

9 DATA QUALITY ASSESSMENT

9.1 Introduction

This chapter provides an overview of the data quality assessment (DQA) process, the third and final process of the overall data assessment phase of a project. Assessment is the last phase in the data life cycle and precedes the use of data. Assessment—in particular DQA—is intended to evaluate the suitability of project data to answer the underlying project questions or the suitability of project data to support the project decisions. The output of this final assessment process is a determination as to whether a decision can or cannot be made within the project-specified data quality objectives (DQOs).

The discussions in this chapter assume that prior to the DQA process, the individual data elements have been subjected to the first two assessment processes, “data verification” and “data validation” (see Chapter 8, *Radiochemical Data Verification and Validation*). The line between these three processes has been blurred for some time and varies from guidance to guidance and practitioner to practitioner. Although the content of the various processes is the most critical issue, a common terminology is necessary to minimize confusion and to improve communication among planning team members, those who will implement the plans, and those responsible for assessment. MARLAP defines these terms in Section 1.4 and discusses assessment in Section 8.2

This chapter is not intended to address the detailed and specific technical issues needed to assess the data from a specific project but rather to impart a general understanding of the DQA process and its relationship to the other assessment processes, as well as of the planning and implementation phases of the project’s data life cycle. The target audience for this chapter is the project planner, project manager, or other member of the planning team who wants to acquire a general understanding of the DQA process; not the statistician, engineer, or radiochemist who is seeking detailed guidance for the planning or implementation of the assessment phase. Guidance on specific technical issues is available (EPA, 2000; MARSSIM, 2000; NRC, 1998).

This chapter emphasizes that assessment, although represented as the last phase of the project’s data life cycle, should be planned for during the directed planning process, and the needed documentation should be provided during the implementation phase of the project.

Section 9.2 reviews the role of DQA in the assessment phase. Section 9.3 discusses the graded approach to DQA. The role of the DQA team is discussed in Section 9.4. Section 9.5 describes the content of DQA plans. Section 9.6 details the activities that are involved in the DQA process.

32 **9.2 Assessment Phase**

33 The assessment phase was discussed in Section 8.2. This subsection provides a brief overview of
34 the individual assessment processes, their distinctions, and how they interrelate.

35 “Data verification” generally evaluates compliance of the analytical process with project-plan
36 and other project-requirement documents, and the statement of work (SOW), and documents
37 compliance and noncompliance in a data verification report. Data verification is a separate
38 activity in addition to the checks and review done by field and laboratory personnel during
39 implementation.

40 Documentation generated during the implementation phase will be used to determine if the
41 proper procedures were employed and to determine compliance with project plan documents
42 (e.g., QAPP), contract-specified requirements, and measurement quality objectives (MQOs). Any
43 data associated with noncompliance will be identified as an “exception,” which should elicit
44 further investigation during data validation.

45 Compliance, exceptions, missing documentation, and the resulting inability to verify compliance
46 should be recorded in the data verification report. Validation and DQA employ the verification
47 report as they address the usability of data in terms of the project DQOs.

48 “Data validation” qualifies the usability of each datum after interpreting the impacts of
49 exceptions identified during verification. *The validation process should be well defined in a*
50 *validation plan that was completed during the planning phase.* The validation plan, as with the
51 verification plan or checklist, can range from sections of a project plan to large and detailed
52 stand-alone documents. Regardless of its size or format, the validation plan should address the
53 issues presented in Section 8.3. Data validation begins with a review of project objectives and
54 requirements, the data verification report, and the identified exceptions. The data validator
55 determines if the analytical process was in statistical control (Section 8.5.1) at the time of sample
56 analysis, and whether the analytical process as implemented was appropriate for the sample
57 matrix and analytes of interest (Section 8.5.2). If the system being validated is found to be under
58 control and applicable to the analyte and matrix, then the individual data points can be evaluated
59 in terms of detection (Section 8.5.3.1), detection capability (Section 8.5.3.2), and unusual
60 uncertainty (Section 8.5.3.3). Following these determinations, the data are assigned qualifiers
61 (Section 8.5.4) and a data validation report is completed (Section 8.6). Validated data are rejected
62 only when the impact of an exception is so significant that the datum is unreliable.

63 While both data validation and DQA processes address usability, the processes address usability
64 from different perspectives. “Data validation” attempts to interpret the *impacts of exceptions*
65 identified during verification and the impact of project activities on the usability of an individual
66 datum. In contrast, “data quality assessment” considers the *results of data validation* while
67 evaluating the usability of the entire data set.

68 During data validation, the guidance in Chapter 8 strongly advises against the rejection of data
69 unless there is a significant argument to do so. As opposed to rejecting data, it is generally
70 preferable that data are qualified and that the data validator details the concerns in the data
71 validation report. However, there are times when data should be rejected, and the rationale for the
72 rejection should be explained in the data validation report. There are times when the data
73 validator may have believed data should be rejected based on a viable concern, yet during DQA,
74 a decision could be made to employ the rejected data.

75 In summary, data validation is a transition from the compliance testing of data verification to
76 usability determinations. The results of data validation, as captured in the qualified data and
77 validation reports, will greatly influence the decisions made during the final assessment process,
78 data quality assessment, which is discussed in Section 9.6.

79 **9.3 Graded Approach to Assessment**

80 The sophistication of the assessment phase—and in particular DQA and the resources applied—
81 should be appropriate for the project (i.e., a “graded approach”). Directed planning for small or
82 less complex projects usually requires fewer resources and typically involves fewer people and
83 proceeds faster. This graded approach to plan design is also applied to the assessment phase.
84 Generally, the greater the importance of a project, the more complex a project, or the greater the
85 ramifications of an incorrect decision, the more resources will be expended on assessment in
86 general and DQA in particular.

