



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

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OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

OSWER Directive 9242.6-06

MEMORANDUM

SUBJECT: Quality Assurance Review for Extramural Projects;
Environmental Measurements-Environmentally Related
Measurements

FROM: Henry L. Longest II, Director
Office of Emergency and Remedial Response

TO: OERR Division Directors
Waste Management Division Directors

Purpose:

To provide all OERR Project Officers and Managers with the revised "Quality Assurance Review for Extramural Projects" form.

Background:

EPA Order 5360.1 (April 3, 1984) established the policy and program requirements for the conduct of quality assurance (QA) for all environmentally related measurements performed by or for this Agency.

The term "environmentally related measurements" is defined in the Order (attached), and is quite comprehensive. Unfortunately, this definition was not contained in the QA review form, "Quality Assurance Review for Extramural Projects" which is required as part of the pre-award procurement package for all extramural projects. The result has been that projects covering environmentally related measurements (per the Order definition) may not be considered as such by the Project Officer. Accordingly, such projects are not covered by any formal QA requirements, and they may be in violation of Order 5360.1.

Objective:

To assure that QA requirements are established as required by 5360.1, four changes have been made to the review form:

- 1) Both Project Officer and Quality Assurance Officer must sign even if no environmentally related measurements are required.

- 2) The term "Environmental Measurements" has been replaced with "Environmentally Related Measurements".
- 3) The definition of Environmentally Related Measurements has been added to the form.
- 4) The statement--"The signatures below verify that the QA requirements have been established."--has been replaced with, "The signatures below verify that the QA requirements have been reviewed and established where appropriate.

In addition, the term "Pre-Award Document" has been added to the header for clarification.

Implementation:

Please ensure that all Project Officers are provided with this memorandum as well as with a copy of the new review form (attached). Thank you for your assistance in the continued improvement of our QA program. If you have any questions regarding the Order or the review form, please contact Duane Geuder at 245-4027.

Attachments

cc: Stan Blacker, QAMS
OERR Branch Chiefs

QUALITY ASSURANCE REVIEW FOR EXTRAMURAL PROJECTS

PRE-AWARD DOCUMENT (contracts)

I. GENERAL INFORMATION

Descriptive Title:

Sponsoring Program Office:

Approximate Dollar Amount:

Duration:

II. THIS CONTRACT REQUIRES ENVIRONMENTALLY RELATED MEASUREMENTS*

(If yes, complete form; if no, sign form - both PO & QA O and submit with procurement request).

yes

no

III. QUALITY ASSURANCE REQUIREMENTS

(Projects involving environmentally related measurements)

yes

no

- a. Submission of a written quality assurance (QA) program plan (commitment of the offeror's management to meet the QA requirements of the scope of work) is to be included in the contract proposal.
- b. Submission of a written QA project plan is to be included in the contract proposal.
- c. A written QA project plan is required as a part of the contract.
- d. Performance on available audit samples or devices shall be required as a part of the evaluation criteria (see list on reverse side).
- e. An on-site evaluation of proposer's facilities will be made to ensure that a QA system is operational and exhibits the capability for successful completion of this project (see schedule on reverse side).
- f. QA reports will be required (see schedule on reverse side).

* See definition on reverse side

QUALITY ASSURANCE REVIEW FOR EXTRAMURAL PROJECTS

(CONTRACTS)

I. GENERAL INFORMATION

Descriptive Title:

Sponsoring Program Office:

Approximate Dollar Amount:

Duration:

II. THIS CONTRACT REQUIRES ENVIRONMENTAL MEASUREMENTS
(If yes, complete form; if no, sign form and
submit with procurement request.)

Yes

No

III. QUALITY ASSURANCE REQUIREMENTS
(Projects involving environmental measurements)

Yes

No

a. Submission of a written quality assurance
(QA) program plan (commitment of the
offeror's management to meet the QA
requirements of the scope of work) is to
be included in the contract proposal.

b. Submission of a written QA project plan is
to be included in the contract proposal.

c. A written QA project plan is required as
a part of the contract.

d. Performance on available audit samples or
devices shall be required as part of the
evaluation criteria (see list on reverse
side).

e. An on-site evaluation of proposer's facili-
ties will be made to ensure that a QA system
is operational and exhibits the capability
for successful completion of this project
(see schedule on reverse side).

f. QA reports will be required (see schedule
on reverse side).

IV. DETERMINATION (Projects involving environmental measurements)

Percentage of technical evaluation points assigned to QA _____

Project Officer estimate of percentage of cost allocated to environmental measurements _____

Parameter Measured	QC Reference Sampling or Device Available (Yes or No)	Split Samples for Cross-Comparison (Yes or No)	Required for Preaward (Yes or No)	FREQUENCY During Contract
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

QA System Audits are required: Preaward _____; during contract: _____

QA Reports are required: with Progress Reports _____; with Final Report _____

The signatures below verify that the QA requirements have been established.

QA Officer:

Project Officer:

_____	_____	_____	_____
Signature	Date	Signature	Date

After signatures, a copy of this form must be included with the procurement request and sent to the Contracts Office and a copy placed on file with the QA Officer.

EPA TRANSMITTAL

CLASSIFICATION NO.: 5360.1

4/3/84

APPROVAL DATE:

ADDRESSEE

EPA ORDER 5360.1 -- POLICY AND PROGRAM REQUIREMENTS TO IMPLEMENT THE MANDATORY QUALITY ASSURANCE PROGRAM

1. PURPOSE. This transmittal provides a new EPA Order 5360.1, Policy and Program Requirements to Implement the Mandatory Quality Assurance Program.

2. EXPLANATION. 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.

3. SUPERSESSSION. None

3. FILING INSTRUCTIONS. File the attached in a three ring binder. Post receipt of Transmittal on Checklist in front of the binder.


Gary M. Katz, Director
Management and Organization Division

ORIGINATOR:

Office of Research and Development

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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.

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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.

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(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 programs, 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 QA 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:

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(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:

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- (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 monitoring 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.



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