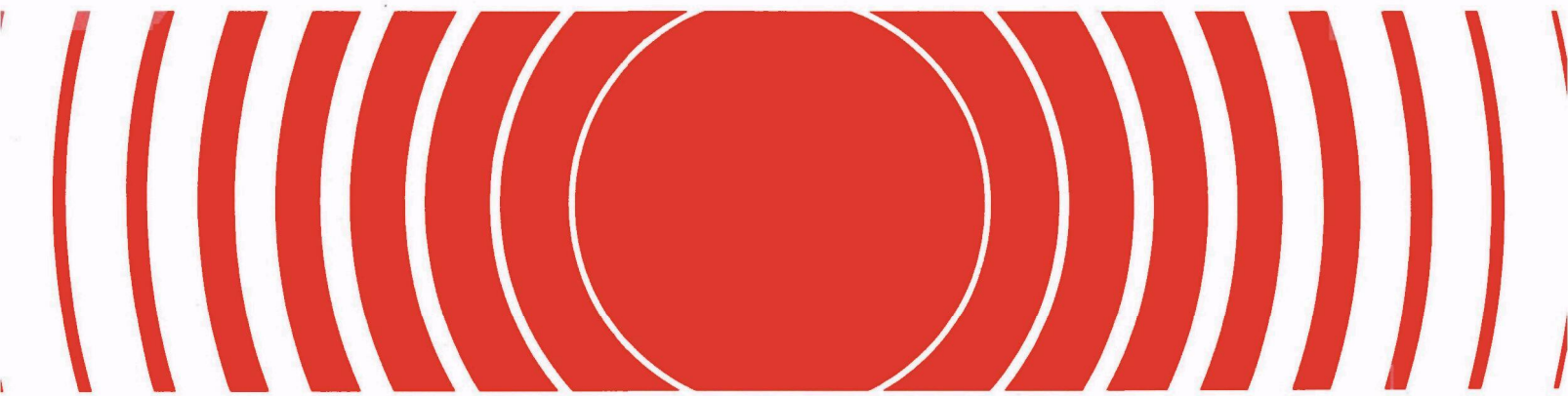
United States
Environmental Protection
Agency

Office of Radiation Programs
(ANR-459)

EPA/520/1-89-030
October 1989

EPA

Quality Assurance Program Plan of the Office of Radiation Programs



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

OCT 5 1989

OFFICE OF
AIR AND RADIATION

MEMORANDUM

SUBJECT: Office of Radiation Programs Quality Assurance Program Plan

FROM: Lewis Battist, Quality Assurance Officers
Office of Radiation Programs (ANR-461)

TO: ORP Staff

Quality Assurance (QA) of environmentally related measurements and data is important to the success of the Environmental Protection Agency's role to protect the environment. The primary goal of the Agency QA program is to ensure that all environmentally related measurement programs supported by the EPA produce data of known quality. It is EPA policy that all EPA organizational units ensure that data representing environmentally related measurements are of known quality, verifiable, documented, and defensible.

Quality Assurance is the management process used to ensure compliance with Agency policy and attainment of Agency goals. Quality Assurance should not be confused with Quality Control.

The attached Quality Assurance Program Plan is the formal statement of the Office of Radiation Programs' (ORP) QA policy. It sets forth the responsibilities for implmentation of QA within the ORP, the QA requirements which must be met and the procedures to follow. The plan is applicable to ORP, is contractors and its grantees. The plan establishes a process to ensure that all aspects of monitoring or measurement projects are carefully defined, goals specified, and all methods and procedures defined and approved before a project is begun. The plan applies to ORP computer models as well as environmental measurement projects. It requires that all computer models be audited. Until specific procedures for audits are defined, individual project plans to audit each model are to be prepared.

The QA process begins with the establishment of Data Quality Objectives (DQOs) for each project. After DOQs are approved a Quality Assurance Project Plan (QAPjP) containing procedures and methods designed to produce data which meets the DQO requirements is prepared. After the QAPjP is approved the project may begin. The development of DQOs and QAPjPs is essential to the success of environmental measurement projects. The EPA Quality Assurance Management Staff conducts training on DQOs and QAPjPs. Staff members who may serve as decision makers or project officers should attend these training classes.

The ORP Quality Assurance Project Plan is furnished to ORP staff members to aquaint them with ORP QA policy and to assist them in discharging their Quality Assurance responsibilities as necessary.

QUALITY ASSURANCE PROGRAM PLAN

OF THE OFFICE OF RADIATION PROGRAMS

Prepared By:

Lewis Battist, Ph.D.
Quality Assurance Officer

Foreword

Quality Assurance is an essential element of reliable environmental data. All data used by the Environmental Protection Agency must be of known quality. The Office of Radiation Programs' (ORP) Quality Assurance Program Plan is based on the EPA QA policies and defines the roles, policies, and procedures used by ORP. This document, the ORP Quality Assurance Program Plan, states current philosophy and meets present ORP needs. The plan is not static and will be changed as needed to insure that measurements performed by or for ORP meet Agency data quality requirements. Inquiries or comments on the plan should be directed to Dr. Lewis Battist.

