



## **DEM Standard Operating Procedure for Developing QAPPs and SAPs**

### **1. APPLICABILITY**

This Standard Operating Procedure (SOP) applies to all environmental programs in the Rhode Island Department of Environmental Management (DEM).

### **2. PURPOSE**

This SOP specifies the process and procedures to be followed by DEM for reviewing and approving Quality Assurance Program / Project Plans (QAPPs) required for environmental data activities.

### **3. DEFINITIONS**

- 3.1. **Quality Assurance Program / Project Plan (QAPP)**  
A Quality Assurance Program / Project Plan describes in comprehensive detail the necessary Quality Assurance (QA) policies and Quality Control (QC) and technical activities that must be implemented to ensure the results of work performed, particularly for environmental data operations, will satisfy the stated performance criteria. QAPPs document the results of certain systematic planning processes (see Rhode Island Quality Management Plan, Section III.D). QAPPs may apply to specific projects/data operations, or to a program area responsible for a number of different specific projects / operations.
- 3.2. **Sampling and Analysis Plan (SAP)**  
A Sampling and Analysis Plan, also referred to as a Work Plan, documents the project-specific objectives, data quality measures, schedules, locations, field and analytic protocols, personnel, and related information needed to apply a program-level QAPP to a particular project or series of related activities.

### **4. RESPONSIBILITIES.**

- 4.1. **QAPP DEVELOPMENT**  
Each DEM program area involved in planning and implementing environmental data operations is responsible for assuring that QAPPs and SAPs are developed in sufficient time prior to the beginning of data gathering to allow for review, comment, revision, and approval. The project manager, in consultation with the program manager, is responsible for determining the extent of review (e.g., internal or external; EPA-NE parallel review; degree of technical complexity) necessary for a particular QAPP, and thus how much time to allow.
- 4.2. **OVERSIGHT**  
The program manager is responsible for assuring that necessary review and approval processes are scheduled and completed before the beginning of data operations.
- 4.3. **ARRANGING REVIEW**  
The Project Manager responsible for the QAPP, in consultation with the Program Manager, shall identify persons to review the QAPP, and arrange for their participation. The Program Manager is also responsible for coordinating any required EPA-NE participation in the review/approval process, such as parallel



review, technical assistance, etc.

#### 4.4. REPORTING

The QA Manager is responsible for:

- Reporting the results of the review and approval process to the EPA-NE Quality Manager;
- Forwarding DEM-approved QAPPs to the EPA-NE Office of Environmental Measurement and Evaluation; and
- Maintaining records of the status of all QAPPs for which DEM has responsibility.

### 5. PROCEDURES.

5.1. The QA Manager should be notified whenever a Program Manager begins work on, or contracts for the external development of, a QAPP. An expected date of completion of the initial draft should be set at this point. The Program Manager and QA Manager should consult on the expected levels of review that may be required, the participation of EPA-NE or an external reviewer, etc.

5.2. At least two weeks before the expected completion of the draft, or submission to DEM of a QAPP developed by an outside party, the Program Manager will convene a review team. Review team members shall be selected on the basis of professional expertise relevant to the content of the QAPP. Once the review team is selected, the Program Manager, in consultation with the DEM review team leader, and any outside reviewers, will specify a date by which initial review and comment will be completed.

5.3. QAPP review shall be comprised of two steps:

- A Level I QAPP Completeness Check, and
- A Level II Technical QAPP Review.

Both levels of review shall use EPA QA/R-5, "Requirements for Quality Assurance Project Plans" as their standard of acceptability.

5.3.1. Level I Completeness may be carried out by any person nominated by the Program Manager on the basis of familiarity with the standards of EPA QA/R-5.

5.3.2. Level II Technical Review shall be carried out by one or more persons who are professionally competent to evaluate the methods, procedures, and protocols in the QAPP and are not subject to the QAPP. A QAPP reviewer may have been involved in developing a portion of the QAPP, provided s/he is not the reviewer of that section. *Example:* someone who consulted on the development of the QAPP field operations protocols may review the analytic protocols.

5.3.3. The Program Manager and the DEM Division Director in whose Division the QAPP is to be used shall determine the degree of independence (e.g., involvement in developing the QAPP; different program area, unit,



division, etc.) required of each reviewer. Where there is doubt regarding the possible independence of the reviewer, the next degree of independence shall automatically be required.

- 5.4. Each separate reviewer, and the review team acting as a whole, shall document their comments in writing. Initial review comments shall be given to the author for inclusion in any revision of the QAPP. The review team leader specifies how any response to comments should be managed, and arranges an agreed date by which a revised QAPP will be returned for further review or final approval.
- 5.5. On receipt of the revised QAPP, the review team leader shall arrange for further review by both Level I and Level II reviewers, and set a date for an approval meeting.
- 5.6. At the approval meeting, the review team shall make a determination as follows:

Approved:

Activities specified in the QAPP may begin immediately;

Conditionally Approved:

Activities specified in the QAPP may begin subject to restrictions related to further required changes. *Example:* A revised field procedure incorporating a requested change must be filed with the Program Manager before that procedure is implemented in the field. The review team leader shall verify successful completion of approval conditions before signature by the Program Manager.

Deferred:

Activities specified in the QAPP may not begin until required changes are submitted, and the full review team approves.

The determination shall be documented in the records of the review team, and communicated to the person responsible for the QAPP as soon as possible.

- 5.7. A QAPP subject to the parallel approval process referred to above (4.3) must be Approved, or Conditionally Approved, by both DEM and EPA-NE before activities specified in the QAPP begin.
- 5.8. SAPs are considered part of the QAPP under which site or project specific activities are carried out. Generic or programs QAPPs shall specify within their main text the procedures for the submission, review, approval, maintenance, and tracking of SAPs.
- 5.9. Generic QAPPs will be developed using the procedures outlined above. Once a generic QAPP has been developed, project Managers only need the approval of the Program Manager to use a project specific QAPP based on the generic QAPP.



## 6. REFERENCES

- 6.1 Rhode Island Department of Environmental Protection, *Quality Management Plan* (Revision 1, April 17, 2001),
- 6.2 *EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations (EPA QA R/5)*. Final, March, 2001.