

APPENDIX D CONTENT OF PROJECT PLAN DOCUMENTS

D1.0 Introduction

Project plan documents were discussed in Chapter 4, *Project Plan Documents*. This appendix will discuss appropriate content of plan documents. The content of project plan documents, regardless of the document title or format, will include similar information, including the project description and objectives, identification of those involved in the project activities and their responsibilities and authorities, enumeration of the quality control (QC) procedures to be followed, reference to specific standard operating procedures (SOPs) that will be followed for all aspects of the projects, and Health and Safety protocols.

The discussion of project plan document content in this appendix will rely on EPA's guidance on elements for a QA project plan (QAPP). MARLAP selected EPA's QAPP as a model for content of a project plan document since it is closely associated with the data quality objective (DQO) planning process and because other plan documents lack widely accepted guidance regarding content. MARLAP hopes that presentation of a project plan document in one of the most commonly used plan formats will facilitate plan writing by those less familiar with the task, provide a framework for reviewing plan documents, and aid in tracking projects.

The discussion of plan content in sections D2 to D5 follows the outline developed by EPA requirements (EPA, 1998b) and guidance (EPA, 1998a) for QAPPs for environmental data operations. The QAPP elements are presented in four major sections (Table D1) that are referred to as "groups":

- Project Management ;
- Measurement/Data Acquisition;
- Assessment/Oversight; and
- Data Validation and Usability.

There are many formats that can be used to present the project plan elements. MARLAP does not recommend any particular plan format over another. The project planning team should focus on the appropriate content of plan documents needed to address the necessary quality assurance (QA), QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. Table D2 provides a crosswalk between the table of contents of two example project plan documents—a QAPP and a work plan—and EPA's (1998a) project plan document elements.

TABLE D1—QAPP Groups and Elements^{a,b}

| GROUP | ID | ELEMENT | APPENDIX SECTION | MARLAP CHAPTER |
|---------------------------------|-----|---|------------------|----------------|
| A Project Management | A1 | Title and Approval Sheet | D2.1 | NA |
| | A2 | Table of Contents | D2.2 | NA |
| | A3 | Distribution List | D2.3 | NA |
| | A4 | Project/Task Organization | D2.4 | 2 |
| | A5 | Problem Definition/Background | D2.5 | 2 |
| | A6 | Project/Task Description | D2.6 | 2 |
| | A7 | Quality Objectives and Criteria for Measurement Data | D2.7 | 2, 3 |
| | A8 | Special Training Requirements/Certifications | D2.8 | 7 |
| | A9 | Documentation and Record | D2.9 | 7, 17 |
| B Measurement/Data Acquisition | B1 | Sampling Process Design | D3.1 | NA |
| | B2 | Sample Methods Requirements | D3.2 | NA |
| | B3 | Sample Handling and Custody Requirements | D3.3 | 11 |
| | B4 | Analytical Methods Requirements | D3.4 | 6 |
| | B5 | QC Requirements | D3.5 | 18 |
| | B6 | Instrument/Equipment Testing, Inspection and Maintenance Requirements | D3.6 | 15 |
| | B7 | Instrument Calibrations and Frequency | D3.7 | 18 |
| | B8 | Inspection/Acceptance Requirements for Supplies and Consumables | D3.8 | NA |
| | B9 | Data Acquisition Requirements (Non-direct Measurements) | D3.9 | 2 |
| | B10 | Data Management | D3.10 | 17 |
| C Assessment/Oversight | C1 | Assessments and Response Actions | D4.1 | 7 |
| | C2 | Reports to Management | D4.2 | 9 |
| D Data Validation and Usability | D1 | Verification and Validation Requirements | D5.1 | 8 |
| | D2 | Verification and Validation Methods | D5.2 | 8 |
| | D3 | Reconciliation with Data Quality Objectives | D5.3 | 9 |

(a) Based on EPA, 1998a.

(b) MARLAP recommends a graded approach to project plan documents. All elements may not be applicable, especially for a small project. See Chapter 4, Section 4.3, “A Graded Approach to Project Plan Documents” and Section 4.5.3, “Plan Content for Small Projects.”

This appendix also will discuss how the project plan document is linked to the outputs of the project planning process. Directed project planning is discussed in Chapter 2, *Project Planning Process*. The discussion of project plan documents in this appendix will use the DQO process

67 (EPA, 1994) as a model for directed planning (see Appendix B, *The Data Quality Objectives*
 68 *Process*). References will be made in this appendix to the steps of the DQO process, where
 69 appropriate, to illustrate the linkage between the direct planning process and plan documents.

70 It should be noted that although the project plan documents will address both sampling and
 71 analysis, MARLAP does not provide guidance on sampling design issues or sample collection.
 72 Discussion in D3.1, “Sample Process Design,” and D3.2, “Sample Methods Requirements,” are
 73 provided for completeness and consistency.

74 **D2.0 Group A: Project Management**

75 This group consists of nine elements that address project management issues such as organiza-
 76 tion of the plan itself, management systems, and a description of project goals, participants and
 77 activities. These elements ensure that the project goals are clearly stated, the approach to be used
 78 is understood, and the project planning decisions are documented.

TABLE D2—Comparison of Project Plan Contents
I. Example QAPP^a using EPA Guidance^b and EPA QAPP Elements^c

| QA PROJECT PLAN FOR RADIOLOGICAL MONITORING TABLE OF CONTENTS | EPA G-5 QA PROJECT PLAN ELEMENTS |
|---|---|
| Title Page Approval Sheet Distribution List | A1 Title and Approval Sheet A3 Distribution List |
| 1.0 Table of Contents | A2 Table of Contents |
| 2.0 Project Description 2.1 Site History 2.2 Project Objectives and Requirements 2.3 DQOs | A5 Problem Definition/Background A6 Project/Task Description |
| 3.0 Project Organization and Responsibility | A4 Project/Task Organization |
| 4.0 QA Objectives for Measurement Data (Precision, Accuracy, Representativeness, Comparability, Completeness) | A7 Quality Objectives and Criteria for Measurement Data |
| 5.0 Sampling Procedures, including QC [Cited Field Sampling and Analysis Plan] | B1 Sampling Process Designs B2 Sampling Methods Requirements |
| 6.0 Sample Custody 6.1 Sample 6.2 Sample Identification 6.3 COC Procedures | B3 Sample Handling and Custody Requirements |
| 7.0 Calibration Procedures and Frequency (Field and Laboratory) | B7 Instrument Calibration and Frequency |

Content of Project Plan Documents

| | QA PROJECT PLAN FOR RADIOLOGICAL MONITORING TABLE OF CONTENTS | EPA G-5 QA PROJECT PLAN ELEMENTS |
|-----|---|--|
| 103 | 8.0 Analytical Procedures | B4 Analytical Methods Requirements |
| 104 | 8.1 Background | |
| 105 | 8.2 Specific Analytical Procedures | |
| 106 | 8.3 Test Methods | B6 Instrument/Equipment Testing, Inspection, and Maintenance Requirements |
| 107 | 8.4 Control of Testing | |
| 108 | 8.5 Limits of Detection | |
| 109 | 9.0 Data Reduction, Validation and Reporting and Record | B10 Data Management D1 Data review, Validation, and Verification Requirements A9 Documentation and Records |
| 110 | | |
| 111 | 10.0 Internal QC Checks | B5 Quality Control Requirements |
| 112 | 11.0 Performance and Systems Audits | C1 Assessment and Response Actions |
| 113 | 11.1 Systems Audits | |
| 114 | 11.2 Surveillance | |
| 115 | 11.3 Performance Audits | |
| 116 | 11.4 Resolution of Discrepancies | |
| 117 | 11.5 Review of Contractor Procedures | |
| 118 | 12.0 Preventive Maintenance | B6 Instrument/Equipment Testing, Inspection, and Maintenance Requirements |
| 119 | 13.0 Specific Routine Procedures to Assess Data Precision, Accuracy, Completeness | D3 Reconciliation with DQOs |
| 120 | | |
| 121 | 14.0 Corrective Action | |
| 122 | 15.0 QA Report to Management | C2 Response to Management |
| 123 | 16.0 References | |
| | | A8 Special Training Requirements/Certification |
| | | B8 Inspection/Acceptance Requirements for Supplies and Consumables |
| | | B9 Data Acquisition Requirement for Non-direct Measurements |
| | | D2 Verification and Validation Methods |