Concurrences

(1) Name Lewis Battist Phone 475-9644

Title Quality Assurance Officer

Signature Lewis Battist Date 10 July, 1989

Approval For Implementation

(1) Name Richard J. Guimond

Title Director, Office of Radiation Programs

Signature Richard J. Guimond Date 7/14/89

Concurrence - AA Level

(1) Name William G. Rosenberg

Title Assistant Administrator for Air and Radiation

Signature [signature] Date 7/26/89

Approval for Agency

(1) Name Stanley Blacker

Title Director, Quality Assurance Management Staff

Signature S Blacker Date 9/15/89

Table of Contents

1 INTRODUCTION

1.1 BACKGROUND

The Environmental Protection Agency (EPA) needs accurate, reproducible, and defensible data to evaluate environmental conditions, to assess potential health hazards, and to insure compliance with its orders and regulations. To achieve these needs, data must be of known and desired quality. Each Program Office is responsible for developing and maintaining a program that insures the quality of its environmental measurement programs. The requirements of each office are documented in its Quality Assurance Program Plan. The Quality Assurance Management Staff of the Office of Research and Development is responsible for overseeing the Agency's Quality Assurance activities.

The EPA's Office of Radiation Programs (ORP) develops and implements programs that include measurements of both ionizing and nonionizing radiation. The largest continuing environmental measurements program is called the Environmental Radiation Ambient Monitoring System, a national network of sampling stations for air particulates, precipitation, surface water, and milk. Measurements are also made to evaluate and define methods to mitigate high radon concentrations, to assist States to evaluate the proficiency of suppliers who perform radon monitoring, and to provide calibration assistance to States and industry.

Special studies are performed to evaluate radiologically contaminated sites and facility effluents, to locate potentially hazardous areas, and to support State programs. These programs are conducted by the Office of Radiation Programs staff, or by contractors, grantees, or cooperating agencies with Office of Radiation Programs oversight.

The Office has historically had an excellent quality assurance and quality control program. Other organizations have often requested ORP advice in establishing Quality Assurance projects and programs. The Performance Audit (Intercomparison) program currently operated by the Office of Research and Development at the Environmental Monitoring Systems Laboratory in Las Vegas originated in what is now the Office of Radiation Programs. ORP facilities in Montgomery and Las Vegas both have quality assurance programs predating the formation of the Agency.

Pursuant to the Administrator's directives of May 30 and June 14, 1979, this Quality Assurance Plan documents this Office's quality assurance program for all monitoring and measurement efforts performed directly, those supported by contracts, or those required by Agency regulations.

1.2 PURPOSE

The plan contains: (1) a description of the program, (2) required Agency procedures, and (3) policies and procedures required to produce data of known and acceptable quality, i.e., in conformance with data quality objectives. The plan documents responsibilities and the management structure for quality assurance in the Office of Radiation Programs.

2 QUALITY ASSURANCE POLICY

2.1 GOALS AND PRIORITIES

The success of any measurement program depends upon the implementation of a good Quality Assurance Program. ORP's policy requires that all radiation measurement under its jurisdiction shall produce data of known and specified quality. Each ORP project shall include sufficient quality assurance to produce and document adequate, valid data without the expenditure of unnecessary resources.

It is also ORP's policy that all QA standards be regularly monitored for adequacy.

2.2 DATA MEASUREMENT REQUIREMENTS

The basic measurement requirement is to produce scientifically valid, defensible data of known and specified precision and accuracy. The quality of data shall be defined in Data Quality Objectives (DQO's) by the Senior Manager having management oversight and responsibility for the project.

The production of satisfactory measurement data requires:

a. Establishment of Data Quality Objectives for the analytical results required for decisionmaking (See Section 7.2).

b. A monitoring protocol capable of producing results adequate for decision making. The design of the environmental monitoring protocol will include the selection of monitoring locations, the frequency of monitoring or sampling, the selection of measurement parameters, and the acceptable accuracy and level of uncertainty in the data. All of these aspects of a monitoring program are to be designed to meet the established DQO's.

c. Appropriate methods to make accurate and precise measurements.

d. Insure that all analytical and sampling data are properly and completely processed.

e. Documentation that items a, b, c, and d are properly designed and performed.

f. Documentation for the requirements and responsibilities defined in Sections 4 through 11.