87 It is important to note that the depth and thoroughness of a DQA will be affected by the
88 thoroughness of the preceding verification and validation processes. Quality control or statement
89 of work (SOW) compliance issues that are not identified as an “exception” during verification, or
90 qualified during validation, will result in potential error sources not being reviewed and their
91 potential impact on data quality will not be evaluated. Thus, while the graded approach to
92 assessment is a valid and necessary management tool, it is necessary to consider all assessment
93 phase processes (data verification, data validation, and data quality assessment) when assigning
94 resources to assessment.

95 **9.4 The Data Quality Assessment Team**

96 The project planning team is responsible for ensuring that its decisions are scientifically sound
97 and comply with the tolerable decision-error rates established during planning. MARLAP
98 recommends the involvement of the data assessment specialist(s) on the project planning team
99 during the directed planning process. This should result in a more efficient assessment plan and
100 should increase the likelihood that flaws in the design of the assessment processes will be
101 detected and corrected during planning. Chapter 2.4 noted that it is important to have an
102 integrated team of operational and technical experts. The data assessment specialist(s) who
103 participated as members of the planning team need not be the final assessors. However, using the
104 same assessors who participated in the directed planning process is advantageous, since they will
105 be aware of the complexities of the project’s goals and activities.

106 The actual personnel who will perform data quality assessment, or their requisite qualifications
107 and expertise, should be specified in the project plan documents. The project planning team
108 should choose a qualified data assessor (or team of data assessors) who is technically competent
109 to evaluate the project’s activities and the impact of these activities on the quality and usability of
110 data. Multi-disciplinary projects may require a team of assessors (e.g., radiochemist, engineer,
111 statistician) to address the diverse types of expertise needed to assess properly the representa-
112 tiveness of samples, the accuracy of data, and whether decisions can be made within the specified
113 levels of confidence. Throughout this manual, the term “assessment team” will be used to refer to
114 the assessor expertise needed.

115 **9.5 Data Quality Assessment Plan**

116 To implement the assessment phase as designed and ensure that the usability of data are assessed
117 in terms of the project objectives, a detailed DQA plan should be completed during the planning
118 phase of the data life cycle. This section focuses on the development of the DQA plan and its
119 relation to DQOs and MQOs.

120 The DQA plan should address the concerns and requirements of all stakeholders and present this
121 information in a clear, concise format. Documentation of these DQA specifications,
122 requirements, instructions, and procedures are essential to assure process efficiency and that
123 proper procedures are followed. Since the success of a DQA depends upon the prior two
124 processes of the assessment phase, it is key that the verification and validation processes also be
125 designed and documented in respective plans during the planning phase. Chapter 8 lists the types
126 of guidance and information that should be included in data verification and validation plans.

127 MARLAP recommends that the DQA process should be designed during the directed planning
128 process and documented in a DQA plan. The DQA plan is an integral part of the project plan
129 documents and can be included as either a section or appendix to the project plan or as a cited
130 stand-alone document. If a stand-alone DQA plan is employed, it should be referenced by the
131 project plan and subjected to a similar approval process.

132 The DQA plan should contain the following information:

- 133 • A short summary and citation to the project documentation that provides sufficient detail
134 about the project objectives (DQOs), sample and analyte lists, required detection limit, action
135 level, and level of acceptable uncertainty on a sample- or analyte-specific basis;
- 136 • Specification of the necessary sampling and analytical assessment criteria (typically
137 expressed as MQOs for selected parameters such as method uncertainty) that are appropriate
138 for measuring the achievement of project objectives and constitute a basis for usability
139 decisions;
- 140 • Identification of the actual assessors or the required qualifications and expertise that are
141 required for the assessment team performing the DQA (Section 9.4);
- 142 • A description of the steps and procedures (including statistical tests) that will constitute the
143 DQA, from reviewing plans and implementation to authoring a DQA report;
- 144 • Specification of the documentation and information to be collected during the project's
145 implementation;
- 146 • A description for any project-specific notification or procedures for documenting the usability
147 or non-usability of data for the project's decision making;
- 148 • A description of the content of the DQA report;
- 149 • A list of recipients for the DQA report; and
- 150 • Disposition and record maintenance requirements.

9.6 Data Quality Assessment Process

MARLAP’s guidance on the DQA process has the same content as other DQA guidance (ASTM D6233; EPA, 2000; MARSSIM, 2000; NRC, 1998; USACE, 1998), however, MARLAP presents these issues in an order that parallels project implementation more closely. The MARLAP guidance on the DQA process can be summarized as an assessment process that—following the review of pertinent documents (Section 9.6.1)—answers the following questions:

- Are the samples representative? (Section 9.6.2)
- Are the analytical data accurate? (Section 9.6.3)
- Can a decision be made? (Section 9.6.4)

Each of these questions is answered first by reviewing the plan and then evaluating the implementation. The process concludes with the documentation of the evaluation of the data usability in a DQA Report (Section 9.7).

The DQA Process is more global in its purview than the previous verification and validation processes. The DQA process should consider the combined impact of all project activities in making a data usability determination. The DQA process, in addition to reviewing the issues raised during verification and validation, may be the first opportunity to review other issues, such as field activities and their impact on data quality and usability. A summary of the DQA steps and their respective output is presented in Table 9.1.

