



## DEM Quality System Management Assessment SOP OD-QM-6

1. **APPLICABILITY.** This Standard Operating Procedure (SOP) applies to all programs in the Rhode Island Department of Environmental Management (DEM) that collect, produce, review or use environmental information and other data in the course of their business functions and that have also been identified by the Director as being required to participate in the DEM Quality Management Plan (QMP). The DEM Quality Assurance (QA) System monitors the data collection functions of many of the agency programs, and is also a requirement of the United States Environmental Protection Agency's (EPA) funded programs. In addition, this SOP applies to all staff, especially the DEM Quality Team, when assisting in QMP implementation.
2. **PURPOSE.** This SOP details the process used by DEM to ensure that the data collection process and its utilization are guided by acceptable quality standards and supports sound agency decision-making. With the assistance of the Quality Team, the DEM Quality Assurance Manager (QAM) performs annual reviews of the Quality System. These reviews gauge whether the Quality System is being successfully implemented and may identify opportunities for improvement such as patterns or issues that can affect project commitments or performance quality.

Each review of the DEM Quality System will be summarized in the Annual QA System Status Report. The six (6) main elements of the DEM Quality System discussed in this SOP are:

- (1) Quality Management Plan (QMP)
- (2) Annual Program Self-assessments
  - a) QA Project Plan (QAPP)
  - b) Standard Operating Procedure (SOP)
  - c) QMP revisions
- (3) Quality Assurance System Status Report
- (4) Input from regular meetings of the Regional QA Roundtable
- (5) Quality Team Meetings
- (6) EPA Assessments of DEM's QA Program

### 3. DEFINITIONS

- 3.1 Program Self-assessment – An annual process where program instituted quality assurance procedures are evaluated and compared to the DEM Quality Management Plan. Each self-assessment will include progress made towards resolution of any issues discussed in the prior years' document, new or revised SOPs & QAPPs and training activities. Programs provide updates to the QAM concerning their QA System through the applicable Self-assessment form identified in Sections 3.2, 3.3 and 3.4.
- 3.2 Program Self-assessment Form A (Streamlined Form) – An annual update to the QAM concerning changes in the program's QA effort including new or revised QAPPs and SOPs. This streamlined form is intended for DEM programs whose operations have



been previously described in one or more EPA-approved Quality Assurance Project Plans (QAPPs) or that currently utilizes Quality Assurance Manuals. This form also documents new or revised QAPPs and SOPs. Form A is filed in each of the two years following QAM approval of the more detailed Form B (See 3.3).

- 3.3 Program Self-assessment Form B (Detailed Form) – Form B is used by new programs entering the DEM Quality System, and it consists of a series of detailed questions specific to particular topics referred to in the QMP. Established programs also file this detailed form every three years to determine if there are any changes in the QA program including documentation of new or revised QAPPs and SOPs.
- 3.4 Program Self-assessment Form C - Restricted to programs that only review data provided by others, Form C is based on an SOP developed by the DEM Quality Team entitled “Summary Guidance for Reviewing Environmental Monitoring Data.”
- 3.5 Quality Assurance Manager (QAM) – Responsible for overseeing the QA activities of the decentralized DEM Quality System, the QAM develops, revises and implements the QMP. Roles include: coordination of System Management Reviews and Project and Program Assessments, preparation of the annual Quality Assurance System Status Report, updating of the DEM Quality Assurance website, establishing a training program to educate and instruct staff on the DEM Quality System and leadership of the DEM’s Quality Team.
- 3.6 Quality Assurance Project Plan (QAPP) - A formal document describing in comprehensive detail, the necessary quality assurance procedures, quality control activities, and other technical activities that need to be implemented, to ensure that the results of the work performed, will satisfy the stated performance or acceptance criteria. Major revisions to QAPPs are reported in the annual Program Self-assessments. All QAPPs should be reviewed at a minimum, every five years to determine if program operations have changed or if addenda from previous versions have been incorporated into a revised QAPP. Changes that are incorporated into a QAPP should be reported in the yearly program self-assessment.
- 3.7 Quality Assurance System Status Report (QASSR) – An annual assessment that summarizes the state of the DEM Quality Assurance System to determine how it is functioning and if there is any need for system element improvement or training. The update provides an overview of the annual self-assessments, updates of the Quality Management Plan and new or revised Quality Assurance Project Plans and Standard Operating Procedures.
- 3.8 Quality Management Plan (QMP) - The document which describes DEM’s quality system. The QMP identifies the policy and procedures, organizational structure, functional responsibilities of management and staff, lines of authority, and its processes for planning, implementing, documenting, and assessing activities that take place in DEM’s quality system.



