

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

APR 17 1984

Office of  
The Administrator

Memorandum

SUBJECT: EPA Order 5360.1, "Policy and Program Requirements to Implement the Quality Assurance Program"

FROM: Alvin L. Alm  
Deputy Administrator

TO: Addressees

One of my major goals is to ensure that all decisions by EPA can be supported by a sound data base. An important step toward achieving this objective is to require that quality assurance become an integral part of all data collection activities. Quality assurance is the total integrated program for assuring the reliability of environmental measurements and consists of multiple steps undertaken to ensure that all acquired data are suitable for the user's intended purpose. Two of the major steps are: the user must first specify the quality of data he needs; then the degree of quality control necessary to assure that the resultant data satisfies his specifications must be determined. Central to this process is assuring that the data is of known quality. The quality of data is known when all components associated with its derivation are thoroughly documented, such documentation being verifiable and defensible.

In order to establish quality assurance solidly in all data collection activities, the important step of issuing this order on quality assurance is being taken. The implementation of the elements in this order will require dedication and hard work by the Quality Assurance Management and Special Studies Staff, by quality assurance officers throughout the Agency, and by senior management. This order identifies the goals, objectives, and general responsibilities of each program area. To carry out the order, specific policy and technical guidance materials need to be prepared. I will be following that progress.

The attached order reflects my commitment to the Agency's QA program and to the promotion of good science in all EPA monitoring and measurement activities. Therefore, I expect that each of you work cooperatively to ensure that the appropriate level of quality assurance is embedded in all data collection

undertaken by or for the Agency.

POLICY AND PROGRAM REQUIREMENTS  
TO IMPLEMENT THE MANDATORY QUALITY ASSURANCE PROGRAM

1. PURPOSE. This Order establishes policy and program requirements for the conduct of quality assurance (QA) for all environmentally related measurements performed by or for this Agency.
  
2. BACKGROUND. Agency policy requires participation in a centrally managed QA program by all EPA organizational units supporting environmentally related measurements. Under Delegation of Authority 1-41, "Mandatory Quality Assurance Program" (dated 4/1/81), the Office of Research and Development (ORD) is the focal point in the Agency for quality assurance policy and is responsible for developing QA requirements and overseeing Agencywide implementation of the QA program. ORD established the Quality Assurance Management and Special Studies Staff (QAMSS) to serve as the central management authority for this program. The QAMSS activities involve the development of policies and procedures; coordination for and direction of the implementation of the Agency QA program; and review, evaluation, and audit of program activities involving environmental monitoring and other types of data generation.

The Agency QA program embraces many functions including: establishing QA policy and guidelines for development of program and project operational plans; establishing criteria and guidelines for assessing data quality; serving as a QA information focal point; auditing to ascertain effectiveness of QA implementation; and identifying and developing QA training programs.

3. GOALS AND POLICY. The primary goal of the QA program is to ensure that all environmentally related measurements supported by the EPA produce data of known quality. The quality of data is known when all components associated with its derivation are thoroughly documented, such documentation being verifiable and defensible. It shall be the policy of all EPA organizational units to ensure that data representing environmentally related measurements are of known quality. Decisions by management rest on the quality of environmental data; therefore, program managers shall be responsible for: 1) specifying the quality of the data

required from environmentally related measurements and 2) providing sufficient resources to assure that an adequate level of QA is performed. All routine or planned projects or tasks involving environmentally related measurements shall be undertaken with an adequate QA project plan that specifies data quality goals acceptable to the data user and assigns responsibility for achieving these goals.

In discharging its responsibility for implementing the Agency-Mandated Quality Assurance Program, the ORD/QAMSS will strive for consensus by submitting for review proposed policies and procedures to affected program offices and regions. Responsibility for adjudication of unresolved issues, with respect to the above and QAMSS conducted audits, will be at the lowest level of authority consistent with the scope of the issues. The QAMSS will refer issues which remain unresolved at lower levels of authority to the AA/ORD for decision, after consultation with the appropriate AA or RA.

The following activities are basic to the implementation of the QA program:

- a. Preparation and annual update of a QA program plan based on guidelines established by QAMSS.
- b. Development of a QA project plan for all projects and tasks involving environmentally related measurements in accordance with guidelines established by QAMSS.
- c. Assuring implementation of QA for all contracts and financial assistance involving environmentally related measurements, as specified in applicable EPA regulations, including subcontracts and subagreements.
- d. Conducting audits (system, performance evaluations, data quality, bench, etc.) on a scheduled basis of organizational units and projects involving environmentally related measurements.
- e. Developing and adopting technical guidelines for estimating data quality in terms of precision (variability), bias (accuracy), representativeness, completeness and comparability, as appropriate, and incorporating data quality requirements in all projects and tasks involving environmentally related

measurements.