TABLE 9.1 — Summary of the DQA process

DQA PROCESS	Input	Output for DQA Report
1. Review Project Plan Document	The project plan document (or a cited stand-alone document) that addresses: (a) Directed Planning Process Report, including DQOs, MQOs and optimized Sampling and Analysis Plan. (b) Revisions to documents in (a) and problems or deficiency reports. (c) DQA Plan.	<ul style="list-style-type: none"> • Identification of project documents. • Clear understanding by the assessment team of project’s DQOs and MQOs. • Clear understanding of assumptions made during the planning process. • If a clear description of the DQOs does not exist, the assessment team should record the DQOs (as they were established for assessment).
2. Are the Samples Representative?	The project plan document (or a cited stand-alone document) that addresses: (a) The sampling portion of the Sampling and Analysis Plan.	<ul style="list-style-type: none"> • Documentation of all assumptions as potential limitations and, if possible, a description of their associated ramifications. • The determination of whether the design

DQA PROCESS	Input	Output for DQA Report
	<ul style="list-style-type: none"> (b) SOPs for sampling. (c) Sample handling and preservation requirements of the APS 	<p>resulted in a representative sampling of the population of interest.</p> <ul style="list-style-type: none"> • The determination of whether the sampling locations introduced bias. • The determination of whether the sampling equipment and their use as described in the sampling procedures were capable of extracting a representative set of samples from the material of interest. • An evaluation of the necessary deviations (documented), as well as those deviations resulting from misunderstanding or error, and a determination of their impact on the representativeness of the affected samples.
<p>175 176</p> <p>3. Are the Data Accurate?</p>	<p>The project plan documents (or a cited stand-alone document) which address:</p> <ul style="list-style-type: none"> (a) The analysis portion of the Sampling and Analysis Plan. (b) The MQOs. (c) SOPs for analysis. (d) Analytical Protocol Specifications, including quality control requirements and MQOs. (e) SOW. (f) The selected analytical protocols. (g) Ongoing evaluations of performance. (h) Data Verification and Validation plans and reports. 	<ul style="list-style-type: none"> • A determination of whether the selected method was appropriate for the intended application. • The identification of any potential sources of inaccuracy. • An assessment of whether the sample analyses were implemented according to the analysis plan. • An evaluation of the impact of any deviations from the analysis plan on the usability of the data set.
<p>177 178</p> <p>4. Can a Decision be Made?</p>		<p>The project plan document (or a cited stand-alone document) that addresses:</p> <ul style="list-style-type: none"> (a) The DQA plan, including the statistical tests to be used. (b) The DQOs and the tolerable decision error rates. • Results of the statistical tests. If new tests were selected, the rationale for their selection and the reason for the inappropriateness of the statistical tests selected in the DQA plan. • Graphical representations of the data set and parameter(s) of interest. • Determination of whether the DQOs and

DQA PROCESS	Input	Output for DQA Report
		tolerable decision error rates were met. <ul style="list-style-type: none"> • A final determination as to whether the data are suitable for decision-making, estimation, or answering questions within the levels of certainty specified during planning.

179 **9.6.1 Review of Project Documents**

180 The first step of the DQA process is for the team to identify and become familiar with the DQOs
 181 of the project and the DQA plan. Like the planning process, the steps of the DQA process are
 182 iterative, but they are presented in this text in a step-wise fashion for discussion purposes.
 183 Members of the assessment team may focus on different portions of the project plan documents
 184 and different elements of the planning process. Some may do an in-depth review of the directed
 185 planning process during this step; others will perform this task during a later step. The
 186 assessment team should receive revisions to the project planning documents and should review
 187 deficiency reports associated with the project. The subsections below discuss the key and
 188 minimum project documents that should be reviewed.

189
 190 9.6.1.1 The Project DQOs and MQOs

191 Since the usability of data is measured in terms of the project DQOs, the first step in the DQA
 192 process is to acquire a thorough understanding of the DQOs. If the DQA will be performed by
 193 more than one assessor, it is essential that the assessment team shares a common understanding
 194 of the project DQOs and tolerable decision error rates. The assessment team will refer to these
 195 DQOs continually as they make determinations about data usability. The results of the directed
 196 planning process should have been documented in the project plan documents. The project plan
 197 documents, at a minimum, should describe the DQOs and MQOs clearly and in enough detail
 198 that they are not subject to misinterpretation or debate at this last phase of the project.

199 If the DQOs and MQOs are not described properly in the project plan documents or do not
 200 appear to support the project decision, or if questions arise, it may be necessary to review other
 201 planning documents (such as memoranda) or to consult the project planning team or the core
 202 group (Section 2.4). If a clear description of the DQOs does not exist, the assessment team
 203 should record any clarifications the assessment team made to the DQO statement as part of the
 204 DQA report.

205 9.6.1.2 The DQA Plan

206 If the assessment team was not part of the directed planning process, the team should familiarize
207 itself with the DQA plan and become clear on the procedures and criteria that are to be used for
208 the DQA Process. If the assessment team was part of the planning process, but sufficient time has
209 elapsed since the conclusion of planning, the assessment team should review the DQA plan. If
210 the process is not clearly described in a DQA plan or does not appear to support the project
211 decision, or if questions arise, it may be necessary to consult the project planning team or the
212 core group. If necessary, the DQA plan should be revised. If it cannot be, any deviations from it
213 should be recorded in the DQA report.

214 During DQA, it is important for the team, including the assessors and statistician, to be able to
215 communicate accurately. Unfortunately, this communication can be complicated by the different
216 meanings assigned to common words (e.g., samples, homogeneity). The assessment team should
217 be alert to these differences during their deliberations. The assessment team will need to
218 determine the usage intended by the planning team.

219 It is important to use a directed planning process to ensure that good communications exist from
220 planning through data use. If the statistician and other experts are involved through the data life
221 cycle and commonly understood terms are employed, chances for success are increased.

222 9.6.1.3 Summary of the DQA Review

223 The review of project documents should result in:

- 224 • An identification and understanding of project plan documents, including any changes made
225 to them and any problems encountered with them;
- 226 • A clear understanding of the DQOs for the project. If a clear description of the DQOs does not
227 exist, the assessment team should reach consensus on the DQOs prior to commencing the
228 DQA and record the DQOs (as they were established for assessment) as part of the DQA
229 report; and
- 230 • A clear understanding of the terminology, procedures, and criteria for the DQA process.

