

Directive No: CIO 2105-P-02.1

Issued by the EPA Chief Information Officer, Pursuant to Delegation 1-19, dated 07/07/2005

EPA QA Field Activities Procedure

1. PURPOSE

To describe how the Agency quality management system shall be applied to sampling and non-sampling field activities. The procedure provides a comprehensive, coordinated approach for consistent implementation of the EPA Field Operations Group Operational Guidelines for Field Activities (hereafter FOG Guidelines).

2. SCOPE

The Procedure applies to all EPA organizations including Headquarters Offices, Program Offices, Regions, National Research Laboratories and Centers, and their sub-organizations whose EPA employees conduct field activities. The management system shall incorporate all 10 elements of these FOG Guidelines unless there is a compelling reason not to do so and sufficient justification is provided and documented (See Section 9, Waivers). Field activities are defined as activities requiring the collection of observations, samples, or data in support of EPA programs, Executive Orders, regulations, or environmental laws, at a site or location (facility, water body, wetland, etc.). Field activities include, but are not limited to:

- 1 Planning and conducting on-site inspections of the following sites: facility permit operations, maintenance practices, self-monitoring practices, field recordkeeping practices and field sampling/measurement practices for gathering data/potential evidence for all EPA programs.
- 2 Planning and carrying out field studies/investigations/evaluations for gathering and developing data/potential evidence, including, but not limited to, field observations (including photographs), field measurements, sample collection, and field engineering evaluations for EPA programs that conduct ambient and compliance monitoring and other comprehensive studies/evaluations (both short and long term).

The Procedure applies to both sampling and non-sampling field activities. Each EPA organization shall define the scope and applicability of this Procedure for their organization.

Each EPA organization shall document its implementation of the Procedure by incorporating it into the organization's existing Quality Management Plan and standard operating procedures, or other applicable controlled documents, and shall take into consideration all applicable agency quality and program-specific guidance and requirements.

The Procedure is not required, but may be informative, for EPA programs carrying out activities with the primary goal of education (e.g., demonstrations, volunteer educational monitoring, etc.).



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3. AUDIENCE

The audience for this Procedure is all Agency employees (managers and staff) responsible for field activities in support of EPA's mission as defined in Section 2 above.

4. BACKGROUND

The Regional Science and Technology (RS&T) Directors established a Field Operations Group (FOG) to promote national consistency among the Agency's field activities. The FOG is comprised of EPA managers and senior personnel from the EPA Regions, Office of Enforcement and Compliance Assurance's National Enforcement Investigations Center (OECA/NEIC), and limited other Program Offices. The FOG developed ten operational guidelines, i.e., Field Operations Group Operational Guidelines for Field Activities, to ensure consistency in managing field practices and to reduce potential vulnerabilities. The FOG Guidelines are based on best practices for field activities as determined by EPA field groups, EPA quality requirements, and concepts of quality management systems established by the International Organization for Standardization (ISO).

A Consistent Field Operations (CFO) Workgroup was chartered by the Deputy Administrator in June 2012 to propose an Agency implementation plan for the FOG Guidelines to be presented to the Agency's Executive Management Council (EMC). In December 2012, the EMC endorsed the ten FOG Guidelines as written (with minor clarification edits), along with other recommendations presented by the CFO Workgroup.

In March 2013, the Acting EPA Administrator issued a memorandum, *Consistent Field Operations at the U.S. Environmental Protection Agency*. In this memorandum, the Acting EPA Administrator requested that all EPA organizations conducting field activities implement the ten FOG Guidelines by February 15, 2016. Since the FOG Guidelines are based on EPA's existing quality requirements, these Guidelines are being issued as a Procedure under the existing Quality Policy.

5. AUTHORITY

<u>The Environmental Information Quality Policy</u> establishes the authority for this Procedure.

6. PROCEDURE

This Procedure describes processes needed to implement EPA quality management system requirements for field activities. These processes define a systematic approach based on the FOG Guidelines.

By adopting and promoting the processes and requirements in this Procedure, Agency leaders will ensure continual improvement in the quality of EPA products and services. Specifically, this Procedure:

- Describes management system requirements necessary for consistent and scientifically sound field activities used in support of EPA decisions.
- Requires AAs/RAs to implement this Procedure.



