9 QUALITY ASSURANCE AND QUALITY CONTROL

9.1 Introduction

The goal of quality assurance and quality control (QA/QC) is to identify and implement sampling and analytical methodologies which limit the introduction of error into analytical data. For MARSSIM data collection and evaluation, a system is needed to ensure that radiation surveys produce results that are of the type and quality needed and expected for their intended use. A *quality system* is a management system that describes the elements necessary to plan, implement, and assess the effectiveness of QA/QC activities. This system establishes many functions including: quality management policies and guidelines for the development of organization- and project-specific quality plans; criteria and guidelines for assessing data quality; assessments to ascertain effectiveness of QA/QC implementation; and training programs related to QA/QC implementation. A quality system ensures that MARSSIM decisions will be supported by sufficient data of adequate quality and usability for their intended purpose, and further ensures that such data are authentic, appropriately documented, and technically defensible.

Any organization collecting and evaluating data for a particular program must be concerned with the quality of results. The organization must have results that: meet a well-defined need, use, or purpose; comply with program requirements; and reflect consideration of cost and economics. To meet the objective, the organization should control the technical, administrative, and human factors affecting the quality of results. Control should be oriented toward the appraisal, reduction, elimination, and prevention of deficiencies that affect quality.

Quality systems already exist for many organizations involved in the use of radioactive materials. There are self-imposed internal quality management systems (*e.g.*, DOE) or there are systems required by regulation by another entity (*e.g.*, NRC) which require a quality system as a condition of the operating license.[1] These systems are typically called Quality Assurance Programs. An organization may also obtain services from another organization that already has a quality system in place. When developing an organization-specific quality system, there is no need to develop new quality management systems, to the extent that a facility's current Quality Assurance Program can be used. Standard ANSI/ASQC E4-1994 (ASQC 1995) provides national consensus quality standards for environmental programs. It addresses both quality systems and the collection and evaluation of environmental data. Annex B of ANSI/ASQC E4-1994

[1] Numerous quality assurance and quality control (QA/QC) requirements and guidance documents have been applied to environmental programs. Until now, each Federal agency has developed or chosen QA/QC requirements to fit its particular mission and needs. Some of these requirements include DOE Order 5700.6c (DOE 1991c); EPA QA/R-2 (EPA 1994f); EPA QA/R-5 (EPA 1994c); 10 CFR 50, App. B; NUREG-1293, Rev. 1 (NRC 1991); Reg Guide 4.15 (NRC 1979); and MIL-Q-9858A (DOD 1963). In addition, there are several consensus standards for QA/AC, including ASME NQA-1 (ASME 1989), and ISO 9000/ASQC Q9000 series (ISO 1987). ANSI/ASQC E4-1994 (ASQC 1995) is a consensus standard specifically for environmental data collection.

(ASQC 1995) and Appendix K of MARSSIM illustrate how existing quality system documents compare with organization- and project-specific environmental quality system documents.

Table 9.1 illustrates elements of a quality system as they relate to the Data Life Cycle. Applying a quality system to a project is typically done in three phases as described in Section 2.3: 1) the planning phase where the Data Quality Objectives (DQOs) are developed following the process described in Appendix D and documented in the Quality Assurance Project Plan (QAPP),[2] 2) the implementation phase involving the collection of environmental data in accordance with approved procedures and protocols, and 3) the assessment phase including the verification and validation of survey results as discussed in Section 9.3 and the evaluation of the environmental data using Data Quality Assessment (DQA) as discussed in Section 8.2 and Appendix E. Detailed guidance on quality systems is not provided in MARSSIM because a quality system should be in place and functioning prior to beginning environmental data collection activities.

Table 9.1 The Elements of a Quality System Related to the Data Life Cycle

Data Life Cycle	Quality System Elements
Planning	Data Quality Objectives (DQOs) Quality Assurance Project Plans (QAPPs) Standard Operating Procedures (SOPs)
Implementation	QAPPs SOPs Data collection Assessments and audits
Assessment	Data validation and verification Data Quality Assessment (DQA)

A graded approach bases the level of controls on the intended use of the results and the degree of confidence needed in their quality. Applying a graded approach may mean that some organizations (*e.g.*, those using the simplified procedures in Appendix B) make use of existing plans and procedures to conduct surveys. For many other organizations, the need for cleanup and restoration of contaminated facilities may create the need for one or more QAPPs suitable to the special needs of environmental data gathering, especially as it relates to the demonstration of compliance with regulatory requirements. There may even be a need to update or revise an existing quality management system.