231 **9.6.2 Sample Representativeness**

232 MARLAP does not provide guidance on developing sampling designs or a sampling plan. The
233 following discussion of sampling issues during a review of the DQA process is included for
234 purposes of completeness.

235 “Sampling” is the process of obtaining a portion of a population (i.e., the material of interest as
236 defined during the planning process) that can be used to characterize populations that are too
237 large or complex to be evaluated in their entirety. The information gathered from the samples is
238 used to make inferences whose validity reflects how closely the samples represent the properties
239 and analyte concentrations of the population. “Representativeness” is the term employed for the
240 degree to which samples properly reflect their parent populations. A “representative sample,” as
241 defined in ASTM D6044, is “a sample collected in such a manner that it reflects one or more
242 characteristics of interest (as defined by the project objectives) of a population from which it was
243 collected” (Figure 9.1). Samples collected in the field as a group and subsamples generated as a
244 group in the laboratory (Appendix F) should reflect the population physically and chemically. A
245 flaw in any portion of the sample collection or sample analysis design or their implementation
246 can impact the representativeness of the data and the correctness of associated decisions.
247 Representativeness is a complex issue related to analyte of interest, geographic and temporal
248 units of concern, and project objectives.

249 The remainder of this subsection discusses the issues that should be considered in assessing the
250 representativeness of the samples: the sampling plan (Section 9.6.2.1) and its implementation
251 (Section 9.6.2.2). MARLAP recommends that all sampling design and statistical assumptions be
252 identified clearly in project plan documents along with the rationale for their use.

253 **9.6.2.1 Review of the Sampling Plan**

254 The sampling plan and its ability to generate representative samples are assessed in terms of the
255 project DQOs. The assessors review the project plan with a focus on the approach to sample
256 collection, including sample preservation, shipping and subsampling in the field and laboratory,
257 and sampling standard operating procedures (SOPs). Ideally the assessors would have been
258 involved in the planning process and would be familiar with the DQOs and MQOs and the
259 decisions made during the selection of the sampling and analysis design. If the assessors were
260 part of the project planning team, this review to become familiar with the project plan will go
261 quickly, and the team can focus on deviations from the plan that will introduce unanticipated
262 imprecision or bias (Section 9.6.2.2).

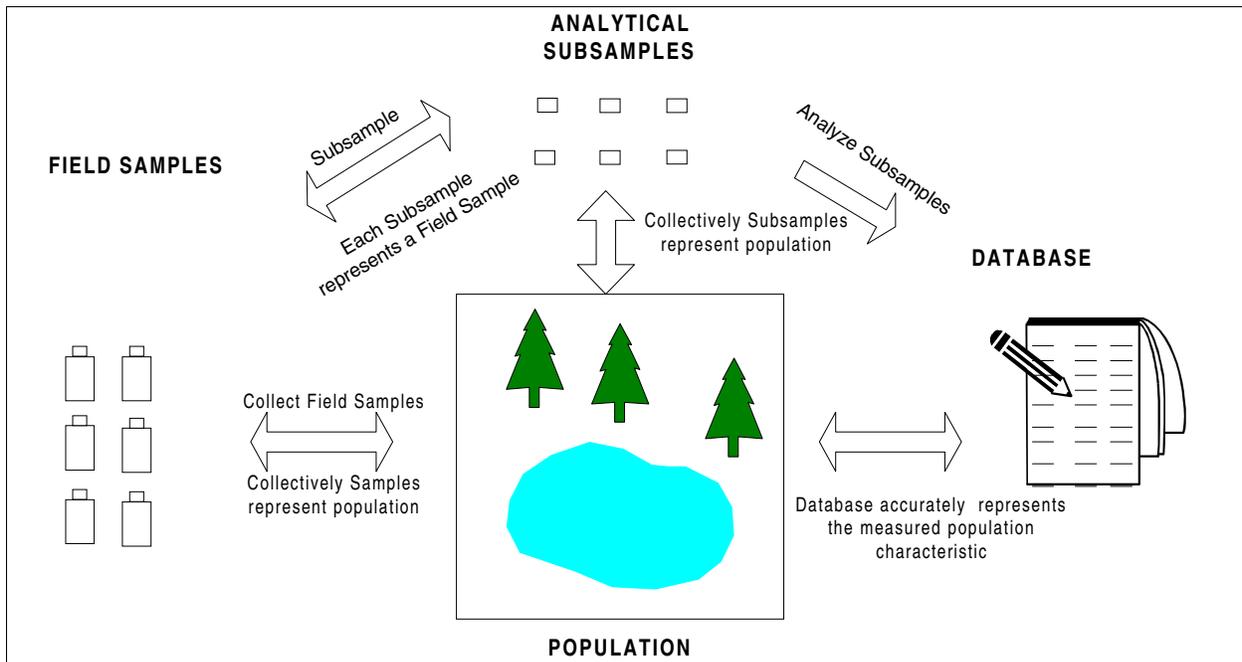


FIGURE 9.1 — Using physical samples to measure a characteristic of the population representatively.

263 APPROACH TO SAMPLE COLLECTION

264 Project plan documents (e.g., QAPP, SAP, Field Sampling Plan) should provide details about the
 265 approach to sample collection and the logic that was employed in its development. At this stage,
 266 the assessment team should evaluate whether the approach, as implemented, resulted in
 267 representative samples. For example, if the approach was probabilistic, the assessment team
 268 should determine if it was appropriate to assume that spatial or temporal correlation is not a
 269 factor, and if all portions of the population had an equal chance of being sampled. If an
 270 “authoritative” sample collection approach was employed (i.e., a person uses his knowledge to
 271 choose sample locations and times), the assessment team—perhaps in consultation with the
 272 appropriate experts (e.g., an engineer familiar with the waste generation process)—should
 273 determine if the chosen sampling conditions do or do not result in a “worst case” or “best case.”