- 3.9 Quality System - A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization, towards ensuring consistent quality in its work processes, products, and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out quality assurance procedures and quality control activities.
- 3.10 Quality Team – The group of DEM representatives who are responsible for QA activities within their respective programs. These individuals provide input to the DEM QA program by coordinating QA activities such as annual self-assessments, commenting on QA documents prepared by team members and by their attendance at regularly scheduled meetings.
- 3.11 Standard Operating Procedure (SOP) – The description of a prescribed method that is used by DEM staff to complete certain routine operations, analyses, or actions. SOPs do not establish policy and are not appropriate to describe procedures or requirements that apply to members of the public, other than persons acting as agents of, or under contract with, the DEM.

#### **4. RESPONSIBILITIES**

- 4.1 The DEM QA System is a decentralized system. The following is a breakdown of the responsibilities of the major QA System elements:
- 4.1.1 The Quality Assurance Manager (QAM) is responsible for coordinating the DEM decentralized QA System through scheduling Quality Team meetings, preparing agendas and providing meeting notes. Technical documentation duties include: QMP revisions, generation of QA System Status Reports, Program revisions to the annual QA Self-assessment Guidance, and DEM Intranet/Internet site maintenance. Staff assistance services provided include QA education coordination and Intranet QA training module updates.
- 4.1.2 The Quality Team members are primarily responsible for:
- a. Commenting on all drafts of the QMP, QA System Status Report, Program Self-assessment Forms and all documents that are discussed at the Quality Team meetings.
  - b. Initiation of QA issues that need to be discussed and coordinated at the program level.
  - c. Preparation of the draft and final program self-assessments.
  - d. Coordination of QA Training within the program.
  - e. Updating the DEM Workplan Reporting System on their QA activities.
- 4.1.3 Upon being informed by management of applicability to their position, DEM employees are responsible for becoming familiar and complying with the contents of the DEM Quality Management Plan and how it relates to their job.



- 4.1.4 Program / Office Chiefs are primarily responsible for:
- a. Providing support and being a conduit at appropriate meetings for discussion of QA issues with the QA team member and others in the program.
  - b. Signature authority for approving SOPs, QAPPs, revisions to the QMP and Program/Office Self-assessments.
- 4.1.5 Assistant Directors are responsible for providing policy definition, leadership, and oversight for the quality system throughout the Bureau and serve as the overall authority for directing activities in accordance with program policy. Responsibilities, concerning quality, include:
- a. Serving as the final authority for resolving quality related issues,
  - b. Advocating for the necessary training,
  - c. Advocating for resources to support the quality approach,
  - d. Ensuring that the Quality Management Plan (QMP) is in place and functioning,
  - e. Ensuring that deficiencies noted in the Quality Assurance System Status Report are added to the Office work plans for resolution, and
  - f. Signature authority for approving Bureau wide SOPs, QAPPs, the QMP and Annual QA System Status Reports.
- 4.1.6 The Director is responsible for:
- a. Ensuring that the DEM QA System has adequate resources to assure that all environmental data that is collected, generated and compiled by DEM and its agents is of known quality and adequate for its intended use.
  - b. Providing QA System support within the Bureaus, and
  - c. Reviewing and approving the revised Quality Management Plans and annual QA System Status Reports.

## 5. GUIDELINES AND PROCEDURES

**5.1 Quality System Overview** – There are six (6) primary areas where the DEM QA Manager is responsible for oversight of the DEM QA System. The following section will provide guidance in the procedures used to complete these program elements.

### 5.1.1. Quality Management Plan (QMP)

The QMP is required by EPA to undergo a comprehensive review every five years. The DEM QMP was last approved in 2005. Future comprehensive reviews are therefore due in years divisible by five. The current QAM has taken the approach that the QMP should be more of a living document and should therefore be incrementally updated on a yearly basis. In this manner, policies and procedures that have been worked on within a year can be incorporated into the QMP for use by DEM employees when the changes are made.