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6.1 Personnel and Training

- 6.1.1 Personnel responsible for field activities shall have appropriate qualifications, education, training, experience and a satisfactory knowledge of the requirements of the activities to be carried out. These requirements include, but are not limited to, health and safety training and program specific inspector training.
- 6.1.2 Field groups shall have a documented system to ensure that up-to-date records of training are maintained for field personnel. These records shall include external or internal courses attended and relevant training received, including on-the-job training. For credentialed employees, training records will be maintained to document personnel compliance with EPA Order 3500.1 A1, EPA Order 1440.2, and field-related requirements.
- 6.1.3 Records shall be sufficiently detailed to document that personnel performing particular tasks have been properly trained and that their subsequent ability to perform these tasks has been formally evaluated.
- 6.1.4 Training records shall be maintained consistent with Agency records retention schedules.

6.2 Document Control

Within the context of field activities and this Procedure, controlled documents are generated internally for each organization and describe how work will be conducted. Examples of controlled documents include policies, standard operating procedures (SOPs), SOP compendiums, guidance, blank template forms, checklists and work instructions pertaining to inspection planning, environmental sampling and standard inspection techniques.

- 6.2.1 Field groups shall maintain a system for the control of all documents relating to their activities including the preparation, review, approval, issuance, revision, revocation and archiving of documents. Procedures shall be developed that ensure:
 - a. All controlled documents are reviewed and approved for use by authorized personnel prior to issue. Review of the controlled documents by various subject matter experts and users is documented:
 - b. Controlled documents include a unique document control identifier/number and all revisions are clearly identified;
 - c. All controlled documents are current and accurate;
 - d. Current versions of appropriate documents are available at all relevant locations;
 - e. Periodically, documents are reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;
 - Superseded documents are removed from use throughout the organization but archived and readily accessible for a determined period consistent with EPA records management schedules;



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- Revisions to documents are reviewed and approved by the same functional position that performed the original review unless specifically designated otherwise;
- h. Where practicable, the revised or new text is identified in the document.
- 6.2.2 Briefings and/or training on the information presented in controlled documents shall be provided for users.
- 6.2.3 There shall be a system for managing and distributing controlled documents so that only current versions of the documents are available for use.

6.3 Records Management

- 6.3.1 Field groups shall maintain a records management system to suit their particular circumstances and to comply with applicable Federal and Agency records management regulations, policies, and retention schedules.
- 6.3.2 Within the context of field activities and this Procedure, records provide objective evidence of actions taken and observations made. Examples of field records include (but are not limited to): field logbook entries, pH strip chart recordings, electronic field measurement data log, completed chain of custody forms, photographs, maps, completed inspection forms, quality assurance project plans, reports, etc.
- 6.3.3 Field groups shall establish and maintain procedures that ensure:
 - a. All records are legible and stored and retained in such a way that they are readily retrievable, either electronically or in hard copy format;
 - All records are held secure and in confidence, consistent with Agency policies and procedures for maintenance of enforcement-related shall documents, when applicable;
 - c. Observations, calculations, and measurement entries shall be clearly and permanently recorded at the time they are made;
 - d. Technical records associated with field activities include the identity of personnel responsible for the sampling or inspection activities;
 - e. Each page of project-related records is traceable back to the project;
 - f. Information that is to be included in files that contain project records is defined:
 - g. Electronic records have back-up processes and protection from unauthorized access or amendment;
 - h. Records that have been recorded manually are recorded in permanent ink. When weather conditions do not make it feasible to use permanent ink, then entries can be made in non-smear pencil. The penciled entries shall be captured permanently by photocopying or photographing the penciled entries, or other acceptable manner;
 - i. Error corrections do not obliterate entries in the original record. Corrections shall be made by marking through the error with a single line then initialing and dating the correction.



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6.4 Sampling and Environmental Information Management

Within the context of field activities and this Procedure, as defined by EPA's Quality Policy, environmental information includes any measurements or information that describe environmental processes, locations, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental information includes information collected directly from measurements, produced from models, and compiled from other sources such as databases or literature. This includes, but is not limited to, observations, environmental media samples (water, sediment, soil, waste, etc), measurements, or documentation, such as field notes, instrument charts, laboratory reports, photographs, or technical reports obtained/created during a field investigation or inspection.