274 The assessment team should evaluate whether the chosen sampling locations resulted in a
 275 negative or positive bias, and whether the frequency and location of sample collection accounted
 276 for the population heterogeneity.

277 Optimizing the data collection activity (Section 2.5.4 and Appendix B3.8) involved a number of
278 assumptions. These assumptions are generally employed to manage a logistical, budgetary, or
279 other type of constraint, and are used instead of additional sampling or investigations. The
280 assessment team needs to understand these assumptions in order to fulfill its responsibility to
281 review and evaluate whether their continued validity based on the project's implementation. The
282 assessment team should review the bases for the assumptions made by the planning team because
283 they can result in biased samples and incorrect conclusions. For example, if samples are collected
284 from the perimeter of a lagoon to characterize the contents of the lagoon, the planning team's
285 assumption was that the waste at the lagoon perimeter has the same composition as that waste
286 located in the less-accessible center of the lagoon. In this example, there should be information to
287 support the assumption, such as historical data, indicating that the waste is relatively homogen-
288 ous and well-mixed. Some assumptions will be stated clearly in project plan documents. Others
289 may only come to light after a detailed review. The assessment team should review assumptions
290 for their scientific soundness and potential impact on the representativeness of the samples.

291 Ideally, assumptions would be identified clearly in project plan documents, along with the
292 rationale for their use. Unfortunately, this is uncommon, and in some cases, the planners may be
293 unaware of some of the implied assumptions associated with a design choice. The assessment
294 team should document any such assumptions in the DQA report as potential limitations and, if
295 possible, describe their associated ramifications. The assessment team may also suggest
296 additional investigations to verify the validity of assumptions which are questionable or key to
297 the project.

298 SAMPLING SOPs

299 Standard operating procedures for sampling should be assessed for their appropriateness and
300 scientific soundness. The assessment team should assess whether the sampling equipment and
301 their use, as described in the sampling procedures, were capable of extracting a representative set
302 of samples from the material of interest. The team also should assess whether the equipment's
303 composition was compatible with the analyte of interest. At this stage, the assessment team
304 assumes the sampling device was employed according to the appropriate SOP. Section 9.6.2.2
305 discusses implementation and deviations from the protocols.

306 In summary, the assessment team should investigate whether:

- 307 • The sampling device was compatible with the material being sampled and with the analytes of
308 interest;

- 309 • The sampling device accommodated all particle sizes and did not discriminate against
310 portions of the material being sampled;
- 311 • The sampling device resulted in contamination or loss of sample components;
- 312 • The sampling device allowed access to all portions of the material of interest;
- 313 • The sample handling, preparation, and preservation procedures maintained sample integrity;
314 and
- 315 • The field and laboratory subsampling procedures resulted in a subsample that accurately
316 represents the contents of the original sample.

317 These findings should be detailed in the DQA report.

318 9.6.2.2 Sampling Plan Implementation

319 The products of the planning phase are integrated project plan documents that define how the
320 planners intend the data collection process to be implemented. At this point in the DQA process,
321 the assessment team determines whether sample collection was done according to the plan,
322 reviews any noted deviations from the protocols, identifies any additional deviations, and
323 evaluates the impact of these deviations on sample representativeness and the usability of the
324 data. The success of this review will be a function of the documentation requirements specified
325 during the planning process, and how thoroughly these requirements were met during sample
326 collection.

327 The determination as to whether the plans were implemented as written typically will be based
328 on a review of documentation generated during the implementation phase, through on-site
329 assessments, and during verification, if sampling activities (e.g., sample preservation) were
330 subjected to verification. In some instances, assessment team members may have firsthand
331 knowledge from an audit that they performed, but in general the assessment team will have to
332 rely upon documentation generated by others. The assessment team will review field notes,
333 sample forms, chain-of-custody forms, verification reports, audit reports, deviation reports,
334 corrective action documentation, QA reports, and reports to management. The assessment team
335 also may choose to interview field personnel to clarify issues or to account for missing
336 documentation, .

337 Due to the uncontrolled environments from which most samples are collected, the assessment
338 team expects to find some deviations even from the best-prepared plans. Those not documented
339 in the project deficiency and deviation reports should be detailed in the DQA report. The
340 assessment team should evaluate these necessary deviations, as well as those deviations resulting
341 from misunderstanding or error, and determine their impact on representativeness of the affected
342 samples. These findings also should be detailed in the DQA report.

343 In summary, the assessment team will develop findings and determinations regarding any
344 deviations from the original plan, the rationale for the deviations, and if the deviations raise
345 question of representativeness.

346 9.6.2.3 Data Considerations

347 Sample representativeness also can be evaluated in light of the resulting data. Favorable
348 comparisons of the data to existing data sets (especially those data sets collected by different
349 organizations and by different methods) offer encouraging evidence of representativeness, but
350 not absolute confirmation of sample representativeness, since both data sets could suffer from the
351 same bias and imprecision. The project plan documents should have referenced any credible and
352 applicable existing data sets identified by the planning team. Comparisons to existing data sets
353 may offer mutual support for the accuracy of each other, and when differences result they tend to
354 raise questions about both data sets. Quite often, the DQA assessors are looking for confirmatory
355 or conflicting information. How existing data sets are used during the DQA will be determined
356 by how much confidence the assessors place in them. If they are very confident in the accuracy of
357 existing data sets, then they may classify the new data as unusable if it differs from the existing
358 data. If there is little confidence in the existing data set, then the assessors may just mention in
359 the DQA report that the new data set was in agreement or not in agreement. However, if the
360 planning team has determined that additional data were needed, they probably will not have
361 sufficient confidence in the existing data set for purposes of decision-making.