2.3 RESPONSIBILITIES

The Director, Office of Radiation Programs, is responsible for ensuring that environmental measurements meet established Data Quality Objectives. The Office Director has delegated the responsibility for overseeing Quality Assurance activities to the Quality Assurance Officer (QAO). This delegation includes all areas covered by the Office of Radiation Programs' Quality Assurance Program Plan. The Quality Assurance Officer is located in the Economics and Control Engineering Branch, Analysis and Support Division (ASD), ORP. An Assistant Quality Assurance Officer (AQAO) is also located in this Branch.

ORP Division and Facility Directors have primary responsibility for their measurement programs. Division Directors exercise this responsibility through Project Officers who work with the ORP Quality Assurance Officer. Each Facility Director appoints a Quality Assurance Coordinator (QAC) to direct the Facility's Quality Assurance Program. QAC's report directly to the Facility Director on all QA matters, work with Facility Project Officers, and provide liaison to the QAO.

3 ORP ENVIRONMENTAL DATA COLLECTION ACTIVITIES

3.1 ENVIRONMENTAL DATA COLLECTION ACTIVITIES

Environmental data collection activities include: (1) special studies (termed assessment monitoring); (2) trend and baseline monitoring; and (3) accident and incident monitoring. Special studies may either support regulatory efforts or be performed as a service to other governmental, State, and Federal agencies. Future activities will include monitoring for compliance with EPA/ORP radiological regulations and standards.

3.2 ASSESSMENT MONITORING

3.2.1 Environmental Radiation Ambient Monitoring System (ERAMS) Program

The ERAMS was originally established to monitor radioactive fallout. ERAMS* now consists of a nationwide network of stations that sample airborne particulates, rainfall, milk, surface and drinking water. Airborne particulates are sampled continuously and analyzed twice weekly. Milk samples from representative

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*The detailed ERAMS sampling schedules and locations are contained in the Environmental Radiation Data Reports, published quarterly by the Eastern Environmental Radiation Facility, Office of Radiation Programs, USEPA, Montgomery, Alabama.

producing areas are collected and analyzed monthly. Surface and drinking water samples are collected at many locations and analyzed quarterly.

The ERAMS program, though routinely used for trend and baseline monitoring, serves an important assessment function especially for emergencies involving the spread of radioactive material contamination. During a radiological emergency, such as Three Mile Island or Chernobyl, the frequency of sampling and analysis can be increased and additional ERAMS standby stations activated.

The ERAMS program has an approved Quality Assurance Project Plan and approved DQO's.

3.2.2 Special Studies

Special Studies include:

a. Analyses of samples supplied by States or others.

b. Studies performed for other Federal agencies. For example, studies are performed by ORP for the Navy of harbors where nuclear ships are serviced to determine if there has been any radiological contamination. For these studies, the decisionmaker (the Navy) only wants to determine if ship operations are contaminating the harbor.

Special studies also include the collection of data to support the development of regulations. Effluents from several types of facilities that emit radioactive materials may require monitoring

for both the quantity and nature of these materials. Airborne concentrations and potential deposition characteristics are among the factors needed to support the regulatory development process. Each such sampling and analytical program requires a Quality Assurance Project Plan (QAPjP) for which specific Data Quality Objectives are established. (See Sections 7.3 and 7.2).

3.3 NEW MONITORING PROGRAMS

Before undertaking any monitoring program, except those of a research or feasibility nature, DQO's and a QAPjP must be established. This insures that necessary thought has been given to the project, that the project is property planned, and proper lines of communications have been defined. Some difficulties in defining DQO's may arise when a new monitoring program begins because previously established DQO's are no longer applicable or need to be adapted to new requirements. Changes to the DQO's require approval of the decisionmaker and QAO. Required changes must be made as soon as possible.

Among ORP's new monitoring programs are those concerned with radon in homes, schools, and other buildings. Radon monitoring presents several difficulties that, with the present state-of-the-art, result in large uncertainties in the monitoring data. The DQO's being established for these programs will reflect these inherent problems and will be changed as more monitoring experience is gained.

3.3.1 Future Programs

In the future, compliance monitoring programs will be established for the standards and regulations promulgated by EPA/ORP. Among the standards and regulations for which monitoring efforts may be considered are those under the Clean Air Act, Uranium Mill Tailings Act, and the Atomic Energy Act, (40 CFR 190). Future standards and regulations may also require compliance monitoring. Wherever necessary QAPjP's will be prepared before each compliance monitoring effort is undertaken.

3.3.2 Environmental Models

Within the Office of Radiation Programs environmental transport computer models are frequently developed to estimate exposure to radioactive materials, doses, and health risks when measurements of such data cannot be made. Information derived from these models creates the base of information upon which environmental standards and guidelines are developed. These models are also used to evaluate compliance with EPA standards. Because of the importance of the information obtained from models it is necessary that the quality of models which contribute to the standard-setting process be assured and that the input data be correct.