Changes to the QMP will be the result of topics discussed and approved in Quality Team meetings including incorporation of policies of the Regional QA Roundtable. Typical yearly updates of the QMP include revisions to SOPs, QAPPs and Sampling Analytical Plans (SAPs) approved by the programs, summary of training activities, changes in personnel active on the QA Team, and discussion of the significant findings of the yearly Program Self-assessments and EPA program assessments.

The Quality Management Plan is updated in the fall of the year in conjunction with the annual Program Self-assessments. The QAM is responsible for drafting the changes to the QMP and presenting the proposed changes to the Quality Team for comment. Approved comments are then incorporated and the document is sent, with a summary memo, to the Assistant Directors in the Bureau of Environmental Protection, the Associate Director of the Bureau of Natural Resources and the Director for review and concurrence. After the QMP has been finalized as an agency document, it is forwarded to the Rhode Island contact in Region I for EPA review and approval. The EPA contact in Region I has historically been a member of the DEM Quality Team and should be aware of any significant changes in the document. After EPA approval, the QMP is posted on the DEM Internet and Intranet sites. An electronic copy of the document is also sent to the Quality Team members who shall distribute the document to appropriate office/division personnel.

#### **5.1.2. Annual Program Self-assessments**

The DEM Quality System is decentralized; therefore individual programs are responsible for ensuring program elements of the QMP are being addressed at each level. One mechanism to address the integrity of the QA system is to conduct program assessments.

DEM has instituted a system of self-assessments that are conducted at the program level. This self-assessment is based on the DEM QMP and evaluates each program to determine conformance with DEM procedures, adequacy of existing quality assurance project plans, standard operating procedures (SOPs) and other applicable requirements. Other objectives of the self-assessments are the determination of the accuracy of data collection and management systems, identification of opportunities for program improvements, and verification of the effectiveness of the Department's QA programs. Other important benefits of assessing are cross-training, assurance that policies and procedures are current and are being followed by staff, and continuous improvement.

On a yearly basis, the QAM reviews the existing "Guidance for Annual Self-Assessments" (Guidance). The Guidance is modified to clarify issues for the upcoming annual self-assessment and will contain revisions (if needed) of Forms A, B and C which are used to conduct program assessments. This assessment is applicable to all programs listed in the Guidance. The QAM, the Quality Team and the Assistant Directors in the Bureau of Environmental Protection may use the previous year's QA System Status Report to identify and prioritize assessment issues, develop annual assessment plans, and ensure that assessments conform to



DEM guidance. The QAM then revises the Guidance document and presents a draft copy to the Quality Team in late spring. After the Guidance document is finalized by the Quality Team, the self-assessment forms are distributed to the programs to initiate the annual self-assessment process cycle.

The Quality Team member of each applicable program will coordinate the self-assessment activities. A program may specify additional procedures or requirements for conducting assessments within that group. The annual draft self-assessment forms are scheduled for submittal by August 30. Upon completion, each program forwards an electronic copy to the QAM for an initial review. After all questions about the self-assessment have been resolved, each program's signed form will be submitted to the QAM.

The QAM will review each program self-assessment for completeness, appropriateness, clarity, and consistency with implementation of specific QAPPs and SOPs. The QAM will then summarize the results of the self-assessments on a spreadsheet or table for analysis which is valuable for later compilation of the Annual QA System Status Report.

### **5.1.3. Annual Quality Assurance System Status Report**

The DEM relies on the collection and analysis of environmental data to support its decision-making processes. In carrying out its mission, DEM relies upon many different types of scientific data that enable it to better evaluate and measure existing environmental conditions, to identify and understand areas of concern, to assign responsibility for these areas, and to promote dialog among a diverse group of stakeholders on environmental issues.

The data DEM collects must be scientifically defensible, and the quality of that data must be appropriate for its intended uses. DEM, through its Quality Assurance System has developed a systematic approach in the management of data and overall quality assurance issues across the department. This QA System is described in the DEM Quality Management Plan and is frequently updated to highlight the evolving improvements to the system.