362 Data comparison is an issue that could be addressed during validation to some degree, depending
363 on the validation plan. However, at this point in the DQA, comparable data sets serve a different
364 purpose. For example, the MDCs, concentration units, and the analytical methods may be the
365 same and allow for data comparison in validation. However, the assessors during DQA would
366 look for similarities and dissimilarities in reported concentrations for different areas of the
367 populations, and whether any differences might be an indication of a bias or imprecision that
368 makes the samples less representative. Temporal and spatial plots of the data also may be helpful
369 in identifying portions of the sampled population that were over- or under-represented by the data
370 collection activity.

371 The planning process and development of probabilistic sampling plans typically require
372 assumptions regarding average concentrations and variances. If the actual average concentrations
373 and variances are different than anticipated, it is important for the assessment team to evaluate
374 the ramifications of these differences on sample representativeness. As reported values approach
375 an action level, the greater the need for the sample collection activities to accurately represent the
376 population characteristics of interest.

377 During the evaluation of sample representativeness, as discussed in the previous subsections, the
378 assessment team has the advantage of hindsight, since they review the sample collection design
379 in light of project outcomes and can determine if the sample collection design could have been
380 optimized differently to better achieve project objectives. Findings regarding the representative-
381 ness of samples and how sampling can be optimized should be expeditiously passed to project
382 managers if additional sampling will be performed.

383 In summary, results of the evaluation of the sample representativeness are:

- 384 • An identification of any assumptions that present limitations and, if possible, a description of
385 their associated ramifications;
- 386 • A determination of whether the design resulted in a representative sampling of the population
387 of interest;
- 388 • A determination of whether the specified sampling locations, or alternate locations as
389 reported, introduced bias;
- 390 • A determination of whether the sampling equipment and their use, as described in the
391 sampling procedures or as implemented, were capable of extracting a representative set of
392 samples from the material of interest; and
- 393 • An evaluation of the necessary deviations from the plan, as well as those deviations resulting
394 from misunderstanding or error, and a determination of their impact on the representativeness
395 of the affected samples.

396 The product of this step is a set of findings regarding the impact of representativeness—or the
397 lack thereof—that affects data usability. Findings and determinations regarding representative-
398 ness will impact the usability of the resulting data to varying degrees. Some findings may be so
399 significant (e.g., the wrong waste stream was sampled) that the samples can be determined to be
400 non-representative and the associated data cannot be used; as a result, the DQA need not progress

401 any further. Typically, findings will be subject to interpretation, and the impacts on representa-
402 tiveness will have to be evaluated in light of other DQA findings to determine the usability of
403 data.

404 **9.6.3 Data Accuracy**

405 The next step in the DQA process is the evaluation of the analysis process and accuracy of the
406 resulting data. The term “accuracy” describes the closeness of the result of a measurement to the
407 true value of the quantity being measured. The accuracy of results may be affected by both
408 imprecision and bias in the measurement process, and by blunders and loss of statistical control
409 (see Chapter 19, *Measurement Statistics*, for a discussion on measurement error).

410 Since MARLAP uses “accuracy” only as a qualitative concept, in accordance with the
411 *International Vocabulary of Basic and General Terms in Metrology* (ISO, 1993), the agreement
412 between measured results and true values is evaluated quantitatively in terms of the
413 “imprecision” and “bias” of the measurement process. “Imprecision” usually is expressed as a
414 standard deviation, which measures the dispersion of results about their mean. “Bias” is a
415 persistent distortion of results from the true value.

416 During the directed planning process, the project planning team should have made an attempt to
417 identify and control sources of imprecision and bias (Appendix B3.8). During DQA, the
418 assessment team should evaluate the degree of imprecision and bias and determine its impact on
419 data usability. Quality control samples are analyzed for the purpose of assessing imprecision and
420 bias. Spiked samples and method blanks typically are used to assess bias, and duplicates are used
421 to assess imprecision. Since a single measurement of a spike or blank principle cannot
422 distinguish between imprecision and bias, a reliable estimate of bias requires a data set that
423 includes many such measurements. Control charts of quality control (QC) data, such as field
424 duplicates, matrix spikes, and laboratory control samples are graphical representations and
425 primary tools for monitoring the control of sampling and analytical methods and identifying
426 precision and bias trends (Chapter 18, *Quality Control*).

427 Measurable types of bias are identified and controlled through the application of quantitative
428 MQOs to QC samples, such as blanks, standard reference materials, performance evaluation
429 samples, calibration check standards, and spikes samples. Non-measurable forms of bias (e.g., a
430 method being implemented incorrectly, such as reagents being added in the incorrect order) are
431 usually identified and controlled by well-designed plans that specify quality assurance systems
432 that detail needed training, use of appropriate SOPs, deficiency reporting systems, assessments,
433 and quality improvement processes.

434 Bias in a data set may be produced by measurement errors that occur in steps of the measurement
435 process that are not repeated. Imprecision may be produced by errors that occur in steps that are
436 repeated many times. The distinction between bias and imprecision is complicated by the fact
437 that some steps, such as instrument calibration and tracer preparation and standardization, are
438 repeated at varying frequencies. For this reason, the same source of measurement error may
439 produce an apparent bias in a small data set and apparent imprecision in a larger data set. During
440 data assessment, an operational definition of bias is needed. A bias may exist if results for
441 analytical spikes (i.e., laboratory control samples, matrix spike, matrix spike duplicate),
442 calibration checks, and performance evaluation samples associated with the data set are mostly
443 low or mostly high, if the results of method blank analyses tend to be positive, or if audits
444 uncover certain types of biased implementation of the SOPs. At times, the imprecision of small
445 data sets can incorrectly indicate a bias, while at other times, the presence of bias may be masked
446 by imprecision. Statistical methods can be applied to imprecise data sets and used to determine if
447 there are statistically significant differences between data sets or between a data set and an
448 established value. If the true value or reference value (e.g., verified concentration for a standard
449 reference material) is known, then statistics can be used to determine whether there is a bias.