II. Example Work Plan^d and EPA QA/G-5 QAPP Elements^c

| | Work Plan Table of Contents | EPA QAPP Elements |
|-----|---|----------------------------------|
| 125 | Cover Letter | A3 Distribution List |
| 126 | Title Page (including Document Number, Prepared by/Prepared for Identification) | A1 Title and Approval Sheet |
| 127 | Approvals | A1 Title and Approval Sheet |
| 128 | Table of Contents | A2 Table of Contents |
| 129 | 1 Introduction/Background | |
| 130 | Site and Regulatory Background | A5 Problem Definition/Background |
| 131 | | |
| 132 | | |

Content of Project Plan Documents

| Work Plan Table of Contents | EPA QAPP Elements |
|---|--|
| 133 Project Scope and Purpose | A6 Project/Task Description |
| 134 Project Organization and Management | A4 Project/Task Organization |
| 135 Data Quality Objectives and Approach | A7 Quality Objectives and Criteria for Measurement Data |
| 136 Environmental Setting | A5 Problem Definition/Background |
| 137 Sampling Site Selection, Locations and 138 Identification | B1 Sampling Process Design |
| 2 Sampling and Analysis Plan | |
| 139 Objective | B1 Sampling Process Design |
| 141 QA Objectives for Field Measurements, Laboratory 142 Measurements (including Calibration Procedures 143 and Frequency) | A7 Quality Objectives and Criteria for Measurement Data B7 Instrument Calibrations and Frequency |
| 144 Sample Collection Procedures | B2 Sample Methods Requirements |
| 145 Sample Identification, Handling and Transport | B3 Sample Handling and Custody Requirements |
| 146 Sample Analysis | B4 Analytical Methods Requirements |
| 147 Sample Tracking and Records | B10 Data Management |
| 148 Data Reduction, Validation and Reporting | D1 Data Review, Verification, and Validation Requirements D2 Verification and Validation Methods |
| 149 Internal QC Checks | B5 QC Requirements |
| 3 QA Project Plan | |
| 151 QA Training and Awareness | |
| 152 Performance and Systems Audits | C1 Assessments and Response Actions |
| 153 Preventive Maintenance | B6 Instrument/Equipment Testing, Inspection, and Maintenance Requirements |
| 154 Quality Improvement | B6 Instrument/Equipment Testing, Inspection, and Maintenance Requirements |
| 155 QA Reports to Management | C2 Reports to Management |
| 156 Purchase Items and Service Control | B8 Inspection/Acceptance Requirements for Supplies and Consumables |
| 157 4 Data and Records Management Plan 158 Objectives 159 Data Management 160 Document Control 161 Records Management System 162 Administrative Records | A9 Documentation and Record B10 Data Management |
| 163 5 Data Interpretation Plan 164 Approach for Data Evaluation 165 Data Interpretation and Comparisons | D3 Reconciliation with DQOs |
| 166 6 Risk Analysis Plan | — |
| 167 7 Health and Safety Plan | — |

Content of Project Plan Documents

| Work Plan Table of Contents | EPA QAPP Elements |
|-----------------------------|--|
| | B9 Data Acquisition Requirements (Non-direct Measurements) |
| | A8 Special Training Requirements/Certifications |

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(a) Plan elements adapted from DOE, 1997.

(b) EPA, 1980.

(c) EPA, 1998a

(d) Plan elements adapted from DOE, 1996.

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D2.1 Project Management (A1): Title and Approval Sheet

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The project title sheet should:

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- Clearly identify the project in an unambiguous manner;

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- Include references to organizational identifiers such as project numbers (when appropriate);

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- Clearly label and distinguish between draft and approved versions;

179

- Include the date of issuance of drafts or final approved version;

180

- Include revision or version numbers;

181

- Indicate if the document represents only a portion of the QAPP (e.g., Volume 1 of 4 Volumes);

182

183

- Include names of the organization(s) preparing the plan document and, if different, for whom the plan was prepared; and

184

185

- Identify clearly on the title page if the document is a controlled copy and subjected to no-copying requirements. If so, indicate the document control number.

186

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QAPPs should be reviewed on an established schedule. QAPPs should be kept current and revised when necessary. Documented approval, as an amendment to the QAPP, should be obtained for modifications to the QAPP.

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The approval sheet documents that the QAPP has been reviewed and approved prior to implementation. The approval sheet should consist of the name, title, organization, signature and signature date for:

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- 193 • The project manager or other person with overall responsibility for the project;
- 194 • The QA manager or other person with overall responsibility for the quality of the project
195 outputs;
- 196 • The project managers or QA managers for all organizations (e.g., sampling organization,
197 laboratories, data validators) implementing project activities; and
- 198 • The representative of any oversight or regulatory organization.

199 The project manager or other person with overall responsibility for the project should require an
200 approved QA program, management plan, or quality manual that supports all technical
201 operations, including data collection and assessment activities.

202 **D2.2 Project Management (A2): Table of Contents**

203 The table of contents should:

- 204 • List all sections and subsections of the document, references, glossaries, acronyms and
205 abbreviations, appendices (including sections and subsections) and the associated page
206 numbers;
- 207 • List all attachments and the associated page numbers;
- 208 • List all tables and associated page numbers;
- 209 • List all figures and diagrams and associated page numbers; and
- 210 • List titles of other volumes, if the QAPP consists of more than one volume.

211 A document control format is useful in maintaining reference to the latest version of the planned
212 document, especially when only portions of a document have been copied and are being used to
213 implement or discuss project activities.

214 **D2.3 Project Management (A3): Distribution List**

215 The distribution list should identify all individuals, along with their titles and organizations, who
216 will receive copies and revisions of the approved QAPP and subsequent revisions. Listed

217 individuals should include, at a minimum, all managers and QA personnel responsible for the
218 implementation and quality of the data collection activities. The project planning team or the core
219 group (see Chapter 2, Section 2.4) should be included on the document distribution list.

220 **D2.4 Project Management (A4): Project/Task Organization**

221 This QAPP element should:

222 • Identify the individuals and/or organizations participating in the project, as well as contact
223 information (address, telephone number, fax number, e-mail). The stakeholders, data users,
224 decision makers, and technical planning team members, and the person or organization that
225 will be responsible for project implementation, are identified during the directed planning
226 process (Appendix B, *The DQO Process*, Steps 1 and 7).

227 • Discuss the roles and responsibilities of the individuals and/or organizations that participate
228 in the data collection, including the roles and responsibilities of the data users, decision
229 makers, and QA manager.

230 • Include an organizational chart clearly showing the relationship, lines of authority and
231 communication, and mechanisms for information exchange among all project participants.

232 Complex projects may require more than one organizational chart to properly describe the
233 relationships among participants. At times, to clearly detail an organizations responsibilities and
234 communications, a general inter-organizational chart with primary contacts, responsibilities, and
235 communications may need to be accompanied by secondary charts that describe intra-
236 organizational contacts, responsibilities, and lines of communication.

237 One of the keys to successful projects is communication. The QAPP should identify the point of
238 contact for resolving field and laboratory problems. The QAPP may also summarize the points of
239 contact for dissemination of data to managers, users and the public.

240 **D2.5 Project Management (A5): Problem Definition/Background**

241 The “Problem Definition/Background” element (A5) and the subsequent elements “Project/Task
242 Description” (A6) and “Quality Objectives and Criteria” (A7) constitute the project description.
243 Separating the project description into three elements focuses and encourages the plan authors to
244 address all key issues (identification of problem to be solved, description of site history,
245 description of tasks and the quality objectives and data-acceptance criteria), some of which can

246 be overlooked if a larger, less-focused section is written. Table D3 provides bulleted components
 247 for these three elements. This section and sections D2.6 and D2.7 provide a more detailed
 248 discussion of these elements.