[2] The quality assurance project plan is sometimes abbreviated QAPjP. MARSSIM adopts the terminology and abbreviations used in ANSI/ASQC E4-1994 (ASQC 1995) and EPA QA/R-5 (EPA 1994c).

9.2 Development of a Quality Assurance Project Plan

The Quality Assurance Project Plan (QAPP)[3] is the critical planning document for any environmental data collection operation because it documents how QA/QC activities will be implemented during the life cycle of a project (EPA 1997). The QAPP is the blueprint for identifying how the quality system of the organization performing the work is reflected in a particular project and in associated technical goals. This section provides information on how to develop a QAPP based on the DQO process. The results of the DQO process provide key inputs to the QAPP and will largely determine the level of detail in the QAPP.

The consensus standard ANSI/ASQC E4-1994 (ASQC 1995) describes the minimum set of quality elements required to conduct programs involving environmental data collection and evaluation. Table 9.2 lists the quality elements for collection and evaluation of environmental data from ANSI/ASQC E4-1994. These quality elements are provided as examples that should be addressed when developing a QAPP. This table also includes references for obtaining additional information on each of these quality elements. Many of these elements will be addressed in existing documents, such as the organization's Quality Assurance Program or Quality Management Plan. Each of these quality elements should be considered during survey planning to determine the degree to which they will be addressed in the QAPP. Additional quality elements may need to be added to this list as a result of organizational preferences or requirements of Federal and State regulatory authorities. For example, safety and health or public participation may be included as elements to be considered during the development of a QAPP.

The QAPP should be developed using a graded approach as discussed in Section 9.1. In other words, existing procedures and survey designs can be included by reference. This is especially useful for sites using a simplified survey design process (*e.g.*, surveys designed using Appendix B).

A QAPP should be developed to document the results of the planning phase of the Data Life Cycle (see Section 2.3). The level of detail provided in the QAPP for relevant quality elements is determined using the DQO process during survey planning activities. Information that is already provided in existing documents does not need to be repeated in the QAPP, and can be included by reference (EPA 1997).

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[3] MARSSIM uses the term Quality Assurance Project Plan to describe a single document that incorporates all of the elements of the survey design. This term is consistent with ANSI/ASQC E4-1994 (ASQC 1995) and EPA guidance (EPA 1994c, EPA 1997), and is recommended to promote consistency. The use of the term QAPP in MARSSIM does not exclude the use of other terms (*e.g.*, Decommissioning Plan, Sampling and Analysis Plan, Field Sampling Plan) to describe survey planning documentation as long as the information in the documentation supports the objectives of the survey.

Table 9.2 Examples of QAPP Elements for Site Surveys and Investigations

QAPP Element	Information Source	
Planning and Scoping (reference the QA Manual for information on the quality system)	ASQC 1995 EPA 1994c EPA 1997 NRC 1997c EPA 1993d	Part A, Sections 2.1 and 2.7; Part B, Section 3.1 Sections A4, A5, A6 and A7 Chapter III, Sections A4, A5, A6, and A7 Chapter 14 Project Objectives
Design of Data Collection Operations (including training)	ASQC 1995 EPA 1994c EPA 1997 EPA 1993d	Part A, Section 2.3; Part B, Section 3.2 Sections A9 and B1 Chapter III, Sections A9 and B1 Sampling Design
Implementation of Planned Operations (including documents and records)	ASQC 1995 EPA 1994c EPA 1997 NRC 1997c EPA 1993d	Part A, Section 2.8; Part B, Section 3.3 Sections A1, A2, A3, B2, B3, B4, B5, B6, B7, B8, B9, and B10 Chapter III, Sections A1, A2, A3, B2, B3, B4, B5, B6, B7, B8, B9, and B10 Chapter 5 Sampling Execution, Sample Analysis
Assessment and Response	ASQC 1995 EPA 1994c EPA 1997 EPA 1993d	Part A, Section 2.9, Part B, Section 3.4 Sections C1 and C2 Chapter III, Sections C1 and C2 Exhibit 3, Reference Box 3
Assessment and Verification of Data Usability	ASQC 1995 EPA 1994c EPA 1997 NRC 1997c EPA 1993d	Part B, Section 3.5 Sections D1, D2, and D3 Chapter III, Sections D1, D2, and D3 Chapter 20, Appendix J, Appendix Q Assessment of Data Quality

For example, the quality system description, personnel qualifications and requirements, and Standard Operating Procedures (SOPs) for the laboratory analysis of samples may simply be references to existing documents (*e.g.*, Quality Management Plan, Laboratory Procedure Manual). SOPs for performing direct measurements with a specific instrument may be attached to the QAPP because this information may not be readily available from other sources.