- 6.4.1 Field groups shall establish and maintain procedures for the identification, transportation, handling, protection, storage, and retention of samples and other appropriate environmental information during field activities. The procedures shall ensure:
 - a. Field samples and appropriate environmental information are maintained under custody at all times during field studies, investigations, and inspections. Samples and data are in custody if they are:
 - Within the direct possession or the control (i.e., within the view) of an individual designated to have sample handling responsibilities; or
 - ii. Placed in a designated secure area to prevent tampering; or
 - iii. Maintained in a manner that ensures the integrity of the samples is not compromised, when placed in an unsecure area
 - b. All samples, measurements, and other appropriate data shall be uniquely identified to ensure items cannot be confused physically or when referred to in records or other documents.
 - c. A chain of custody record shall be maintained for the collection of environmental samples which details each person who takes possession of the samples.
 - d. If electronic systems (i.e., bar coding of potential evidence/samples, Scribe, etc.) are used for sample labeling or chain of custody generation, hardcopy/manual systems should be available in the event of failure of the primary electronic system or device.
- 6.4.2 For organizations that collect potential evidence for enforcement purposes, custody and sample security procedures must be in place and documented to demonstrate sample and data tampering did not occur (for example, samples placed within containers that have been secured with custody seals) from the time the potential evidence is collected until introduced into legal proceedings.

6.5 Field Documentation

6.5.1 Field groups shall establish and maintain procedures to document field activities. The documentation procedures shall ensure that:



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- a. Field activities are thoroughly documented;
- b. Field documentation contains facts and objective observations;
- c. Observations and/or data which are obtained in the course of inspections are recorded contemporaneously, when observed or collected, to prevent a loss of information;
- d. Documentation consists of individual photographs, video and other audiovisual materials collected during inspections and field activities. Recommended procedures are outlined in *Digital Camera Guidance for EPA Civil Inspections and Investigations*, U.S. EPA Office of Compliance, OECA, July 2006.
- e. The following information shall be included in all field documentation:
 - Project/facility or field study name
 - ii. Project/facility or field study location
 - iii. Project/inspection or field study leader
 - iv. Project/inspection or field study team members
 - v. Project/inspection or field study dates
- 6.5.2 When logbooks are used to document field activities, the documentation will be in a dedicated, bound logbook with sequentially numbered pages. If bound field logbooks cannot be used, then the field group should make provision for the notes to be bound, such as binding loose-leaf data sheets, prior to going in the field.

When electronic field documentation is utilized, such as electronic notebooks or PDAs, then provisions must be made to document the above-mentioned items within the notes and to back-up the notes. The original data must be backed up to another media, such as a laptop computer, USB drive, or CD prior to leaving the site, when possible. It is recommended that the data shall be backed up on at least a daily basis and preferably more frequently when field notes and/or measurements are recorded electronically.

- 6.5.3 For field measurements and sample collection, documentation shall include as appropriate, but not be limited to:
 - a. Date and time of measurement or sample collection
 - b. Location description and/or global positioning system (GPS) coordinates
 - c. Measurement/Sample identification
 - d. Measurement/Sample collection method
 - e. Measurement/Sample collection equipment used, including identification numbers and the manufacturer name/model number, as appropriate
 - f. Calibration standards, buffers, etc. including manufacturer, lot numbers, and expiration date
 - g. Initial and continual calibration data and meter end checks
 - h. Measurement values for non-logging equipment



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- i. Sample containers (number and type)
- j. Sample preservation (chemical, ice, etc.)
- k. Physical description of matrix measured or sampled
- Maps/sketches
- m. Conditions that may adversely impact the quality of measurements/samples, if applicable (for example, rain, wind, smoke, dust, extreme temperatures, etc.)
- n. Photograph log

6.6 Field Equipment

Field groups shall establish and maintain procedures for field equipment that ensure:

- a. All measurement equipment is uniquely identified (i.e., identification number);
- b. Procedures established by the manufacturer and field staff are followed to ensure measurement equipment is properly maintained and calibrated;
- c. Measurement equipment is calibrated before being put into service and thereafter according to an established procedure;
- d. Calibration records for each piece of measurement equipment are maintained;
- e. Up-to-date instructions on the use and maintenance of measurement equipment, including any relevant manuals provided by the manufacturer of the equipment, are readily available for use by the appropriate personnel;
- f. Equipment records are established for measurement equipment that include at least the following:
 - i. the identity of the equipment and its software, if applicable;
 - ii. the manufacturer's name,
 - iii. the equipment's serial number or other unique identifier;
 - iv. the manufacturer's instructions or a reference to their location;
 - v. dates, results and copies of reports and certificates of all calibrations and the due date next calibration;
 - vi. any damage, malfunction, modification or repair to the equipment; and
 - vii. each project the item is used on and a record of sign-in and sign-out;
- g. Equipment that has been shown to be defective or outside specified quality control limits is taken out of service. Such equipment shall be isolated to prevent its use and clearly labeled/marked as being out of service until it has been repaired and shown by calibration or test to perform correctly;
- h. Whenever practicable, equipment requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration including the date when calibration is due. The date when last calibrated may also be included.
- i. Records shall be maintained to document the standards, reagents, etc. used to calibrate equipment and shall contain (at a minimum): the manufacturer, the standard/reagent lot number, and the expiration date of the standard/reagent; and
- j. If possible, field groups shall have an individual designated with overall responsibility for on-going field equipment maintenance, facilitating equipment repairs, etc. either conducted in-house or through established service contracts/vendors.



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6.7 Field Inspections and Investigations

- 6.7.1 Field groups shall establish and maintain procedures for the planning of field investigations, including inspections. The procedures shall take into consideration all applicable Agency and program-specific requirements.
- 6.7.2 Field sampling and measurement activities shall be conducted in accordance with applicable SOPs, quality assurance project plans and sampling and analysis plans.
- 6.7.3 All instructions, standards or written procedures, worksheets, check lists and reference data, relevant to the field investigations/inspections, shall be current, accurate and readily accessible by the staff.

6.8 Reports

- 6.8.1 Field groups shall establish and maintain a procedure for the preparation of a written report to summarize results of routine field activities, including compliance inspections or as in the case of many field studies, a peer reviewed publication.
- 6.8.2 Each report shall include at least the following information unless there are valid reasons for not doing so, such as publication in a peer reviewed journal:
 - a. report title;
 - b. name of the organization preparing the report;
 - c. name of the customer;
 - d. sample/measurement/inspection results;
 - e. name, title and signature of the individual authorizing the report;
 - f. details of any environmental conditions during the field investigation that may affect the interpretation of the report results.

6.9 Internal Audits

- 6.9.1 Field groups shall periodically conduct internal audits to verify that their operations comply with this procedure.
- 6.9.2 The personnel performing the audits shall be qualified and independent from the functions being audited, whenever possible.
- 6.9.3 The roles and responsibilities of management and staff for planning, implementing and reporting of internal audits (including the need for corrective actions) shall be described in a procedure.
- 6.9.4 Internal audit reports shall specify which implemented program(s) were audited and the results including positive findings and findings which require corrective actions.

6.10 Corrective Action

6.10.1 Field groups shall establish and maintain a procedure for addressing findings from internal audits through corrective actions whenever nonconformities with this Procedure are identified. The roles and responsibilities for management and staff in the corrective action process shall be specified.



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- 6.10.2 The procedure shall include an investigation to determine the root cause(s) of the problem. Corrective actions shall be commensurate with the magnitude and the risk of the finding.
- 6.10.3 Field groups shall document and implement any required changes resulting from corrective actions.

7. ROLES AND RESPONSIBILITIES

7.1 EPA Administrator

The Administrator promotes the use of consistent field operations as an integral component to mission assurance through these best management practices that support EPA's field activities and meet the needs and expectations of our customers.

7.2 Assistant Administrators and Regional Administrators

Assistant Administrators (AAs) and Regional Administrators (RAs) will ensure that policies and procedures to support field activities are developed and implemented for their programs consistent with their specific missions, and will dedicate sufficient resources to support the effective implementation of this Procedure within their organizational units.