249 **TABLE D3—Content of the Three Elements that Constitute the Project Description**

| Problem Definition/Background (A5) | Project/Task Description (A6) | Objectives and Criteria (A7) |
|---|---|--|
| <ul style="list-style-type: none"> • Serves as an Introduction • Identifies the “problem to be solved” or the “question to be answered” • Identifies the regulatory, legal or “informational needs” drivers • Presents the historical perspective | <ul style="list-style-type: none"> • Describes measurements • Identifies regulatory standards and action levels • Identifies special personnel, procedural and equipment requirements • Summarizes assessment tools • Details schedule and milestones • Identifies record and report requirements | <p style="text-align: center;">Quality Objectives</p> <ul style="list-style-type: none"> • Problem definition/Site history • Data inputs • Population boundaries • Tolerable decision error rates <p style="text-align: center;">Criteria for Measurement Data</p> <ul style="list-style-type: none"> • Measurement quality objectives (MQOs; such as the measurement uncertainty at some concentration; the detection capability; the quantification capability; the range; the specificity; and the ruggedness of the method) |

263 The Problem Definition/Background element provides a discussion of the problem and pertinent
 264 background so that the implementation team can understand the context of the project. This
 265 section does not discuss the details of project activities, which are described in a subsequent
 266 project management element. Much of the information needed for this element was collected and
 267 discussed during Step 1 of the DQO process (Appendix B3.1). The decision statement was
 268 developed during Step 2 of the DQO process.

269 The “Problem Definition/Background” element should:

- 270 • Serve as an introduction to the project;
- 271 • Identify the “problem to be solved” or the “question to be answered” upon successful
272 completion of the project—the decision rule (Appendix B3.6);
- 273 • Discuss the assumptions, limitations, and scope of the project;
- 274 • Identify the regulatory, legal, or “informational needs” drivers that are the underlying reasons
275 for the project;
- 276 • Describe the context of the project so that it can be put into a historical perspective. This
277 section may include a description and maps of a facility or site, its location, its use, site
278 topography, geology and hydrogeology, past data collection activities, historical data
279 including analytes and concentrations, past and present regulatory status, past releases,
280 seriousness and potential risk of any release, site maps, and utilities; and
- 281 • If the data collection activity is in support of a technology evaluation, include a discussion of
282 the purpose of the demonstrations, how the technology works, operating conditions, required
283 utilities, effluents and waste by-products and residues, past and expected efficiencies and
284 multi-media mass-balances by analyte and matrix.

285 **D2.6 Project Management (A6): Project/Task Description**

286 This element of the QAPP provides a discussion of the project and underlying tasks for the
287 implementation teams. It should provide a description of the work to be performed to resolve the
288 problem or answer the question, including the following information:

- 289 • A description of the measurements and the associated QA/QC procedures that are to be made
290 during the course of the project. DQO Step 3 describes existing and needed data inputs, while
291 Step 7 yields the optimized sampling and analytical designs as well as quality criteria.
 - 292 – Identification of the analytes of interest.
 - 293 – A summary (preferably a table) of samples type (e.g., grab, spatial or temporal
294 composite), number of samples, analyte or analyte class (e.g., ⁹⁹Tc, transuranic, gamma
295 emitters) and analytical protocol specifications or method.
- 296 • A discussion of applicable regulatory standards or action levels to which measurements will
297 be compared. Identify any applicable regulatory standard (e.g., gross alpha drinking water
298 maximum contamination limit), or applicable or relevant and appropriate requirements

- 299 (ARARs) that will be used as a metric or action level during decision-making. The DQO Step
300 6 details action levels and tolerable decision errors that will be the basis for decisions.
- 301 • Identify any special requirements required to implement project tasks.
- 302 – Identify any special training (e.g., hazardous waste site health and safety training (29 CFR
303 1910.120), radiation safety training).
- 304 – Identify any special protective clothing and sampling equipment.
- 305 – Identify any boundary conditions (e.g., only sample after a rainfall of more than 1 inch).
- 306 – Specify any special document format, chain-of-custody, or archival procedures.
- 307 – Identify any special sample handling (e.g., freezing of tissue samples), instrumentation, or
308 non-routine analytical protocols that are required to achieve specified performance
309 criteria (e.g., very low detection limits) (see also Chapter 3, *Critical Analytical Planning*
310 *Issues and Developing Analytical Protocol Specifications*).
- 311 • Summarize the assessment tools that will be employed to determine whether measurement
312 data complied with performance criteria and are suitable to support decision-making. Include
313 a schedule of the assessment events. Assessment tools include performance evaluations,
314 program technical reviews, surveillance, technical and systems audits, and verification and
315 validation. Briefly outline:
- 316 – A first tier of reviews (e.g., when field or lab personnel check each other’s notes or
317 calculations).
- 318 – Reviews of the work, notes and calculations of subordinates by the supervisor (e.g.,
319 review and sign all notebook entries).
- 320 – The percentage of data subject to review by internal QA staff.
- 321 – Data verification and validation to be performed by an independent party and the
322 guidelines or plan to be used.
- 323 – Assessment of project activities to be conducted by personnel independent of project
324 activities (e.g., performance evaluation samples, surveillance, audits).
- 325 – Assessment of how results of the project will be reconciled with the project DQOs (“data
326 quality assessment”).
- 327 • Supply a schedule that includes start and completion dates for tasks and a list of completion
328 dates for important milestones. Dates can be calendric, or as number of days following
329 approval of the QAPP, or number of days following commencement of field operations.
330 DQO Steps 1 and 4 identify deadlines and other constraints that can impact scheduling.
- 331 • Identify the records and reports that will be required. This should be a brief but complete
332 listing of necessary reports and records (e.g., field and lab notebooks, sample logbooks,

333 spectra, sample tracking records, laboratory information system print-outs, QA reports,
334 corrective action reports).

- 335 • Identify whether the original documents are required or if photocopies are sufficient. More
336 detailed information will be presented in “Documentation and Records” (A9) and “Data
337 Management” (B10).

338 **D2.7 Project Management (A7): Quality Objectives and Criteria for Measurement Data**

339 This element addresses two closely related but different issues, quality objectives for the project
340 and criteria used to evaluate the quality of measurement data. The element summarizes outputs
341 from all steps of the DQO process. A fundamental principle underlying plan documents is that
342 requirements for the data quality must be specified by the project planning team and documented.
343 By clearly stating the intended use of the data and specifying qualitative and quantitative criteria
344 for system performance, a critical link between the needs of the project planning team and the
345 performance requirements to be placed on the laboratory data is established. (See Chapter 3 for a
346 discussion of MQOs.)

347 D2.7.1 Project’s Quality Objectives

348 The project’s quality objectives or data quality objectives (DQOs) are qualitative and quantitative
349 statements that:

- 350 • Clarify the intended use of the data (e.g., data will be used to determine if lagoon sediment
351 contains ²³²Th at concentrations greater than or equal to the action level);
- 352 • Define the type and quantity of data per matrix needed to support the decision (e.g., ²³²Th
353 concentrations in 300 composite sediments samples each composite consisting of 10 samples
354 randomly collected from a 100 m² sampling grid adjacent to the point of discharge);
- 355 • Identify the conditions under which the data should be collected (e.g., sediment samples
356 collected from the top 6 cm of sediment within a 100 m radius of the point of discharge into
357 lagoon #1, following de-watering of the lagoon and prior to sediment removal); and
- 358 • Specify tolerable limits on the probability of making a decision error due to uncertainty in the
359 data and any associated action levels (e.g., 95 percent confidence that the true concentration
360 is actually below the action level).

361 Authors of project plan documents are often encouraged to condense the DQO outputs in a
362 summary statement. This approach can have value as long as critical information is not lost in the
363 summary process and the original information is cited and available for all project participants.
364 The following is an example of a DQO summary statement:

365 “The purpose of this project is to determine, to within a lateral distance of 10 m, the extent of
366 ²³²Th in soil along a pipeline at concentrations at or above 1,145 mBq/g, with a false positive
367 rate less than or equal to 5 percent; and to define within 1 m the vertical extent of measured
368 ²³²Th concentrations greater than 7,400 mBq/g.”

369 D2.7.2 Specifying Measurement Quality Objectives

370 Measurement quality objectives (MQOs) or measurements performance criteria are essential to
371 the success of a project since they establish the necessary quality of the data. The quality of data
372 can vary as a result of the occurrence and magnitude of three different types of errors (Taylor,
373 1990).