- f. Establishing achievable data quality limits for methods cited in regulations based on results of methods evaluations arising from the methods standardization process, e.g., ASTM Standard D2777-77.
- g. Implementation of corrective actions, based on audit results, and for incorporating this process into the management accountability system.
- h. Provision for appropriate training based on perceived needs, for all levels of QA management, to assure that QA responsibilities and requirements are understood at every stage of project implementation.

4. RESPONSIBILITIES.

- a. In conformity with the oversight responsibility for the mandatory QA program, the AA/ORD shall:
  - (1) Establish Agency policies and procedures for implementing the mandatory QA program.
  - (2) Provide guidance for determining precision, bias, representativeness, completeness, and comparability of data.
  - (3) Review QA Program Plans from Agency components involved in environmentally related measurements.
  - (4) Conduct QA audits of all organizational units supporting environmentally related measurements based on established audit criteria and procedures.
  - (5) Recommend corrective actions, based on audit results, for inclusion in the management accountability system.
  - (6) Establish achievable data quality limits for methods provided by ORD for citation in regulations, based on results of methods evaluations arising from the methods standardization process, e.g., ASTM Standard D2777-77, to help project officers define data quality goals.

- (7) Serve as the Agency QA information focal point.
  - (8) Develop generic training program, based on perceived needs, for all levels of management to assure that QA responsibilities and requirements are understood at every stage of project implementation.
  - (9) Ensure that all ORD investigations involving data collection are covered by an acceptable QA plan with resources adequate to accomplish program objectives.
  - (10) Ensure that deficiencies highlighted in review of ORD program plans or in audits of ORD components are appropriately addressed.
- b. In accordance with policies and procedures established by AA/ORD, National Program Managers shall:
- (1) Ensure that QA is an identifiable activity with associated resources adequate to accomplish program goals in the development and execution of all projects and tasks, both intramural and extramural, involving environmentally related measurements.
  - (2) Ensure that appropriate QA criteria are included in operating guidance.
  - (3) Establish data quality acceptance criteria for all projects and tasks conducted by the program office.
  - (4) Ensure that an adequate degree of auditing is performed to determine compliance with QA requirements.
  - (5) Ensure that deficiencies highlighted in audits are appropriately addressed.
  - (6) Ensure that all projects and tasks involving environmentally related measurements are covered by an acceptable CA project plan and that the plan is implemented.
  - (7) Identify program-specific QA training needs and provide for the required QA training.
- c. In accordance with policies and procedures established by AA/ORD, Regional Administrators shall:

(1) Ensure that QA is an identifiable activity with associated resources adequate to accomplish program and regional goals in the development and execution of all projects and tasks involving environmentally related measurements, both intramural and extramural.

(2) Ensure that QA guidelines are specified for estimating data quality in terms of precision, bias, representativeness, completeness, and comparability, for all environmentally related measurements which meet the operating guidance established by the program offices.

(3) Establish data quality acceptance criteria for all projects and tasks initiated by the Region.

(4) Ensure that all projects and tasks involving environmentally related measurements are covered by an acceptable QA project plan and that the plan is implemented.

(5) Ensure that an adequate degree of auditing is performed to determine compliance with QA requirements.

(6) Ensure that deficiencies highlighted in audits are corrected expeditiously.

(7) Identify program-specific QA training needs and provide for the required QA training.

d. The AA for Administration shall establish a mechanism for incorporating QA in the Agency's planning and budgeting cycle.

5. DEFINITIONS. The following terms have special meanings in relation to this Order.

(a) Documentation. The use of documentary evidence; a written record furnishing information that a procedure has been performed. When applied to environmentally related measurements it includes all calculations related to sampling design; all steps in the chain of custody, where appropriate; and all notes and raw data generated in the sampling, analysis, or data validation process.

(b) Defensible. The ability to withstand any reasonable challenge related to veracity or truthfulness.

(c) Environmentally Related Measurement. Any laboratory or field data gathering activity or investigation involving the determination of chemical, physical, or biological factors related to the environment.

The following are representative examples of environmentally related measurements. Data collection or investigation of chemical, physical, or biological factors for determination of:

- (1) pollutant concentrations from sources, in the ambient environment, or pollutant transport and fate;
- (2) response of organisms to pollutants;
- (3) the effects of pollutants on human health and on the environment;
- (4) risk/benefit analysis;
- (5) environmental or economic impact.
- (6) the environmental impact of cultural and natural processes;
- (7) pollutant levels, exposure levels, etc., used in modeling.

(d) Organizational Unit. Any administrative entity (national program office, regional office, ORD or NEIC laboratory) which engages in environmentally related measurements.

(e) Project. An organized undertaking or specified unit of investigation involving environmentally related measurements.

(f) Quality Assurance. The total integrated program for assuring the reliability of semitoring and measurement data.

(g) Verifiable. The ability to prove or substantiate any claim or result related to the documented record.

6. ADDITIONAL REFERENCE. This Order will be amplified by a detailed implementation plan.

EPA ORDER

5360.1  
APR 3 1984

Howard M. Messner  
Assistant Administrator  
Office of Administration and  
Resources Management