Each AA or RA may re-delegate the responsibilities for this Procedure to appropriate senior managers. These officials are responsible for determining needs and prioritizing the development of new policies, procedures, and guidance to ensure the consistency of their field activities. It is recommended that Management shall designate one or more individuals, as appropriate, who irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to field activities is implemented and followed at all times.

7.3 Office of Mission Support (OMS), Deputy Assistant Administrator (DAA) for Environmental Information (EI)/Chief Information Officer (CIO)

OMS's Deputy Assistant Administrator (DAA) for Environmental Information (EI)/Chief Information Officer (DAA/CIO) acts as the Agency Senior Management Official for quality management and is responsible for the oversight of the Agency's Quality Program and this Quality Procedure. The DAA/CIO is responsible for informing AAs and RAs of any issues or problems related to the quality of Agency products or services encompassed by this Procedure.

The OMS DAA/CIO will review an EPA organization's appeal regarding the implementation of this Procedure and make a final determination.

7.4 Field Operations Group (FOG)

The EPA FOG will assist organizations as necessary with the implementation of this Procedure.

7.5 OMS, Office of Enterprise Information Programs (OEIP), Enterprise Quality Management Division (EQMD)

The Office of Enterprise Information Programs (OEIP), Enterprise Quality Management Division (EQMD) conducts Quality Program Assessments (QPAs) of



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EPA organizations to evaluate their conformance with the Agency's Quality Policies and Procedures. The OMS, OEIP, EQMD will document the results of this evaluation in the EPA Organization's QPA Final Report.

7.6 EPA QA Managers

EPA QA Managers, and/or other designated staff, will assure that the appropriate aspects of this Procedure are documented in their organization's Quality Management Plan and any additional needed procedures. EPA QA Managers, and/or other designated staff, will oversee their organization's implementation of this Procedure.

8. RELATED INFORMATION

- Field Operations Group Operational Guidelines for Field Activities (attached to April 23, 2013, memorandum from Joyce C. Kelly, Director, Region 10, Office of Environmental Assessment – RS&T and ORD Lead Region).
- Consistent Field Operations at the U.S. Environmental Protection Agency, memorandum issued by Acting EPA Administrator, Bob Perciasepe, March 1, 2013.
- Training and Development for Individuals Who Lead Compliance Inspections/Field Investigations, EPA Order 3500.1 A1 (December 23, 2002).
- Safety and Health Training Requirements for Agency Employees, EPA Order 1440.2 (January 10, 2011).
- Digital Camera Guidance for EPA Civil Inspections and Investigations, U.S. EPA Office of Compliance, OECA (July 2006).

9. **DEFINITIONS**

Credentialed Employees: An authorized representative of EPA with the authority to conduct inspections, investigations and sampling under EPA's statutes.

Environmental Information: Any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental information includes information collected directly from measurements, produced from models, and compiled from other sources such as databases or literature.

Field Activities: Activities conducted by EPA employees, that require the collection of observations, samples, or data in support of EPA programs, Executive orders, regulations, or environmental laws, at a site or location (facility, water body, wetland, etc.). (See Section 2. Scope and Applicability)

Management System: A system to establish policy and objectives and to achieve those objectives (ISO 9001). A management system may describe the policies, objectives, principles, authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing products and services

Product: The intended result or final output of an activity or process that is disseminated or distributed among EPA organizations or outside of EPA.



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Quality Assurance: A management or oversight function that deals with setting policy and running an administrative system of management controls that cover planning, implementation, review and maintenance to ensure products and services are meeting their intended use

Quality Management: That aspect of the overall management system of the organization that determines and implements the quality policy. Quality management typically includes strategic

10. WAIVERS

The management system shall incorporate all 10 of these FOG Guidelines, unless there is a compelling reason not to do so and sufficient justification is provided and documented.

Organizations that wish to appeal a particular Procedure requirement shall address their request to the EPA DAA, CIO.

11. MATERIAL SUPERSEDED

This Procedure does not change the authorities or responsibilities of individual EPA organizations to apply their quality management system to field activities.

12. CONTACTS

For further information about this Procedure or the Quality Program, please contact the OMS, OEIP, EQMD.

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and Chief Information Officer
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