On a yearly basis, DEM assesses the Quality System to determine functionality and any need for system element improvement. In general, the QA System Status Report will have the four main elements as described below.

The first section will address assessments of the DEM QA system that will be based on the yearly annual program self-assessments. The QAM will present a summation of the process. Included in this section will be a discussion of any EPA assessment of the DEM QA Program.

The second section of the report will discuss areas for improvement that should be worked on in the following year. This section will also touch on QA system



challenges and vulnerabilities. The material from this section will generally be information provided in the program self-assessments.

The third section will discuss:

- Any issues concerning how information can be better communicated to departmental employees about changes to the DEM QA System.
- QA training efforts and needs for the coming year.
- Any QA best practices that have been instituted by any of the programs. This description will be used both to support the initiative of the programs that developed the best practice and to also allow others to consider adoption of these practices.

The fourth section will be a summary of the changes to the DEM Quality Management Plan with respect to new or revised QAPPs and SOPs implemented in the previous year.

After completion of the DEM Programs Self-assessment Summary, the QAM prepares the draft QA System Status Report and provides it to the Quality Team prior to one of the fall meetings. The report is finalized based on comments of the Quality Team and then sent along with a summary memo to the Assistant Directors in the Bureau of Environmental Protection, the Associate Director of the Bureau of Natural Resources and the Director for review and concurrence. After the QA System Status Report has been finalized as an agency document, it is forwarded to EPA, Region I. The submission of the report is a requirement of the DEM/EPA Performance Partnership Agreement. The QA System Status Report will then be posted on the DEM intranet sites. An electronic copy of the document is sent to the Quality Team members who are requested to distribute the document to office/division personnel.

#### **5.1.4. Input from Regular Meetings of the Regional QA Roundtable**

EPA Region I, Chelmsford Lab, organizes three meetings a year with their QA personnel and the Quality Assurance Managers of the six New England states. The purpose of these meetings is to provide a forum to discuss QA issues that need to be resolved in the state's program. Each meeting also allows the states to be alerted to future activities of the EPA that will have an impact on the state's QA program. Information from the QA Roundtable is discussed at the DEM Quality Team meetings. When appropriate, DEM program guidance may result from a discussion of these issues and may be included in the QMP.

#### **5.1.5. Quality Team Meetings**

Since DEM's QA Program is a decentralized system, the QAM convenes regular meetings of representatives from the major programs within the EPA Performance Partnership Agreement programs. Meetings are scheduled for the second Tuesday of the month. The group meets on an as-needed basis anywhere from three to six times a year, depending on the issues that need to be discussed. The QA Manager



develops meeting agendas and notes. All final agendas and meeting notes will be posted on the DEM intranet site.

#### **5.1.6. EPA Assessments of DEM's QA Program**

EPA Region I conducts assessments of the Rhode Island QA System every three years. The QA Manager will work with EPA and the Quality Team to determine the nature of the EPA assessment. The assessment can either be an in-depth assessment of the DEM QA System or an assessment of any number of DEM Programs. Once the direction of the assessment has been finalized, the QA Manager will work with the EPA's Assessment Team to develop the general format of the program assessments. The QA Manager coordinates the EPA assessment with the programs and is the point of contact for DEM's comments on EPA prepared Draft Assessment Report. The QAM will provide copies of the Draft Assessment to the programs and appropriate Associate/Assistant Directors. The QAM will provide the final copy of the EPA Assessment Report to the Director, the appropriate Associate/Assistant Directors, Division/Office Chiefs of the assessed programs, members of the Quality Team. The final assessment will be posted on the DEM website under Quality Assurance.

## **6. REFERENCE DOCUMENTS**

- 6.1.1. DEM Quality Management Plan – February 8, 2010
- 6.1.2. Annual QA Program Self-assessments Guidance – June 30, 2010
- 6.1.3. Annual Quality Assurance System Status Report – January 19, 2010





## DEM Quality System Management Oversight SOP - OD-QM-6

Originator:

Thomas Getz \_\_\_\_\_ Thomas Getz \_\_\_\_\_ Date: 12/14/10  
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\* Copy of the signed page is held by the DEM QA Manager.

### **DISTRIBUTION:**

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- (x) Division of Agriculture.....by: TDG Date: 1/11/11
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