There is no particular format recommended for developing a QAPP. Figure 9.1 provides an example of a QAPP format presented in EPA QA/R-5 (EPA 1994c). Appendix K compares the quality elements presented in this example to the quality elements found in EPA QAMS-005-80 (EPA 1980d), ASME NQA-1 (ASME 1989), DOE Order 5700.6c (DOE 1991c), MIL-Q-9858A (DOD 1963), and ISO 9000 (ISO 1987).

Project Management
- Title and Approval Sheet
- Table of Contents
- Distribution List
- Project/Task Organization
- Problem Definition/Background
- Project Task Description
- Quality Objectives and Criteria for Measurement Data
- Special Training Requirements/Certification

Measurement/Data Acquisition
- Sampling Process Design (Experimental Design)
- Sampling Methods Requirements
- Sample Handling and Custody Requirements
- Analytical Methods Requirements
- Quality Control Requirements
- Instrument/Equipment Testing, Inspection, and Maintenance Requirements
- Instrument Calibration and Frequency
- Inspection/Acceptance Requirements for Supplies and Consumables

Assessment/Oversight
- Assessments and Response Actions
- Reports to Management

Data Validation and Usability
- Data Review, Validation, and Verification Requirements
- Validation and Verification Methods
- Reconciliation with User Requirements

Figure 9.1 Example of a QAPP Format

9.3 Data Assessment

Assessment of environmental data is used to evaluate whether the data meet the objectives of the survey, and whether the data are sufficient to determine compliance with the DCGL (EPA 1992a, 1992b, 1996a). The assessment phase of the Data Life Cycle consists of three phases: data verification, data validation, and Data Quality Assessment (DQA). This section provides guidance on verifying and validating data collected during a final status survey designed to demonstrate compliance with a dose- or risk-based regulation. Guidance on DQA is provided in Chapter 8 and Appendix E. As with all components of a successful survey, the level of effort associated with the assessment of survey data should be consistent with the objectives of the survey (*i.e.*, a graded approach).

9.3.1 Data Verification

Data verification ensures that the requirements stated in the planning documents (*e.g.*, Quality Assurance Project Plan, Standard Operating Procedures) are implemented as prescribed. This means that deficiencies or problems that occur during implementation should be documented and reported. This also means that activities performed during the implementation phase are assessed regularly with findings documented and reported to management. Corrective actions undertaken should be reviewed for adequacy and appropriateness and documented in response to the findings. Data verification activities should be planned and documented in the QAPP. These assessments may include but are not limited to inspections, QC checks, surveillance, technical reviews, performance evaluations, and audits.

To ensure that conditions requiring corrective actions are identified and addressed promptly, data verification activities should be initiated as part of data collection during the implementation phase of the survey. The performance of tasks by personnel is generally compared to a prescribed method documented in the SOPs, and is generally assessed using inspections, surveillance, or audits. Self-assessments and independent assessments may be planned, scheduled, and performed as part of the survey. Self-assessment also means that personnel doing work should document and report deficiencies or problems that they encounter to their supervisors or management.

The performance of equipment such as radiation detectors or measurement systems such as an instrument and human operator can be monitored using control charts. Control charts are used to record the results of quantitative QC checks such as background and daily calibration or performance checks. Control charts document instrument and measurement system performance on a regular basis and identify conditions requiring corrective actions on a real time basis. Control charts are especially useful for surveys that extend over a significant period of time (*e.g.*, weeks instead of days) and for equipment that is owned by a company that is frequently used to collect survey data. Surveys that are accomplished in one or two days and use rented instruments may not benefit significantly from the preparation and use of control charts. The use of control charts is usually documented in the SOPs.

A technical review is an independent assessment that provides an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification to ensure that established requirements are satisfied (ASQC 1995). A technical review typically requires a significant effort in time and resources and may not be necessary for all surveys. A complex survey using a combination of scanning, direct measurements, and sampling for multiple survey units is more likely to benefit from a detailed technical review than a simple survey design calling for relatively few measurements using one or two measurement techniques for a single survey unit.