4 QUALITY ASSURANCE (QA) MANAGEMENT

4.1 RESPONSIBILITIES AND FUNCTIONS

This section defines responsibilities assigned to ORP staff engaged in quality assurance activities. In addition to these specific responsibilities ORP personnel are required to insure that data for which they are responsible complies with the ORP QA requirements contained in the Quality Assurance Program Plan.

4.1.1 Office Director and Quality Assurance Officer

The Office Director has the overall responsibility for quality assurance. The Director exercises this responsibility principally through periodic reviews of the program. The implementation of the QA Program is delegated to the Quality Assurance Officer.

4.2 QUALITY ASSURANCE OFFICER'S RESPONSIBILITIES

The Quality Assurance Officer (QAO) is responsible for implementing the Quality Assurance Program Plan. His specific functions are to:

a. Develop, evaluate, and document quality assurance policy, guidelines, and procedures,

b. Act as a source of information and liaison between ORP and the ORD Quality Assurance Management Staff (QAMS); to oversee quality assurance work in the ORP Facilities and with contractors and grantees; and to advise program offices of QA requirements,

c. Advise, guide, and support training of Quality Assurance Coordinators, Project Officers, and technical staff,

d. Inventory quality assurance requirements and procedures for existing measurement programs and recommend any needed changes,

e. Review and approve all Quality Assurance Project Plans for projects administered by ORP,

f. Audit the Quality Assurance programs of Divisions, Facilities, and contractors and spot-audit the implementation of quality assurance programs of selected measurement projects and recommend corrective actions,

g. Submit an annual quality assurance report to QAMS through the Office Director,

h. Assist in the preparation of DQO's, and

i. Review and approve any Standard Operating Procedure (SOP) prepared in ORP.

The Assistant Quality Assurance Officer (AQAO) will assist the QAO in document preparation, audits, information collection, and act for the QAO in his absence.

4.3 DIVISION AND FACILITY DIRECTOR RESPONSIBILITIES

ORP Division and Facility Directors have primary responsibility for their measurement programs including quality assurance. Directors will not authorize projects, contracts, or interagency agreements which do not have an approved Quality Assurance Project Plan. Facility Directors shall appoint QAC's to oversee the operation of their QA programs.

Facility and Division Directors are responsible for:

a. Establishing DQO's;

b. Approving new SOP's and revisions to SOP's, and for conducting periodic (annual or more frequent) reviews of SOP's;

c. Ensuring that audits have been scheduled and are performed at required intervals;

d. Taking needed corrective actions for problems encountered or uncovered by QAC or QAO audits; and

e. Reviewing the results of the corrective actions to insure that problems have been resolved.

4.4 QUALITY ASSURANCE COORDINATORS (QAC's)

Quality Assurance Coordinators oversee the quality assurance activities at ORP Facilities. They serve as the contact between the Quality Assurance Officer and Project Officers and other technical staff. They assist Project Officers in establishing quality assurance requirements and review and approve Quality

Assurance Project Plans. They review the quality of data produced by measurement projects and recommend any needed corrective action to the Project Officer. QAC's report to the QAO on QA operations semi-annually or when there are unusual QA problems or unexpected difficulties in any aspect of the QA program. QAC's perform system audits with quality control samples (spikes, etc.), review results of intercomparison studies and institute corrective actions when necessary.

4.5 PROJECT OFFICERS

Project Officers are responsible for the preparation of Quality Assurance Project Plans. Plans prepared in Washington by Project Officers or contractors are reviewed and approved by the Quality Assurance Officer. At Facilities, plans prepared by Project Officers or contractors are approved by the Quality Assurance Coordinator or QA staff. The approved project plans are submitted to the Quality Assurance Officer for review and approval.

Project Officers are responsible for ensuring that Quality Assurance requirements for each contract are clearly stated in the Scope of Work; that the technical evaluation criteria of each proposal includes an evaluation of the contractor's proposed QAPjP; and that suitable weight is given to the evaluation of the QA evaluation plan submitted by the contractor. Project Officers will audit projects for conformance with the QAPjP, to identify and correct problems, and to document the measurement quality achieved on each project. They will report the project QA results to the QAO semi-annually. All contract task and work orders require QAO signature prior to submission. Project

Officers or Work Assignment Managers are responsible for obtaining the QAO's approval. Task or work orders may not be issued without QAO approval.

4.6 COMMUNICATION

The ORD Quality Assurance Management Staff (QAMS) coordinates the Agency's Quality Assurance program. QAMS provides Quality Assurance information, guidance, and policy through the Quality Assurance Officer.

The Quality Assurance Officer maintains a file of material provided by the QAMS. The Quality Assurance Officer's principal line of communication is directly to Project Officers in Washington and through the Quality Assurance Coordinators at the Montgomery and Las Vegas Facilities. The Quality Assurance Officer maintains contact with the Office Director and Division and Facility Directors on matters involving QA within ORP.