- 374 • BLUNDERS—mistakes that occur on occasion and produce erroneous results (e.g., mis-
375 labeling or transcription errors);
- 376 • SYSTEMATIC ERRORS—mistakes that are always the same sign and magnitude and produce
377 bias (i.e., they are constant no matter how many measurements are made); and
- 378 • RANDOM ERRORS—mistakes that vary in sign and magnitude and are unpredictable on an
379 individual basis (i.e., random differences between repetitive readings) but will average out if
380 enough measurements are taken.

381 The frequent occurrence of these types of errors is the reason why data quality is subject to
382 question, why there is uncertainty when using data to make decisions and why measurement
383 performance criteria are necessary.

384 During the DQO process, project DQOs are used to establish the MQOs. An MQO is a statement
385 of a performance objective or requirement for a particular method performance characteristic.
386 Examples of method performance characteristics include the measurement uncertainty at some
387 concentration; the detection capability; the quantification capability; the range; the specificity;
388 and the ruggedness of the method. MQOs for the project should be identified and described
389 within this element of the QAPP. MARLAP provides guidance for developing MQOs for select
390 method performance characteristics in Chapter 3 and Appendix C.

391 D2.7.3 Relation between the Project DQOs, MQOs, and QC Requirements

392 The ultimate goal of all data collection operations is the collection of appropriately accurate data.
393 Appropriately accurate data are data for which errors caused by imprecision and bias are
394 controlled such that it is suitable for use in the context outlined by the DQOs (i.e., the overall
395 error is less than that specified in the acceptable decision error). During the optimization of
396 design in the planning process, DQO-specified decision error rates are translated into MQOs with
397 the intention of monitoring, detecting, quantifying and controlling imprecision and analytical
398 bias. During optimization, precautions are also incorporated into the design with the intention of
399 preventing blunders and types of non-measurable bias not susceptible to measurement by QC
400 samples.

401 The MQOs provide acceptance or rejection criteria for the quality control samples whose types
402 and frequency are discussed in the Quality Control Requirements element (B5) (Appendix C).
403 QC samples and the project's associated MQOs are key—but not the sole mechanisms—for
404 monitoring the achievement of DQOs.

405 In summary, translating acceptable decision error rates into a design that will produce data of
406 appropriate precision and bias is often a complex undertaking. The team must consider the
407 synergistic and antagonistic interactions of the different options for managing errors and
408 uncertainty. Accurate data require not only control of imprecision, but must also control the
409 various forms of bias.

410 **D2.8 Project Management (A8): Special Training Requirements/Certification**

411 All project personnel should be qualified and experienced in their assigned task(s). The purpose
412 of this element is to add additional information regarding special training requirements and how
413 they will be managed during implementation of the project. This element should:

- 414 • Identify and describe any mandated or specialized training or certifications that are required;
- 415 • Indicate if training records or certificates are included in the QAPP as attachments;
- 416 • Explain how training will be implemented and certifications obtained; and
- 417 • Identify how training documentation and certification records will be maintained.

418 **D2.9 Project Management (A9): Documentation and Record**

419 This element of the QAPP will identify which records are critical to the project, from data
420 generation in the field to final use. It should include what information needs to be contained in

421 these records and reports, the formats of the records and reports, and a brief description of
422 document control procedures. The following are suggested records and content:

- 423 • SAMPLE COLLECTION RECORDS should include sampling procedures, the names of the persons
424 conducting the activity, sample number, sample collection points, maps and diagrams,
425 equipment/protocol used, climatic conditions, and unusual observations. Bound field
426 notebooks, pre-printed forms, or computerized notebooks can serve as the recording media.
427 Bound field notebooks are generally used to record raw data and make references to
428 prescribed procedures, changes in planned activities and implementation of corrective
429 actions. Preferably, notebooks will contain pre-numbered pages with date and signature lines
430 and entries will be made in ink. Field QC issues such as field, trip, and equipment rinsate
431 blanks, co-located samples, field-spiked samples, and sample preservation should be
432 documented. Telephone logbooks and air bill records should be maintained.

- 433 • SAMPLE TRACKING RECORDS document the progression of samples as they travel from the
434 original sampling location to the laboratory and finally to their disposal or archival. These
435 records should contain sample identification, the project name, signatures of the sample
436 collector, the laboratory custodian and other custodians, and the date and time of receipt. The
437 records should document any sample anomalies. If chain-of-custody (COC) is required for
438 the project, the procedures and requirements should be outlined (Chapter 11, *Sample Receipt,*
439 *Inspection and Tracking*).

- 440 • ANALYTICAL QC issues that should be documented include standard traceability, and
441 frequency and results of QC samples, such as, method and instrument blanks, spiked
442 samples, replicates, calibration check standards and detection limit studies.

- 443 • ANALYTICAL RECORDS should include standard operating procedures for sample receipt,
444 preparation, analysis and report generation. Data report formats and the level of supporting
445 information is determined by data use and data assessment needs.

- 446 • PROJECT ASSESSMENT RECORDS should include audit check lists and reports, performance
447 evaluation (PE) sample results, data verification and validation reports, corrective action
448 reports. The project may want to maintain copies of the laboratory proposal package, pre-
449 award documentation, initial precision and bias test of the analytical protocol and any
450 corrective action reports.

451 The QAPP should indicate who is responsible for creating, tracking, and maintaining these
452 records and when records can be discarded, as well as any special requirements for computer,
453 microfiche, and paper records.

454 **D3.0 Group B: Measurement/Data Acquisition**

455 The Measurement/Data Acquisition group consists of 10 elements that address the actual data
456 collection activities related to sampling, sample handling, sample analysis and the generation of
457 data reports. Although these issues may have been previously considered by project management
458 elements, the project management section of the QAPP dealt with the overall perspective. The
459 measurement/data section contains the details covering design and implementation to ensure that
460 appropriate protocols are employed and documented. This section also addresses quality control
461 activities that will be performed during each phase of data collection from sampling to data
462 reporting.

463 **D3.1 Measurement/Data Acquisition (B1): Sampling Process Design**

464 This element of the QAPP describes the finalized sampling design that will be used to collect
465 samples in support of project objectives. The design should describe the matrices to be sampled,
466 where the samples will be taken, the number of samples to be taken, and the sampling frequency.
467 A map of the sampling locations should be included to provide unequivocal sample location
468 determination and documentation.

469 If a separate sampling and analysis plan or a field sampling and analysis plan has been
470 developed, it can be included by citation or as an appendix. This element will not address the
471 details of standard operating procedures for sample collection, which will be covered in
472 subsequent elements. This element will describe the sampling design and the underlying logic, so
473 that implementation teams can understand the rationale behind and better implement the
474 sampling effort. Understanding the rationale for the decisions will help if plans have to be
475 modified due to conditions in the field. DQO Step 7 establishes the rationale for and the details
476 of the sampling design.

477 This element should restate the outputs of the planning process and any other considerations and
478 assumptions that impacted the design of the sampling plan, such as:

- 479 • The number of samples, including QC samples, sample locations and schedule, and rationale
480 for the number and location of samples;

- 481 • A brief discussion of how the sampling design will facilitate the achievement of project
482 objectives;
- 483 • A discussion of the population boundaries (temporal and spatial) and any accessibility
484 limitations;
- 485 • A description of how the sampling design accommodates potential problems caused by the
486 physical properties of the material being sampled (e.g., large particle size), the characteristic
487 of concern (e.g., potential losses due to the volatility of tritium) or heterogeneity;
- 488 • A discussion of the overarching approach to sampling design (e.g., worse case or best case
489 sampling versus average value) and assumptions made in selecting this approach (e.g., an
490 assumption that the darkened soil adjacent to the leaking tank would present a worse case
491 estimate of soil contamination);
- 492 • A listing of guidance and references that were relied upon when designing the sampling plan;
- 493 • Identification of the characteristics of interest (e.g., ⁹⁹Tc activity), associated statistical
494 parameters (e.g., mean, standard deviations, 99th percentile), and acceptable false error rates
495 (e.g., false negative rate of less than 5%);
- 496 • Identification of relevant action level and how data will be compared to the action level
497 (Appendix B3.2);
- 498 • A discussion of the anticipated range of the characteristic of interest and assumed temporal
499 and spatial variations (heterogeneity), anticipated variance, anticipated sources and
500 magnitude of error (e.g., heterogeneity of material being sampled, sampling imprecision,
501 analytical imprecision), anticipated mean values and distribution of measurements and the
502 basis (e.g., historical data, similar processes or sites) for any associated assumptions;
- 503 • If any level of bias is assumed, what is the assumed magnitude and the basis of the
504 assumption (e.g., historical data, typical analytical bias for matrix type);
- 505 • It is usually assumed that the magnitude of measurements made at individual sampling
506 locations are independent of each other (e.g., no correlation of concentration with location).
507 Geostatistical approaches may be more appropriate if measurements are significantly
508 correlated with locations (e.g., serial-correlation, auto-correlation) since serial-correlation can

509 bias estimates of variance and invalidate traditional probabilistic techniques such as
510 hypothesis testing; and

- 511 • A discussion of the rationale for choosing non-routine sampling protocols and why these non-
512 routine protocols are expected to produce acceptable precision and bias.

