$ = the average difference between the true value and the measured values; the average bias.

s_d = the standard deviation of the differences, d_i.

n = the number of measurements made.

B. Chi-square test.

If one has a reasonable estimate of the expected standard deviation of a set of measurements, the existence of a defined "excess variability" can be tested as follows:

$$\frac{\chi^2}{f} = \frac{s_d^2}{\sigma^2\{x\}}$$

where χ^2/f = a random variable with tabulated values (f = n - 1 = number of degrees of freedom).

$\sigma^2\{x\}$ = the expected variance of the measurements of x.

If χ^2/f is larger than the chosen tabulated value (with specified probability), it is concluded that the measurements are exhibiting excess variability. The chi-square test is a measure of the validity of a series of measurements based on an "expected" variability. The test is worthwhile only whenever a measurement technique has been tested thoroughly, so that a realistic expectation can be estimated.

IV. CONFIDENCE LIMITS

Confidence limits take two forms. One form defines a numerical range within which one has a (arbitrarily chosen) probability of finding the true mean value of the measured variable. If the measurement variability is expressed as a standard deviation, the confidence limits as defined above can be calculated as follows:

$$CL = \bar{X} \pm ts/\sqrt{n}$$

where all symbols have been previously defined. Note that as the number of measurements, n, increases, the magnitude of CL decreases. Also, for higher probabilities of containing the true mean within CL, the larger the value of t and therefore the larger the size of CL.

The second form of confidence limit defines an interval within which the next individual measurement can be expected to fall with a given probability. The calculation of this limit, sometimes called a tolerance limit, is by the following relationship:

$$TL = \bar{X} \pm ts$$

While n, the number of measurements, does not explicitly appear in the equation for TL, it does determine (along with the selected probability) the value of t; i.e., as n increases, t decreases.

V. TESTING FOR OUTLIERS

An outlier is an extreme value, either high or low, which has questionable validity as a member of the measurement set with which it is associated.

Detection of outliers may be on one of the following basis:

a) A known experimental aberration, such as an instrument failure or a technique inconsistency.

b) A statistical test for significance, such as the Dixon ratio test. This test is described below.

The Dixon criteria is based entirely on ratios of differences between observations where it is desirable to avoid calculation of s or where quick judgment is called for. For the Dixon test, the sample criterion or statistic changes with sample size. Critical values of the statistic for various levels of significance are tabulated.

Table 1* below, presents selected significance (probability) levels for criteria over the n range 3 to 25. Note that the measurement values are first, arranged in order of ascending magnitude; i.e., x_n is the largest value.

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* Taken from "Processing Data for Outliers," by W. J. Dixon, Biometrics, Vol. 9, No. 1, 1953.

Table 1. DIXON CRITERIA FOR TESTING OF EXTREME OBSERVATION (SINGLE SAMPLE)[a]

n	Criterion	Significance Level		
		10%	5%	1%
3	$r_{10} = (x_2 - x_1)/(x_n - x_1)$ if smallest	0.886	0.941	0.988
4	value is suspected;	0.679	0.765	0.889
5	$= (x_n - x_{n-1})/(x_n - x_1)$ if	0.557	0.642	0.780
6	largest value is suspected.	0.482	0.560	0.698
7		0.434	0.507	0.637
8	$r_{11} = (x_2 - x_1)/(x_{n-1} - x_1)$ if	0.479	0.554	0.683
9	smallest value is suspected;	0.441	0.512	0.635
10	$= (x_n - x_{n-1})/(x_n - x_2)$ if largest value is suspected.	0.409	0.477	0.597
11	$r_{21} = (x_3 - x_1)/(x_{n-1} - x_1)$ if	0.517	0.576	0.679
12	smallest value is suspected;	0.490	0.546	0.642
13	$= (x_n - x_{n-2})/(x_n - x_2)$ if largest value is suspected.	0.467	0.521	0.615
14	$r_{22} = (x_3 - x_1)/(x_{n-2} - x_1)$ if	0.492	0.546	0.641
15	smallest value is suspected;	0.472	0.525	0.616
16	$= (x_n - x_{n-2})/(x_n - x_3)$ if	0.454	0.507	0.595
17	largest value is suspected.	0.438	0.490	0.577
18		0.424	0.475	0.561
19		0.412	0.462	0.547
20		0.401	0.450	0.535
21		0.391	0.440	0.524
22		0.382	0.430	0.514
23		0.374	0.421	0.505
24		0.367	0.413	0.497
25		0.360	0.406	0.489

[a] $x_1 \leq x_2 \leq x_n$.