Periodic briefings, discussions and annual reports by the Quality Assurance Officer on the status of the Quality Assurance program are the QAO's principal communication link with the Office Director. Special reports on the programmatic aspects of data quality are made as the QAO or the Office Director deem necessary.

QA reports, plans, and directives will be maintained under the document control procedure described in EPA-600/9-76-005, Section 1.4.1. Document control procedures require that each page carry a document number, revision number, date, and page number.

4.7 PROGRAM ASSESSMENT AND AUDIT

Effective management of the QA program requires periodic assessment of data quality and functioning of the program. The QAO and the Facility QAC's perform audits to ascertain that data generated by the analytical and sampling programs meet the ORP QA/QC requirements. Any problems found are to be addressed immediately. Actions taken to correct problems and deficiencies must be reviewed and documented. Several types of routine audits are used to perform the periodic assessments.

The Project Officer will periodically audit the quality of the data and the overall QA effort of each project to assure conformance with the project plan (see Section 7.3). Audit reports shall be made to the appropriate Division or Facility Director and QAO. The Quality Assurance Officer or Quality Assurance Coordinator will audit selected projects for compliance with ORP Quality Assurance requirements.

The QAO will perform a Management Audit of each ORP Facility at least annually.

The Management Audit is an essential part of Quality Assurance. Management Audits will review Facility documentation, records, and procedures, which demonstrate adherence to Agency and ORP QA requirements. A review will be made of the procedures that lead to the preparation of QAPjP's, contents of these plans, SOP's, and the documentation and procedures used for approval. A part of the Audit will evaluate the processes used to establish DQO's. The Audit will insure that procedures for the internal management

review process and reporting procedures are in place and followed. The QAO may designate an alternate to conduct Management Audits.

Contractors or grantees may be requested to demonstrate their ability to conduct the required monitoring program. This demonstration may include the analysis of quality control samples as a performance and/or system audit, or a comparison of results via interlaboratory control sample analyses. All programs and contracts involving measurements shall be included in EPA performance and system audits, interlaboratory comparisons, and analysis and comparison with the ORD Environmental Monitoring Systems Laboratory (EMSL) standards. Audits of contractors and grantees will be made at least once during the period of the contract or grant.

A Performance Audit evaluates the ability of a laboratory to obtain data of known and required precision and accuracy. Samples of known composition and concentration are provided to a laboratory for analysis as blind samples. The analytical results are reviewed. Specific accuracy and precision must be achieved by the laboratory for the laboratory to be judged acceptable.

System Audits are similar to Performance Audits. Specific samples of known concentration (spike samples), along with samples of unknown concentration, are entered into the analytical system to evaluate a particular analytic process for accuracy and precision. Satisfactory completion of Performance Audits and/or System Audits may be required before beginning work or award of a contract or grant.

Project Officers, the Quality Assurance Officer, or the Quality Assurance Coordinator, shall recommend corrective actions to correct deficiencies found during Performance or System Audits. They shall also evaluate the effectiveness of the corrective actions. If corrective actions do not remove deficiencies, the Quality Assurance Officer, or the Quality Assurance Coordinator, may recommend to the Division or Facility Director that the measurements be halted.

Computer models for assessment and evaluation of environmental paramenters require a specialized and unique audit procedure. These procedures will be defined in the Project Plan for the model (See Section 7.3). An audit of each computer model will be conducted by the Project Officer in accordance with the Project Plan. The audit will be completed and approved by the ORP Quality Assurance Officer before model outputs are used for standard setting. Deficiencies noted in the audit and corrective actions taken will be reported in the Audit Report. The Audit Report will be furnished to the QAO for his review and approval.

Records of Quality Control checks taken to assure accuracy of Computer model input data will be maintained in Project files. The records will document any discrepancies found, causes for the discrepancies, and corrective actions taken. The QAO or his designated representative will periodically audit these records to insure that proper corrective actions have been taken.

4.8 TRACKING QUALITY ASSURANCE ACTIVITIES

To date, there has not been a need to establish a management tracking system for the development, implementation, review, and revision for DQO's, QAPjP's, and SOP's. However, due to the establishment of the Radon monitoring program and the increased programmatic emphasis on QA, we plan to establish an automated tracking system.

5 PERSONNEL QUALIFICATIONS

5.1 GENERAL

All personnel (ORP employees, contractors or others) working on environmentally related measurements shall have appropriate training and experience. Competency may be acquired through formal education, on-the-job training, or experience. Division and Facility Directors, working through their own organizations and in consultation with the QAO, will evaluate the qualifications of these personnel.

5.2 QUALITY ASSURANCE STAFF

5.2.1 Quality Assurance Officer (QAO)

The Quality Assurance Officer shall have a broad technical knowledge of the measurements made by or for ORP. He or she should have experience with several types of these measurements and education and training sufficient for an understanding of other types of measurements. The QAO shall have been trained or have experience in quality control and or quality assurance.