513 **D3.2 Measurement/Data Acquisition (B2): Sampling Methods Requirements**

514 This element of the QAPP describes the detailed sampling procedures that will be employed
515 during the project. The preliminary details of sampling methods to be employed were established
516 during Step 7 of the DQO process. The selected sampling procedures should be appropriate to (1)
517 ensure that a representative sample is collected, (2) avoid the introduction of contamination
518 during collection, and (3) properly preserve the sample to meet project objectives. Written SOPs
519 should be included as attachments to the QAPP. This element and the appendices or other
520 documents that it references should in total contain all the project specific details needed to
521 successfully implement the sampling effort as planned. If documents to be cited in the QAPP are
522 not readily available to all project participants, they must be incorporated as appendices. All
523 sampling personnel should sign that they have read the sampling procedures and the health and
524 safety procedures.

525 Correct sampling procedures and equipment used in conjunction with a correct sampling design
526 should result in a collection of samples that in total will represent the population of interest. A
527 detailed discussion of sampling procedures, equipment and design are beyond the scope of
528 MARLAP. In general, the selected procedures must be designed to ensure that the equipment is
529 used properly and that the collected samples represent the individual sampling unit from which
530 samples are collected. The sampling equipment should be chemically and physically compatible
531 with the analyte of concern as well as the sample matrix. The sampling design should facilitate
532 access to individual sampling units, result in an appropriate mass/volume of sample such that it
533 meets or exceeds minimum analytical sample sizes, accommodates short-range heterogeneity
534 (*i.e.*, does not preclude large particle sizes or lose small particles) and reduce or prevent loss of
535 volatile components, if appropriate.

536 This element of the QAPP should:

- 537 • Identify the sampling methods to be used for each matrix, including the method number if a
538 standardized method. If methods are to be implemented differently than specified by the
539 standard method or if the standard method offers alternatives for implementation, the
540 differences and alternatives should be specified;

- 541 • Identify the performance requirements of the sampling method. If the sampling method of
542 choice is unlikely to be able to achieve the level of performance demanded by the project
543 DQO, the project planning team should be notified;
- 544 • Identify the required field QC samples (e.g., trip blank, co-located duplicate);
- 545 • Identify any sample equipment preparation (e.g., sharpening of cutting edges, degreasing and
546 cleaning) or site preparation (e.g., removal of overburden, establishing dust-free work space
547 for filtering) for each method;
- 548 • Identify and preferably generate a list of equipment and supplies needed. For example, the
549 sampling devices, decontamination equipment, sampling containers, consumables (e.g., paper
550 towels), chain-of-custody seals and forms, shipping materials (e.g., bubble-pack, tape), safety
551 equipment and paper work (e.g., pens, field books);
- 552 • Identify and detail logistical procedures for deployment, sample shipment and demobili-
553 zation. If a mobile lab will be used, explain its role and the procedures for sample flow to the
554 mobile lab and data flow to the data-user;
- 555 • Identify, preferably in a tabular form, sample container types, sizes, preservatives, and
556 holding times;
- 557 • Identify procedures that address and correct problems encountered in the field (variances and
558 nonconformance to the established sampling procedures);
- 559 • Identify for each sampling method, decontamination procedures and the procedures for
560 disposing of contaminated equipment and used-decontamination chemicals and waters;
- 561 • Identify the disposal procedures for waste residuals generated during the sampling process
562 (e.g., purged well waters, drilling dregs) for each method; and
- 563 • Identify oversight procedures (e.g., audits, supervisor review) that ensure that sampling
564 procedures are implemented properly. The person responsible for implementing corrective
565 actions should be identified.

566 **D3.3 Measurement/Data Acquisition (B3): Sample Handling and Custody Requirements**

567 This element of the QAPP details how sample integrity will be maintained and how the sample
568 history and its custody will be documented ensuring that (1) samples are collected, transferred,
569 stored, and analyzed by authorized personnel, (2) the physical, chemical and legal integrity of
570 samples is maintained, and (3) an accurate written record of the history of custody is maintained.
571 DQO Step 1 describes the regulatory situation which can be used to identify the appropriate level
572 of sample tracking. The QAPP should state whether COC is required. Sample handling, tracking
573 and COC requirements are discussed in detail in Chapter 11, *Sample Receipt and Tracking*.

574 In the QAPP, the following elements should be documented:

- 575 • **INTEGRITY OF SAMPLE CONTAINERS:** Describe records to be maintained on the integrity of
576 sample container and shipping container seals upon receipt. Describe records to be
577 maintained if specially prepared or pre-cleaned containers are required.

- 578 • **SECURITY:** If wells are being sampled, whether the wellheads were locked or unlocked should
579 be noted. Security of remote sampling sites or automatic samplers not maintained in locked
580 cages should be discussed.

- 581 • **SAMPLE IDENTIFICATION:** The assignment of sample numbers and the labeling of sample
582 containers is explained. If samples are to be assigned coded sample identifications (IDs) to
583 preclude the possibility of bias during analysis, the sample code is one of the few items that
584 will not be included in the QAPP, since the lab will receive a copy. The code and sample ID
585 assignment process will have to be described in a separate document, which is made available
586 to the field team and the data validators. An example of a sample label should be included in
587 the QAPP.

- 588 • **TRACKING OR CUSTODY IN THE FIELD:** Procedures for sample tracking or custody while in the
589 field and during sample shipment should be described. When COC is required, a copy of the
590 COC form and directions for completion should be included. A list of all materials needed
591 for tracking or custody procedures should be provided (e.g., bound notebooks, shipping
592 containers, shipping labels, tape, custody seals, COC forms).

- 593 • **SAMPLE PRESERVATION:** Sample preservation procedures, if desired, should be clearly
594 described. Preservation of radiological samples is discussed in Chapter 10, *Requirements*
595 *When Collecting, Preserving, and Shipping Samples That Require Analytical Measurement*.

- 596 • TRACKING OR CUSTODY IN THE LABORATORY: A decision must be made as to whether the
597 laboratory in general is considered a secure area such that further security is not required once
598 the sample is officially received by the laboratory or whether internal tracking or custody
599 procedures will be required as the samples are handled by different personnel within the lab.
600 The laboratory's sample receipt SOP, laboratory security procedures, and—if needed—
601 internal tracking or custody procedures should be described.

- 602 • SPECIAL REQUIREMENT: Any special requirements, such as shipping of flammable or toxic
603 samples, or requirements for verification of sample preservation upon sample receipt by the
604 laboratory should be clearly described.

- 605 • ARCHIVAL: Document the rationale for the request to archive samples, extracts, and
606 digestates. Describe how samples, extracts, and digestates will be archived. Identify how long
607 samples, extracts, digestates, reports, and supporting documentation must be maintained.