APPENDIX D SOME STANDARD AMBIENT AIR AND SOURCE SAMPLING TECHNIQUES

SOURCE SAMPLING TECHNIQUES [a]

Pollutant	EPA Method or Number	Bias (absolute, or percent of mean concentration)	Precision (absolute, or coefficient of variation)		Comments	Reference
			within laboratory	between laboratory		
SO_2	6	0	3.9	5.5	Major error source is difficulty of obtaining reproducible titration endpoints. Minimum detectable limit is 3 ppm.	EPA-650/14-74-005-e
SO_2 and SO_3/H_2SO_4	8	-2% (analysis only)	0.1 g/m^3	0.11 g/m^3	Same analysis technique as Method 6 above.	EPA-650/14-74-005-g
		-2% (analysis only)	60%	65%		
NO_x	7	0	7%	10%	Grab sample; largest error source is failure to recalibrate spectrophotometer.	EPA-650/14-74-005-f
CO	10	+7 ppm	13 ppm	25 ppm	Analyzer drift and CO_2 interference are largest problems. Minimum detectable limit is 20 ppm.	EPA-650/14-74-005-h
Particulates	5	No information	10-30%	20-40%	Numerous small error sources associated with stack sampling.	EPA-650/14-74-005-d
Visible emissions	9	+1.4% opacity	2% opacity	2.5%	Good results depend to a great extent on the effective training of observers.	EPA-650/14-74-005-i
Be	104	-20%, average	44%	58%		EPA-650/14-74-005-k

a This table is a summary of information contained in the cited references, all of which are Quality Assurance Guidelines Manuals.

AMBIENT AIR TECHNIQUES[a]

Pollutant	EPA Method or Number	Bias (absolute, or percent of mean concentration)	Precision (absolute, or coefficient of variation)		Comments	Reference
			within laboratory	between laboratory		
SO_2	6	0	5-13 $\mu g/m^3$, from x = 0-1000 $\mu g/m^3$	10-25 $\mu g/m^3$ from x = 0-1000 $\mu g/m^3$	Lower limit of detection is 25 $\mu g/m^3$. Flow rate changes, sampling train leakage are primary error sources.	EPA-R4-73-028d
NO, NO_2 NO_x	Chemiluminescent	0	7-8% at 100 $\mu g/m^3$ (0.05 ppm)	———	Lower limit of detection is 10 $\mu g/m^3$ (0.005 ppm). Errors are associated with calibration and instrument drift (from zero and span settings).	d
Photochemical oxidants	Chemiluminescent	-35 to -15% from 0.05 to 0.50 ppm[c]	0.0033 + 0.0255 x[c] (0-0.5 ppm)	0.0008 + 0.0355 x (0-0.15 ppm) -0.0051 + 0.0690 x (0.15-0.5 ppm)	Lower detection limit is 0.0065 ppm	EPA-R4-73-028c
CO	NDIR	+2.5	0.6 mg/m^3	0.8 - 1.6 mg/m^3 (nonlinear variation) over 0-60 mg/m^3	Lower detection limit is 0.3 mg/m^3. Interference of water vapor is significant.	EPA-R4-73-028a

a This table is a summary of information contained in the cited references, all of which are Quality Assurance Guideline Manuals published by EPA. Collaborative test results are cited, if available, in the manuals.
b x = pollutant concentration.
c EPA-650/4-75/016.
d Guidelines for Development of a Quality Assurance Program for The Continuous Measurement of Nitrogen Dioxide in the Ambient Air (Chemiluminescent), Smith & Nelson, Research Triangle Institute, Research Triangle Park, N.C. 27709

AMBIENT AIR TECHNIQUES (cont.)

Pollutant	EPA Method or Number	Bias (absolute, or percent of mean concentration)	Precision (absolute, or coefficient of variation)		Comments	Reference
			within laboratory	between laboratory		
Particulates	High Volume	No information	3%	3.7%	Minimum detectable limit is 3 mg. Shorter sampling periods give less precise results, biased high.	EPA-R4-73-028b
NO_2	Arsenite	-3% (50-300 $\mu g/m^3$)	8 $\mu g/m^3$ (50-300 $\mu g/m^3$)	11 $\mu g/m^3$ (50-300 $\mu g/m^3$)	A tentative method. Lower detectable limit is 9 $\mu g/m^3$.	EPA-R4-73-280o

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16. ABSTRACT The manual gives guidelines for the establishment and maintenance of an integrated data quality program for EPA's Industrial Environmental Research Laboratory--Research Triangle Park (IERL-RTP). Administrative systems dedicated to the data quality program are delineated. These systems include quality policies and objectives, organizational structure and key quality personnel, and a schedule for implementation. Components of both quality control programs and quality assurance programs are given. IERL-RTP projects are divided into six categories. Projects within a given category have common characteristics (e.g., size, duration, objectives, and data quality requirements), making them amenable to the same general set of quality control and quality assurance practices and procedures. Quality control and quality assurance procedures applicable to each of the six categories are given for each phase of the project's life cycle. These phases include: Request for Proposal preparation, proposal evaluation, work plan evaluation, project implementation and maintenance, and reports.

17. KEY WORDS AND DOCUMENT ANALYSIS

a. DESCRIPTORS		b. IDENTIFIERS/OPEN ENDED TERMS	c. COSATI Field/Group
Pollution	Evaluation	Pollution Control	13B
Data	Proposals	Stationary Sources	
Quality	Reporting	IERL-RTP	
Quality Control		Work Plans	13H,14D
Quality Assurance			
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