9.3.2 Data Validation

Data validation activities ensure that the results of data collection activities support the objectives of the survey as documented in the QAPP, or support a determination that these objectives should be modified. Data Usability is the process of ensuring or determining whether the quality of the data produced meets the intended use of the data (EPA 1992a, EPA 1997). Data verification compares the collected data with the prescribed activities documented in the SOPs; data validation compares the collected data to the DQOs documented in the QAPP. Corrective actions may improve data quality and reduce uncertainty, and may eliminate the need to qualify or reject data.

9.3.2.1 Data Qualifiers

Qualified data are any data that have been modified or adjusted as part of statistical or mathematical evaluation, data validation, or data verification operations (ASQC 1995). Data may be qualified or rejected as a result of data validation or data verification activities. Data qualifier codes or flags are often used to identify data that has been qualified. Any scheme used should be fully explained in the QAPP and survey documentation. The following are examples of data qualifier codes or flags derived from national qualifiers assigned to results in the contract laboratory program (CLP; EPA 1994g).

U or <MDC — The radionuclide of interest was analyzed for, but the radionuclide concentration was below the minimum detectable concentration (MDC). Section 2.3.5 recommends that the actual result of the analysis be reported so this qualifier would inform the reader that the result reported is also below the MDC.

J — The associated value reported is a modified, adjusted, or estimated quantity. This qualifier might be used to identify results based on surrogate measurements (see Section 4.3.2) or gross activity measurements (*e.g.*, gross alpha, gross beta). The implication of this qualifier is that the estimate may be inaccurate or imprecise which might mean the result is inappropriate for the statistical evaluation of the results. Surrogate measurements that are not inaccurate or imprecise may or may not be associated with this qualifier. It is recommended that the potential uncertainties associated with surrogate or gross measurements be quantified and included with the results.

R — The associated value reported is unusable. The result is rejected due to serious analytical deficiencies or quality control results. These data would be rejected because they do not meet the data quality objectives of the survey.

O — The associated value reported was determined to be an outlier.

9.3.2.2 Data Validation Descriptors

Data validation is often defined by six data descriptors. These six data descriptors are summarized in Table 9.3 and discussed in detail in Appendix N. The decision maker or reviewer examines the data, documentation, and reports for each of the six data descriptors to determine if performance is within the limits specified in the DQOs during planning. The data validation process for each data descriptor should be conducted according to procedures documented in the QAPP.

Table 9.3 Suggested Content or Consideration, Impact if Not Met, and Corrective Actions for Data Descriptors

Data Descriptor	Suggested Content or Consideration	Impact if Not Met	Corrective Action
Reports to Decision Maker	• Site description • Survey design with measurement locations • Analytical method and detection limit • Detection limits (MDCs) • Background radiation data • Results on per measurement basis, qualified for analytical limitations • Field conditions for media and environment • Preliminary reports • Meteorological data, if indicated by DQOs • Field reports	• Unable to perform a quantitative radiation survey and site investigation	• Request missing information • Perform qualitative or semi-quantitative site investigation
Documentation	• Chain-of-custody records • SOPs • Field and analytical records • Measurement results related to geographic location	• Unable to identify appropriate concentration for survey unit measurements • Unable to have adequate assurance of measurement results	• Request that locations be identified • Resurveying or resampling • Correct deficiencies
Data Sources	• Historical data used meets DQO's	• Potential for Type I and Type II decision errors • Lower confidence of data quality	• Resurveying, resampling, or reanalysis for unsuitable or questionable measurements

Table 9.3 (continued)

Data Descriptor	Suggested Content or Consideration	Impact if Not Met	Corrective Action
Analytical Method and Detection Limit	• Routine methods used to analyze radionuclides of potential concern	• Unquantified precision and accuracy • Potential for Type I and Type II decision errors	• Reanalysis • Resurveying, resampling, or reanalysis • Documented statements of limitation
Data Review	• Defined level of data review for all data	• Potential for Type I and Type II decision errors • Increased variability and bias due to analytical process, calculation errors, or transcription errors	• Perform data review
Data Quality Indicators	• Surveying and sampling variability identified for each radionuclide • QC measurements to identify and quantify precision and accuracy • Surveying, sampling, and analytical precision and accuracy quantified	• Unable to quantify levels for uncertainty • Potential for Type I and Type II decision errors	• Resurveying or resampling • Perform qualitative site investigation • Documented discussion of potential limitations

Data collected should meet performance objectives for each data descriptor. If they do not, deviations should be noted and any necessary corrective action performed. Corrective action should be taken to improve data usability when performance fails to meet objectives.