608 **D3.4 Measurement/Data Acquisition (B4): Analytical Methods Requirements**

609 This element of the QAPP should identify the Analytical Protocol Specifications (APSS)
610 including the MQOs that were employed by the laboratory to select the analytical protocols. (See
611 Chapter 3 for guidance on developing APs.) This element integrates decisions from three DQO
612 steps: Step 3 which identified the analyte of interest and needed inputs to the decision, Step 6
613 which identifies the allowable uncertainty, and Step 7 which identifies the optimized analytical
614 design. Input from all three steps drive the choice of analytical protocols. The discussion of the
615 selected analytical protocols should address: subsampling, sample preparation, sample clean-up,
616 radiochemical separations, the measurement system, confirmatory analyses and pertinent data
617 calculation and reporting issues. A tabular summary of the analytical protocol by matrix type can
618 facilitate reference for both the plan document development team and the laboratory analytical
619 team.

620 This element of the QAPP should clearly describe the expected sample matrices (e.g.,
621 groundwater with no sediments, soils with no rocks larger than 2 cm in diameter) and what
622 should be done or who should be contacted if sample matrices are different than expected.
623 Subsampling is a key link in the analytical process which is often overlooked during planning
624 leaving important decisions to laboratory staff, this element should specify appropriate
625 subsampling procedures.

626 This QAPP element should:

Content of Project Plan Documents

- 627 • Identify the laboratories supplying analytical support. If more than one laboratory will be
628 used, detail the analyses supplied by each laboratory;
- 629 • Identify analyses to be performed in the field using portable equipment or by a mobile lab;
- 630 • Identify the sample preparation techniques. Non-routine preparatory protocols, such as novel
631 radiochemical separations, should be described in detail and documented in an SOP including
632 pertinent literature citations and the results of validations studies and other performance data,
633 when they exist;
- 634 • Identify the analytical protocols to be used. The protocol documentation should describe all
635 necessary steps including the necessary reagents, apparatus and equipment, standards
636 preparation, calibration, sample introduction, data calculation, quality control, interferences,
637 and waste disposal;
- 638 • If the selected analytical protocols have not been demonstrated for the intended application,
639 the QAPP should include information about the intended procedure, how it will be validated,
640 and what criteria must be met before it is accepted for the project's application (Chapter 6,
641 *Selection and Application of an Analytical Protocol*);
- 642 • If potential analytical protocols were not identified during the project planning process and
643 existing analytical protocols can not meet the MQOs, an analytical protocol will have to be
644 developed and validated (Chapter 6, Section 6.5, "Method Validation"). If this issue was not
645 identified by the project planning team, the project planning team must be contacted because
646 the original project objectives and the associated MQOs may have to be revisited and
647 changed (Appendix B);
- 648 • If both high concentration and low concentration samples are expected, discuss how the two
649 sample types will be identified and handled in a manner that will prevent cross-contamination
650 or other analytical problems;
- 651 • Discuss reporting requirements (e.g., suitable data acquisition and print-outs or electronic
652 data archival that will capture all necessary information), the proper units (dry weight versus
653 wet weight), the method to be employed to report the final result and its uncertainty, and
654 reporting package format requirements; and
- 655 • Identify oversight procedures (e.g., QC samples, audits, supervisor review) for ensuring that
656 analytical procedures are implemented properly and procedures for correcting problems

657 encountered in the laboratory. The person responsible for implementing corrective actions in
658 the lab should be identified.

659 The project plan document should be a dynamic document, used and updated over the life of the
660 project as information becomes available or changes. For example, under a performance based
661 approach, the analytical protocols requirements in the project plan documents should initially
662 reflect the Analytical Protocol Specifications established by the project planning team and issued
663 in the statement of work (or task order). When the analytical laboratory has been selected
664 (Appendix E, *Contracting Analytical Services*) the project plan document should be updated to
665 reflect the identification of the selected laboratory and the analytical protocols, that is, the actual
666 analytical protocols to be used should be included by citation or inclusion of the SOPs as
667 appendices.

668 **D3.5 Measurement/Data Acquisition (B5): Quality Control Requirements**

669 This element of the QAPP should include enough detail that the use and evaluation of QC
670 sample results and corrective actions will be performed as planned and support project activities.
671 The QC acceptance limits and the required corrective actions for non-conformances should be
672 described. DQO Step 7 identified the optimized analytical design and the desired MQOs which
673 will help determine the QC acceptance criteria. Refer to Chapter 19.8.1 for information on
674 control charts and Chapter 18, *Quality Assurance and Quality Control*, for a detailed discussion
675 of radioassay QC and quality indicators. A discussion of QC requirements in the QAPP should
676 include the following information:

- 677 • A list of all QC sample types by matrix;
- 678 • The frequency of QC sample collection or analysis, preferably a tabular listing;
- 679 • A list of QC sample acceptance criteria or warning limits and control limits;
- 680 • Procedures for documenting QC sample results;
- 681 • Equations and calculations used to evaluate QC sample results and to determine measurement
682 performance acceptability;
- 683 • Actions to be taken if QC samples fail to meet the acceptance criteria; and
- 684 • Identification of the appropriate responsible person to whom QC reports should be sent.

685 Acceptance criteria for QC samples should be based on the project MQOs, in particular the MQO
686 for measurement uncertainty at some concentration. Appendix C provides guidance on
687 developing acceptance criteria for QC samples based on the project's MQO for the method's
688 measurement uncertainty at some concentration, typically the action level.

689 **D3.6 Measurement/Data Acquisition (B6): Instrument/Equipment Testing, Inspection,**
690 **and Maintenance Requirements**

691 The QAPP should include a discussion of testing, inspection and maintenance requirements that
692 will be followed to ensure that equipment and instrumentation will be in working order during
693 implementation of project activities. An instrument or testing equipment will be deemed to be in
694 working order if it is maintained according to protocol and it has been inspected and tested and
695 meets acceptance criteria.

696 This element of the QAPP should:

- 697 • Discuss the maintenance policy for all essential instrumentation and equipment, what it
698 involves, its frequency, whether it is performed by internal staff or if it is a contracted service,
699 and whether an inventory of spare parts is maintained;
- 700 • Describe the inspection protocols for instrumentation and equipment. This ranges from the
701 routine inspections (i.e., gases, nebulizers, syringes and tubing) prior to instrument or
702 equipment use and more detailed inspections employed while troubleshooting an instrument
703 or equipment problem. Mandatory inspection hold points, beyond which work may not
704 proceed, should be identified; and
- 705 • Address the frequency and details of equipment and instrument testing. This may involve the
706 weighing of volumes to test automatic diluters or pipets, the use of a standard weight prior to
707 weighing sample aliquots to the use of standards to test sophisticated instrumentation. If
708 standards (e.g., National Institute of Standards and Technology [NIST] standard reference
709 material [SRM]) are used during testing, the type, source and uncertainty of standard should
710 be identified.

711 There is not always a clear distinction between the testing component of this element and the
712 previous element addressing the use of QC samples to determine whether an instrument is within
713 control. In any case, it is important to describe in either of these elements of the QAPP, all

714 procedures that are deemed important to determining whether an instrument/equipment is in
715 working order and within control.

716 **D3.7 Measurement/Data Acquisition (B7): Instrument Calibration and Frequency**

717 This element of the QAPP details the calibration procedures including standards, frequencies,
718 evaluation, corrective action measures and documentation. Summary tables may be used to
719 complement the more detailed discussions in the text. The following issues should be addressed
720 in this element:

- 721 • Identify all tools, gauges, sampling devices, instruments, and test equipment that require
722 calibration to maintain acceptable performance;
- 723 • Describe the calibration procedures in enough detail in this element or by citation to readily
724 available references so that the calibration can be performed as intended;
- 725 • Identify reference equipment (e.g., NIST thermometers) and standards, their sources, and how
726 they are traceable to national standards. Where national standards are not available, describe
727 the procedures used to document the acceptability of the calibration standard used;
- 728 • Identify the frequency of calibration and any conditions (e.g., failed continuing calibration
729 standard, power failure) that may be cause for unscheduled calibration;
- 730 • Identify the procedure and the acceptance criteria (i.e., in control) to be used to evaluate the
731 calibration data;
- 732 • Identify the corrective actions to be taken if the calibration is not in control. When calibration
733 is out of control, describe the evaluations to be made to determine the validity and
734 acceptability of measurements performed since the last calibration; and
- 735 • Identify how calibration data will be documented, archived and traceable to the correct
736 instrument/equipment.

737 See Chapter 16, *Instrument Calibration and Test Source Preparation*, for a discussion of
738 radiochemical instrument calibration.