5.2.2 Quality Assurance Coordinators

Quality Assurance Coordinators shall have a general technical understanding of the measurements used by or for their organization. They should understand the statistical aspects of Quality Control (QC) and Quality Assurance (QA). They should be able to evaluate QAPjP's, SOP's, and the results of System and Performance Audits.

5.3 PROJECT OFFICERS

Project Officers shall have a working knowledge of Agency Quality Assurance requirements. They should be sufficiently familiar with laboratory and related measurement techniques to develop Quality Assurance Project Plans and make QA Performance Audits. Project Officers should attend training programs to acquire and maintain their QA skills.

6 FACILITIES, EQUIPMENT, CONSUMABLES, AND SERVICES

6.1 GENERAL

The Project Officer is responsible for establishing and evaluating the requirements for each project and the quality assurance requirements for ORP-supported facilities, equipment, consumables, and services. These requirements must appear in the Quality Assurance Project Plan.

6.2 FACILITIES AND EQUIPMENT

Project Officers should evaluate the facilities used for production of environmental measurement data. Attention will be given to space, ventilation, and utility services. Electrical supplies must be stable, and resistant to transients. Locations where environmental samples are analyzed will be separate from those where calibration standards are used. They shall also be separate from areas where measurements are made on high activity radioactive materials to reduce the chances of contamination.

Project Officers will evaluate the suitability of all measurement equipment used for the project. The Quality Assurance program will include requirements for equipment evaluation and preventive maintenance. The QAC will retain equipment calibration and maintenance records, records of QA inspections, and audit records. The evaluation of facilities and equipment is particularly important for work done by contractors. The Scope of Work for all contracts will require prospective contractors to submit records of equipment calibrations and tests.

7 DATA GENERATION

7.1 GENERAL

The most important management tool to insure the quality of data generated in a measurement project are the QAPjP's. Each Project Plan shall include steps to assure the production of scientifically valid data. The data shall be defensible, of known precision and accuracy, of acceptable completeness, and in a form suitable for comparison with other measurement data and with regulatory requirements. Wherever possible, calibrations shall be traceable to the National Institute of Standards and Technology (NIST) and validated through participation in interlaboratory comparisons.

7.2 DATA QUALITY OBJECTIVES (DQO's)

Data Quality Objectives are "...statements of the level of uncertainty that a Decisionmaker is willing to accept in results derived from environmental data."* Included in DQO's are specifications of the desired analytical accuracy and associated errors. These specifications are necessary to establish the DQO's. The DQO's are established prior to the preparation of the QAPjP, which will define the analytical program required to meet the DQO's.

The DQO's should include a clear statement of:

a. The decision required;

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*The designation of the "Decisionmaker" is the responsibility of the Director, ORP. It will depend upon who has the ultimate responsibility for the project. There is no single designation of the "Decisionmaker" within ORP.

b. The need for the data and the intended use of the data; and

c. A description of supporting data.

Guidelines which the Decisionmaker considers in establishing the DQO's are presented in QAMS Quality Assurance and DQO courses. The course manuals are available from the QAO.

Once established, DQO's need not be fixed or unyielding. As a project progresses, the DQO's shall be reviewed and changed to meet program or analytical requirements.

7.2.1 Establishing Data Quality Objectives (DQO's)

DQO's are established through iteration in a process involving the technical and management staff and the Office Director or their designee. The process involves consideration of several factors which include the type of data sought, available technology, cost tradeoffs, data timeliness, level of uncertainty, data availability, and sampling design. These factors do not constitute a complete list; however, they are among the generic considerations used to establish DQO's. The effort to establish DQO's is to be proportional to the significance and magnitude of the project. The DQO process should meet the needs and requirements of the project. The DQO process is to be sufficiently flexible to permit matching of the effort to the project.

7.3 QUALITY ASSURANCE PROJECT PLANS (QAPjP's)

Each ORP measurement project, including those supported by contract, interagency agreement, or grant shall have a Quality Assurance Project Plan. The Project Plan is prepared to insure that the analytical and sampling programs meet the required DQO's that have been established for this project. The Project Plan shall provide the following information*:

a. Experimental design,

b. Document sampling procedures and plans,

c. Specification of Data Quality Objectives,

d. Analytical and sample handling procedures,

e. Specific quality control procedures and frequency employed,

f. Management and technical audits, and

g. Management reporting systems.

Precision shall be demonstrated by measurements on replicate samples (including blinds and duplicates), reagent blanks, split

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*Content, procedures, and instructions are contained in "Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans", QAMS-005/80, QAMS, ORD, EPA, December 29, 1980.

samples, or co-located monitors or samplers. The Project Plan shall require periodic checking of measurement devices for proper operation and calibration. Precision is important in determining the consistency and reliability of the method or instrument.