450 Figure 9.2 employs targets to depict the impacts of imprecision and bias on measurement data.
451 The true value is portrayed by the bulls-eye and is 100 units (e.g., dpm, Bq, pCi/g). Ideally, all
452 measurements with the same true value would be centered on the target, and after analyzing a
453 number of samples with the same true value, the reported data would be 100 units for each and
454 every sample. This ideal condition of precise and unbiased data is pictured in Figure 9.2(a). If the
455 analytical process is very precise but suffers from a bias, the situation could be as pictured in
456 Figure 9.2(b) in which the data are very reproducible but express a significant 70 percent
457 departure from the true value—a significant bias. The opposite situation is depicted in Figure
458 9.2(c), where the data are not precise and every sample yields a different concentration. However,
459 as more samples are analyzed, the effects of imprecision tend to average out, and lacking any
460 bias, the average measurement reflects the true concentration. Figure 9.2(d) depicts a situation
461 where the analytical process suffers from both imprecision and bias, and even if innumerable
462 samples with the same true value are collected and analyzed to control the impact of imprecision,
463 the bias would result in the reporting of an incorrect average concentration.

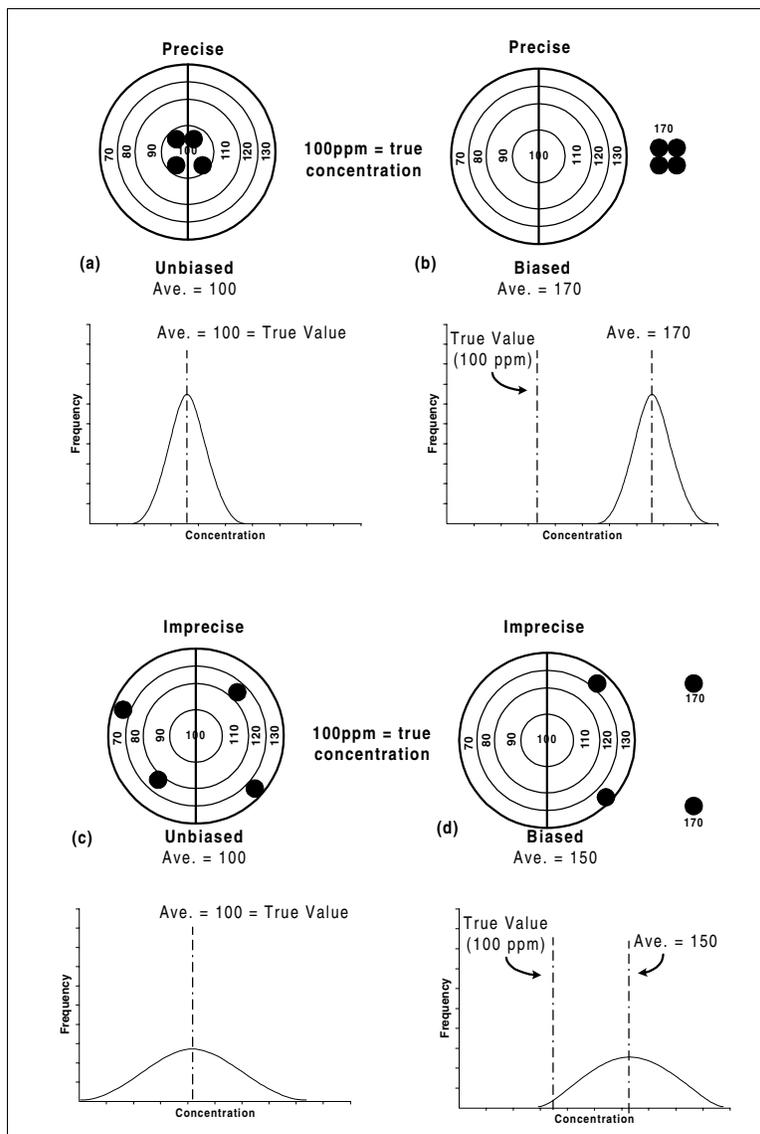


FIGURE 9.2 — Types of sampling and analytical errors.

464 Each target in Figure 9.2 has an associated frequency distribution curve. Frequency curves are
 465 made by plotting a concentration value versus the frequency of occurrence for that concentration.
 466 Statisticians employ frequency plots to display the imprecision of a sampling and analytical
 467 event, and to identify the type of distribution. The curves show that as imprecision increases the
 468 curves flatten-out and there is a greater frequency of measurements that are distant from the

469 average value (Figures 9.2c and d). More precise measurements result in sharper curves (Figures
470 9.2a and b), with the majority of measurements relatively closer to the average value. The greater
471 the bias (Figures 9.2b and d), the further the average of the measurements is shifted from the true
472 value. The smaller the bias (Figures 9.2a and c), the closer the average of the measurements is to
473 the true value.

474 The remainder of this subsection focuses on the review of analytical plans (Section 9.6.3.1) and
475 their implementation (Section 9.6.3.2) as a mechanism to assess the accuracy of analytical data
476 and their suitability for supporting project decisions.

477 9.6.3.1 Review of the Analytical Plan

478 The analytical plan is that portion of the project plan documentation (e.g., in QAPP or SAP) that
479 addresses the optimized analytical design and other analytical issues (e.g., analytical protocol
480 specifications, SOPs). Its ability to generate accurate data is assessed in terms of the project
481 DQOs. The assessment team will refer to the DQOs and the associated MQOs as they review the
482 analytical protocol specifications to understand how the planning team selected methods and
483 developed the analytical plan. If the assessors were part of the project planning team, this review
484 process will go quickly and the team can focus on deviations from the plan that will introduce
485 unanticipated imprecision or bias. (The term “analytical plan” is not meant to indicate a separate
486 document.)