739 **D3.8 Measurement/Data Acquisition (B8): Inspection/Acceptance Requirements for**
740 **Supplies and Consumables**

741 This element of the QAPP deals with inspecting and accepting all supplies and consumables that
742 may directly or indirectly affect the quality of the data. For some projects, this information may
743 be provided by citation to a chemical safety and hygiene plan. The contents of this element
744 should contain enough supportive information that the project and the data will be sufficient to
745 undergo solicited and unsolicited reviews. The following detail should be included in this
746 element, so the inspection process can be accurately implemented:

- 747 • Identify and document all supplies and consumables (e.g., acids, solvents, preservatives,
748 containers, reagents, standards) that have the potential of directly or indirectly impacting the
749 quality of the data collection activity;
- 750 • Identify the significant criteria that should be used when choosing supplies and consumables
751 (e.g., grade, purity, activity, concentration, certification);
- 752 • Describe the inspection and acceptance procedures that will be used for supplies or
753 consumables, including who is responsible for inspection, the timing of inspections and the
754 acceptance and rejection criteria. This description should be complete enough to allow
755 replication of the inspection process. Standards for receiving radiological packages are
756 provided in 10 CFR 20 Section 20.1906 “Procedures for Receiving and Opening Packages”
757 or an Agreement State equivalent;
- 758 • Describe the procedures for checking the accuracy of newly purchased standards, other than
759 SRMs, by comparison to other standards purchased from other sources;
- 760 • Identify any special handling and storage (e.g., refrigerated, in the dark, separate from high
761 concentration standards, lead shielding) conditions that must be maintained;
- 762 • Describe the method of labeling, dating and tracking supplies and consumables and the
763 disposal method for when their useful life has expired; and
- 764 • Describe the procedures and indicate by job function who is responsible for documenting the
765 inspection process and the status of inventories.

766 **D3.9 Measurement/Data Acquisition (B9): Data Acquisition Requirements for Non-Direct**
767 **Measurement Data**

768 This element of the QAPP addresses the use of existing data. Non-direct measurement data is
769 defined as existing data that is independent of the data generated by the current project's
770 sampling and analytical activities. Non-direct data may be of the same type (e.g., mBq/g of ²³²Th
771 in soil) that will complement the data being collected during the project. Other non-direct data
772 may be of a different type such as weather information from the National Weather Service, or
773 geological and hydrogeological data from the U.S. Geological Survey.

774
775 To achieve project objectives it is important that the data obtained from non-direct sources be
776 subjected to scrutiny prior to acceptance and use. Use of existing data is discussed during Step 1
777 and 3 of the DQO process. If existing data of the same type is to be used to achieve project
778 objectives, it has to be evaluated in terms of its ability to comply with MQOs established in DQO
779 Step 7. The limitations on the use of non-direct measurements should be established by the
780 project planning team.

781 This element should:

- 782 • Identify the type and source of all non-direct data that will be needed to achieve the project
783 objectives;
- 784 • State whether the same quality criteria and QC sample criteria will be applied to the non-
785 direct measurement data. If the same criteria cannot be applied, then identify criteria that will
786 be acceptable for the non-direct data but at the same time won't bias or significantly add to
787 the uncertainty of decisions for the project;
- 788 • Identify whether the data will support qualitative decisions (e.g., rain occurred on the third
789 day of sampling) or if the data will be used quantitatively (e.g., used to calculate a mean
790 concentration that will be compared to an action level);
- 791 • Identify whether enough information exists to evaluate the quality of the non-direct data (e.g.,
792 spike and collocated sample data, minimum detectable concentrations, reported measurement
793 uncertainties); and
- 794 • If the non-direct data are to be combined with project-collected data, identify the criteria that
795 will be used to determine if the non-direct data are comparable (e.g., sampled the same
796 population, same protocol).

797 **D3.10 Measurement/Data Acquisition (B10): Data Management**

798 This element of the QAPP should present an overview of the data management process from the
799 receipt of raw data to data storage. The overview should address all interim steps, such as, data
800 transformations, transmittals, calculations, verifications, validations and data quality assess-
801 ments. The procedures should address how internal checks for errors are made. Laboratories
802 should follow accepted data management practices (EPA, 1995). Applicable SOPs should be
803 included as attachments to the QAPP. (See Chapter 17, *Data Generation, Reduction and*
804 *Reporting* for a discussion of radiochemical data generation and reduction.)

805 The discussion of data management should address the following issues:

- 806 • **DATA RECORDING:** The process of the initial data recording steps (e.g., field notebooks,
807 instrument printouts, electronic data storage of alpha and gamma spectra) should be
808 described. Examples of unique forms or procedures should be described. Describe the
809 procedures to be used to record final results (e.g., negative counts) and the uncertainty.

- 810 • **CONVERSIONS AND TRANSFORMATIONS:** All data conversions (e.g., dry weight to wet weight),
811 transformations (conversion to logs to facilitate data analysis) and calculation of statistical
812 parameters (e.g., uncertainties) should be described, including equations and the rationale for
813 the conversions, transformations and calculations. Computer manipulation of data should be
814 specified (e.g., software package, macros).

- 815 • **DATA TRANSMITTALS:** Data transmittals occur when data are sent to another location or
816 person or when it is converted to another format (incorporated into a spreadsheet) or media
817 (hardcopy reports keyed into a computer database). All transmittals and associated QA/QC
818 steps taken to minimize transcription errors should be described in enough detail to ensure
819 their proper implementation.

- 820 • **DATA REDUCTIONS:** Identify and explain the reasons for data reductions. Data reduction is the
821 process of changing the number of data items by arithmetic or statistical calculations,
822 standard curves, or concentration factors. A laboratory information management system may
823 use a dilution factor or concentration factor to change raw data. These changes often are
824 irreversible and in the process the original data are lost.

- 825 • DATA VERIFICATION, VALIDATION AND ASSESSMENTS: Since these assessment issues are
826 discussed in a subsequent element of the QAPP (D2), only an overview should be provided
827 identify the timing and frequency of these assessments.

- 828 • DATA TRACKING, STORAGE AND RETRIEVAL: Describe the system for tracking and compiling
829 data as samples are being analyzed, how data are stored, and the mechanism for retrieving
830 data (e.g., from archived back-up tapes or disks).

- 831 • SECURITY: Describe procedures for data and computer security.

832 **D4.0 Group C: Assessment/Oversight**

833 The elements of this group are intended to assess progress during the project, facilitate corrective
834 actions in a timely manner (Section D4.1), and provide reports to management (Section D4.2). It
835 should be stressed that early detection of problems and weaknesses—before project commence-
836 ment or soon thereafter—and initiation of corrective actions are important for a project’s success.
837 The focus of the elements in this group is the implementation of the project as defined in the
838 QAPP. This group is different from the subsequent group, data validation and usability, which
839 will assesses project data after the data collection activity is complete.

840 **D4.1 Assessment/Oversight (C1): Assessment and Response Actions**

841 The QAPP authors have a range of assessment choices that can be employed to evaluate on-going
842 project activities, which include surveillance, peer review, systems reviews, technical systems
843 audits (of field and laboratory operations), and performance evaluations. A detailed discussion of
844 laboratory evaluation is presented in Chapter 7, *Evaluating Radiological Laboratories*. It is
845 important to schedule assessments in a timely manner. An assessment has less value if its
846 findings become available after completion of the activity. The goal is to uncover problems and
847 weaknesses before project commencement or soon thereafter and initiate corrective actions so the
848 project is a success.

849 This element of the QAPP should:

- 850 • Identify all assessments by type, frequency and schedule;
- 851 • Identify the personnel who will implement the assessments;
- 852 • Identify the criteria, documents, and plans upon which assessments will base their review;
- 853 • Describe the format of assessment reports;
- 854 • Identify the time frame for providing the corrective action plan; and

- 855 • Identify who is responsible for approving corrective actions and ensuring that they are
856 implemented.

857 **D4.2 Assessment/Oversight (C2): Reports To Management**

858 Reports to management are a mechanism for focusing management’s attention on project quality
859 and on project issues that may require the management’s level of authority. To be effective
860 reports to management and management’s review and response must be timely. The benefit of
861 these status reports is the opportunity to alert management of data quality problems, propose
862 viable solutions and procure additional resources.