Each Quality Assurance Project Plan shall contain a means of demonstrating the relationship of the reported data to the "true" value or accuracy. To the extent possible, "true" values are obtained by using radionuclides whose concentrations have been certified by the National Institute of Science and Technology (NIST) to calibrate instrumentation and measurement techniques. The use of radioactive standards obtained from NIST or laboratory who prepare secondary standards based on NIST standards are termed "NIST-traceable".

7.3.1 Contents of Quality Assurance Project Plans (QAPjP's)

Each of the 16 items listed below must be included in Quality Assurance Project Plans:

a. Title page with provision for approval and signatures;
b. Table of contents;
c. Project description;
d. Project organization and responsibility;
e. QA objectives for measurement data in terms of precision, accuracy, completeness, representativeness, and comparability;
f. Sampling procedures;
g. Sample custody;
h. Calibration procedures and frequency;

i. Analytical procedures;
j. Data reduction, validation, and reporting;
k. Internal quality control checks and frequency;
l. Performance and System Audits and frequency;
m. Preventive maintenance procedures and schedules;
n. Specific routine procedures used to assess data precision, accuracy and completeness of specific measurement parameters involved;
o. Data Quality Assessment for precision and accuracy;
p. Corrective actions; and
q. Quality Assurance report to management.

If an item is not appropriate it may be omitted; however, the reason for its omission shall be explained.

7.3.2 Environmental Model Project Plans

Quality Assurance Project Plans will be developed for all computer models which contribute to the standard setting process. These plans will include methods to:

a. Verify that the computer code correctly represents the model's logic.

b. Verify that the computer code correctly implements the model's mathematical operations.

c. Use Quality Control measures to insure the accuracy of input data used by the model.

7.4 STANDARD OPERATING PROCEDURES (SOP's)

7.4.1 QA SOP Policy

SOP's contain specific details and procedures which ensure that data generated by their use will be satisfactory and adequate. Examples of activities for which SOP's may be appropriate are procedures for sampling, analysis, counting, calibration, equipment inspection, and preventive maintenance. SOP's shall be developed and used, wherever appropriate. They permit inclusion of detailed procedures in Quality Assurance Project Plans by reference.

Analytical and measurement procedures must provide results of suitable quality for project needs. EPA approved analytical and measurement procedures shall be used wherever feasible or required. These procedures, if used, shall be designated as SOP's and referenced by the appropriate SOP number. Any procedure designated as an SOP shall have been tested and verified as to accuracy, capability, and specified as to type of sample, matrix, etc. for which it is applicable. SOP's will be concurred in by ORP QAO.

7.4.2 Establishment and Approval of SOP's

The SOP's are procedures that have usually been developed and employed over a period of time during which they have been refined and proven valid. These procedures must be approved by the Facility QAC's, and then by the Facility Director.

Contractor laboratory SOP's are approved by contractor QA staff, and forwarded to ORP project officer for concurrence. These procedures then become part of the Facility, or contractor-approved SOP's and can be incorporated in the QAPjP by reference. EPA-approved procedures can be designated as SOP's.

8 DATA PROCESSING

Data processing includes all the manipulations performed on raw and processed data to change its form, its location, or its quantity. Errors in the recording, reduction, calculation, and transcription of data can result in the loss and the production of flawed information. Each Quality Assurance Project Plan shall include quality assurance for data processing. The Project Plan shall include checks on:

a. Data collection, recording and entry.

b. Data Validation--Data shall be accepted or rejected based upon criteria contained in the SOP's.

c. Data Transfers--Data transfers either manually or by machine, including preparation of punched cards, conversion from cards to tapes, and telemetering, shall include provisions for error checking.

d. Data Storage--Data shall be securely stored to avoid alteration or deletion. To prevent destruction or loss, backup copies of important data should be kept separate from the original data. Computer systems shall include provisions to avoid the destruction or unwanted or unauthorized modification of data.

e. Data Reduction--Data reduction includes calculation and statistical analysis. Data reduction by computer shall be documented and calculation procedures will be tested whenever practical.

f. Data Quality Assessments--Environmental measurements must include data quality assessments (See Section 9.0). Environmental databases must be capable of accepting, storing, and retrieving these assessments with each measurement. The assessments may be compressed into a directory that may be automatically accessed during data retrieval. Guidelines for assessments are contained in "Calculation of Data Quality Indicators", Section 6.0, by James E. Longbottom and Paul W. Britton of EMSL, Cincinnati, OH, August 15, 1983. A reference copy is maintained by the QAO.

9 DATA QUALITY ASSESSMENT

Generated and processed data should be assessed for completeness, accuracy, precision, representativeness, and comparability to see that it meets the needs expressed in the Quality Assurance Project Plan, and the DQO's established for the project. DQO requirements may be modified in the event analytical sensitivity cannot be achieved. In that instance, data quality indicators accepted by the scientific community for radiological measurements, namely lower limits of detection (LLD) may be used; however, the official who established the DQO's must approve the use of these indicators.

a. The data from each monitoring project shall be frequently compared with the Project Plan to ensure that the planned measurements were obtained and the analytical results are in accord with the objectives desired as stated by the DQO's. In the event that the only analytical results obtained are stated as LLD's the DQO's shall be immediately reviewed and new ones established.

b. All measurements and data shall be "trackable" as to analysis, receipt, handling, and analyst, including identification of samples and, where necessary, identification of instrumentation and equipment used.

c. The values obtained on known reference or spiked samples shall be compared with the known values. EPA or other intercomparison system or Performance Audit programs shall be used to assess the facility's performance ability to obtain true values; i.e., the accuracy of the method.

d. The Project Plan shall require that the data be representative of a locale or sampled media. Examples of suitable evidence include reasons for selection of measurement sites, descriptions of measurement sites, the basis for selection of sampling or measurement frequencies, the method or methods of homogenizing or mixing a sample or samples, and other sampling conditions, as appropriate.

e. Each QAPjP shall contain procedures to ensure comparability of data on the basis of consistency of reporting units, standardized data format, and adequacy of procedures utilized. The procedures may also include a demonstration that a particular method used on two different media; e.g., water and soil, is consistent from media to media in terms of results; i.e., percent recovery in extractions, instrument response, etc.

10 CORRECTIVE ACTION

Each Quality Assurance Project Plan includes provisions to determine quickly the failure of data to meet the predetermined quality levels. The routine internal quality control program should detect degradation of component or system performance before the data becomes unacceptable. The internal quality control procedures are described in Section 9.

The Project Officer shall take necessary action to prevent the generation of further inaccurate data, and to start procedures for corrective action. He shall notify the Quality Assurance Officer or Quality Assurance Coordinator, as well as the people performing the measurements when problems arise. The Project Officer, with the cooperation of the QAO or QAC, shall work with the responsible measurement staff to correct the difficulty. Persons recommending or taking corrective action should search out the basic reason for the difficulty, and not merely take actions that will correct the problem temporarily or superficially. For example, difficulties with instruments may originate in inadequate electrical supply or inadequate grounding, rather than in the instrument. Corrective actions shall be reported to the Project Officer and to the Quality Assurance Officer or the Quality Assurance Coordinator. Facility Directors or Division Directors are to be informed of any problems that arise, corrective actions taken and the results of these actions. Sampling and analytical programs are to cease if corrective actions are not effective or the cause of problem cannot be found.

11 IMPLEMENTATION REQUIREMENTS AND SCHEDULES

Implementation of the ORP QA program will be reported to QAMS in annual reports. Milestones are given in Section 11.1.

11.1 MILESTONES

	MILESTONE	DATE PLANNED
1.	Revise Program Plans, Project Plans, SOP's, and other pertinent program QA documents	Continuous
2.	Audit programs	
	a. ORP-LVF	Annual
	b. EERF	Annual
	c. Selected projects	Continuous
3.	QAC Report to QAO	Semi-annual
4.	Prepare administrative guides	
	a. QA Project Plans	As Needed
5.	Review and revise technical guides	
	a. Internal Quality Control	Continuous Laboratory
	b. Laboratory QC	Responsibility.
6.	Conduct training	
	a. ORP-LVF	To be Determined
	b. EERF	
7.	Report to QAMS	Annually

11.2 ANNUAL RESOURCES

Annual resources needed to accomplish the ORP QA program are as follows:

1.0 person-years in ASD
1.2 person-years in EERF
0.3 person-years in LVF
0.3 person-years in RD
0.1 person-years in CSD
QA consultant, FTE 10 days
Travel, supplies, printing
Special laboratory cross-checks and intercomparisons
(Estimated at 1 percent of analytical workload)

DISTRIBUTION

QAMS - Stanley Blacker, Director (RD-680)

ORP - Richard J. Guimond, Director (ANR-458)

CSD - J. William Gunter, Director (ANR-460)

ASD - David E. Janes, Director (ANR-461)

RD - Margo T. Oge, Director (ANR-464)

EERF - Charles R. Porter, Director

ORP/LVF - Wayne A. Bliss, Director

ORP/ASD/ECEB - Lewis Battist, QAO

ORP/ASD/ESSB - Philip Cuny, AQAO

Radiation Program Managers

Tom D'Avanzo
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Gerald Fontenot
Carl Walter
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Michael S. Bandrowski
Jerry Leitch

Quality Assurance Coordinators

Robert Lyon, ORP/LVF
James Moore, EERF

Project Officers - ORP

ORP Policies and Procedures