863 At the end of the project, a final project report which includes the documentation of the DQA
864 findings should be prepared (Chapter 9, *Data Quality Assessment*). It may also be beneficial for
865 future planning efforts for the project planning team to provide a summary of the “lesson
866 learned” during the project, such as key issues not addressed during planning and discovered in
867 implementation or assessment, specialist expertise needed on the planning team, experience with
868 implementing performance-based analytical protocol selection.

869 This element of the QAPP should address the following issues:

- 870 • Identify the various project reports that will be sent to management;
- 871 • Identify non-project reports that may discuss issues pertinent to the project (e.g., backlog
872 reports);
- 873 • Identify QA reports that provide documentary evidence of quality (e.g., results of independent
874 performance testing, routine QC monitoring of system performance);
- 875 • Identify the content of “reports to management” (e.g., project status, deviations from the
876 QAPP and approved amendments, results of assessments, problems, suggested corrective
877 actions, status on past corrective actions);
- 878 • Identify the frequency and schedule for reports to management;
- 879 • Identify the organization or personnel who are responsible for authoring reports; and
- 880 • Identify the management personnel who will receive and act upon the assessment reports.

881 **D5.0 Group D: Data Validation and Usability**

882 This group of elements ensures that individual data elements conform to the project specific
883 criteria. This section of the QAPP discusses data verification, data validation and data quality
884 assessment (DQA), three processes employed to accept, reject or qualify data in an objective and
885 consistent manner. Although there is good agreement as to the range of issues that the three
886 elements, in total, should address, within the environmental community there are significant
887 differences as to how verification, validation and DQA are defined. The discussion of this group
888 of elements will use the definitions which are defined Chapter 8, *Radiochemical Data*
889 *Verification and Validation*.

890 **D5.1 Data Validation and Usability (D1): Verification and Validation Requirements**

891 This element of the QAPP addresses requirements for both data verification and data validation.
892 The purpose of this element is to clearly state the criteria for deciding the degree to which each
893 data item and the data set as a whole has met the quality specifications described in the
894 “Measurement/Data Acquisition” section of the QAPP. The strength of the conclusions that can
895 be drawn from the data is directly related to compliance with and deviations from the sampling
896 and analytical design. The requirements can be presented in tabular or narrative form.

897 Verification procedures and criteria should be established prior to the data evaluation.
898 Requirements for data verification include the following criteria:

- 899 • Criteria for determining if specified protocols were employed (e.g., compliance with essential
900 procedural steps);
- 901 • Criteria for determining if methods were in control (e.g., QC acceptance criteria);
- 902 • Criteria for determining if a data report is complete (e.g., list of critical components that
903 constitute the report);
- 904 • Criteria for determining if the analysis was performed according to the QAPP and the SOW;
- 905 • Criteria and codes used to qualify data; and
- 906 • Criteria for summarizing and reporting the results of verification.

907 A discussion of verification can be found in Chapter 8, *Radiochemical Data Verification and*
908 *Validation*.

909 Data validation should be performed by an organization independent of the group that generated
910 the data to provide an unbiased evaluation. Validation procedures and criteria should be
911 established prior to the data evaluation. Requirements for data validation include the following:

- 912 • An approved list of well-defined MQOs and the action level(s) relevant to the project DQOs;
- 913 • Criteria for assigning qualifiers based on the approved list of MQOs;
- 914 • Criteria for identifying situations when the data validator's best professional judgement can
915 be employed and when a strict protocol must be followed; and
- 916 • Criteria for summarizing and reporting the results of validation.

917 A discussion of verification can be found in Chapter 8, *Radiochemical Data Verification and*
918 *Validation*.

919 **D5.2 Data Validation and Usability (D2): Verification and Validation Methods**

920 D5.2.1 Data Verification

921 Data verification or compliance with the SOW is concerned with: complete, consistent,
922 compliant and comparable data. Since the data verification report documents whether laboratory
923 conditions and operations were compliant with the SOW, the report is often used to determine
924 payment for laboratory services. Chapter 5, *Obtaining Laboratory Services*, discusses the need to
925 prepare a SOW for all radioanalytical laboratory work regardless of whether the work is
926 contracted out or performed in-house.

927 This element of the QAPP should address the following issues to ensure that data verification
928 will focus on the correct issues:

- 929 • Identify the documents (e.g., other QAPP sections, SOW, contracts, standard methods) that
930 describe the deliverables and criteria that will be used to evaluate compliance;

- 931 • Identify the performance indicators that will be evaluated (e.g., yield, matrix spikes,
932 replicates). See Chapter 18, *Laboratory Quality Control*, for a discussion of radiochemistry
933 performance indicators;

- 934 • Identify the criteria that will be used to determine “in-control” and “not-in-control”
935 conditions;

- 936 • Identify who will perform data verification;

- 937 • Describe the contents of the verification report (e.g., a summary of the verification process as
938 applied; required project activities not performed or not on schedule or not according to
939 required frequency; procedures that were performed but did not meet acceptance criteria;
940 affected samples; exceptions); and

- 941 • Identify who will receive verification reports and the mechanism for its archival.

942 D5.2.2 Data Validation

943 Chapter 8, *Radiochemical Data Verification and Validation*, discusses radiochemical data
944 validation in detail. MARLAP recommends that a data validation plan document be included as
945 an appendix to the QAPP. The data validation report will serve as the major input to the process
946 that evaluates the reliability of measurement data.

947 This element of the QAPP should address the following issues:

- 948 • Describe the deliverables, measurement performance criteria and acceptance criteria that will
949 be used to evaluate data validity;

- 950 • Identify who will perform data validation;

- 951 • Describe the contents of the validation report (e.g., a summary of the validation process as
952 applied; summary of exceptional circumstances; list of validated samples, summary of
953 validated results); and

- 954 • Identify who will receive validation reports and the mechanism for its archival.

955 **D5.3 Data Validation and Usability (D3): Reconciliation with Data Quality Objectives**

956 This element of the QAPP describes how project data will be evaluated to determine its usability
957 in decision-making. This evaluation is referred to as the “data quality assessment.” DQA is the
958 process that scientifically and statistically evaluates project-wide knowledge in terms of the
959 project objectives to assess the usability of data. DQA should be ongoing and integrated into the
960 project data collection activities. On project diagrams and data life cycles, it is often shown as the
961 last phase of the data collection activity. However, like any assessment process, DQA should be
962 considered throughout the data collection activity to ensure usable data. EPA guidance (EPA,
963 1996) provides a detailed discussion of that part of the DQA process that addresses statistical
964 manipulation of the data. In addition to statistical considerations, the DQA process integrates and
965 considers information from the validation report, assessment reports, the field, the conceptual
966 model and historical data to arrive at its conclusions regarding data usability. DQA is discussed
967 in Chapter 9, *Data Quality Assessment*.

968 The DQA considers the impact of a myriad of data collection activities in addition to measure-
969 ment activities. This element of the QAPP should direct those performing the DQA to:

- 970 • Review the QAPP and DQOs;
- 971 • Review the validation report;
- 972 • Review reports to management;
- 973 • Review identified field, sampling, sample handling, analytical and data management
974 problems associated with project activities;
- 975 • Review all corrective actions; and
- 976 • Review all assessment reports and findings (e.g., surveillances, audits, performance
977 evaluations, peer reviews, management and technical system reviews).

978 In addition to the above, this element of the QAPP should address the following issues:

- 979 • Identify who will perform the DQA;
- 980 • Identify what issues will be addressed by the DQA;
- 981 • Identify any statistical tests that will be used to evaluate the data (e.g., tests for normality);
- 982 • Describe how MQOs will be used to determine the usability of measurement data (i.e., did
983 the measurement uncertainty in the data significantly affect confidence in the decision?);
- 984 • Describe how the representativeness of the data will be evaluated (e.g., review the sampling
985 strategy, the suitability of sampling devices, subsampling procedures, assessment findings);
- 986 • Describe how the potential impact of non-measurable factors will be considered;
- 987 • Identify what will be included in the DQA report; and

- 988 • Identify who will receive the report and the mechanism for its archival.

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