487 REVIEW OF THE MQOs, ANALYTICAL PROTOCOL SPECIFICATIONS, AND OPTIMIZED ANALYTICAL 488 DESIGN

489 The assessment team’s review of the analytical plan first should focus on the analytical protocol
490 specifications, including the MQOs, which were established by the project planning team
491 (Chapter 3). The team should understand how the analytical protocol specifications were used to
492 develop the SOW (Chapter 5) and select the method (Chapter 6). If the project and contractual
493 documentation are silent or inadequate on how they address these key issues, the assessment
494 team may be forced to review the analytical results in terms of the project DQOs and determine if
495 the MQOs achieved were sufficient to meet the project’s objectives.

496 As with the approach to sample collection, optimizing the analytical activity involved a number
497 of assumptions. Assumptions were made when analytical issues were resolved during planning
498 and the decisions were documented in the analytical protocol specifications (Chapter 3). It is
499 important for the assessment team to be aware of these assumptions because they can result in
500 biases and incorrect conclusions. Some assumptions will be clearly stated in the project plan

501 documents. Others may only come to light after a detailed review. The assessment team should
502 review assumptions for their scientific soundness and potential impact on the data results.

503 Ideally, assumptions would be identified clearly in project plan documents, along with the
504 rationale for their use. Unfortunately, this is uncommon, and in some cases, the planners may be
505 unaware of some of the implied assumptions associated with a design choice. The assessment
506 team should document any such assumptions in the DQA report as potential limitations and, if
507 possible, describe their associated ramifications. The assessment team may also suggest
508 additional investigations to verify the validity of assumptions which are questionable or key to
509 the project.

510 REVIEW OF THE ANALYTICAL PROTOCOLS

511 The analytical plan and the associated analytical protocols will be reviewed and assessed for their
512 scientific soundness, applicability to the sample matrix and the ability to generate precise and
513 unbiased data. The analytical protocols review should consider the entire analytical process, from
514 sample preparation through dissolution and separations, counting, data reduction, and reporting.
515 MARLAP, whose focus is on the analytical process, defines “analytical process” as including
516 sample handling in the field (e.g., filtration, sample preservation) to ensure that all activities that
517 could impact analyses would be considered. The assessment team should consider both sampling
518 and analytical processes in assessing data quality—and such field activities as sample preserva-
519 tion—along with other issues that can affect representativeness (Section 9.6.2). The assessment
520 team also should review the contract evaluation (under the performance-based approach) for the
521 selection of the analytical protocols to assure that the documentation showed that the protocol
522 could meet the analytical protocol specifications (which defines the MQOs).

523 Since the review of the analytical protocols will be performed with the advantage of hindsight
524 gained from the data verification and data validation reports, the assessment team also should
525 attempt to identify any flaws in the analytical protocols that may have resulted in noncompliance
526 with MQOs. The identification of these flaws is essential if future analyses will be required.

527 REVIEW OF VERIFICATION AND VALIDATION PLANS

528 To understand how the verification and validations processes were implemented and the degree
529 to which the assessors can rely upon their findings, the assessors should familiarize themselves
530 with the verification and validation plans that were developed during the planning phase. A
531 review of these plans will indicate whether the issues deemed of importance to the assessors were
532 evaluated and the thoroughness of the evaluations.

533 9.6.3.2 Analytical Plan Implementation

534 After reviewing the analytical plan, the assessment team should assess whether sample analyses
535 were implemented according to the analysis plan. Typically, the first two steps of the assessment
536 phase—data verification and data validation—have laid most of the groundwork for this
537 determination. However, the issue of whether the plan was implemented as designed needs to be
538 reviewed one final time during the DQA process. This final review is needed since new and
539 pertinent information may have been uncovered during the first steps of the DQA process.

540 The goal of this assessment of the analytical protocols and associated MQOs is to confirm that
541 the selected method was appropriate for the intended application and to identify any potential
542 sources of inaccuracy, such as:

- 543 • Laboratory subsampling procedures that resulted in the subsample that may not accurately
544 represent the content of the original sample;
- 545 • Sample dissolution methods that may not have dissolved sample components quantitatively;
- 546 • Separation methods whose partitioning coefficients were not applicable to the sample matrix;
- 547 • Unanticipated self-absorption that biased counting data;
- 548 • Non-selective detection systems that did not resolve interferences; or
- 549 • Data reduction routines that lacked needed resolution or appropriate interference corrections
550 .

551 The success of the assessment of the analytical plan implementation will be a function of the
552 documentation requirements specified during the planning process, and how thoroughly these
553 requirements were met during sample analysis. In some instances, assessment team members
554 may have firsthand knowledge from an audit that they performed, but in general the assessment
555 team will have to rely upon documentation generated by others.

556 In addition to verification and validation reports, the assessment team will review pertinent
557 documents such as: laboratory notebooks, instrument logs, quality control charts, internal
558 sample-tracking documentation, audit reports, deviation reports, corrective action documentation,
559 performance evaluation sample reports, QA reports, and reports to management provided for
560 verification and validation. To clarify issues or to account for missing documentation, the
561 assessment team may choose to interview laboratory personnel.

562 Verification and validation reports will be used to identify nonconformance, deviations, and
563 problems that occurred during the implementation of the analytical plan. The challenge during
564 DQA is to evaluate the impact of nonconformance, deviations, problems, and qualified data on
565 the usability of the overall data set and the ability of the data set to support the decision.

566 Deviations from the plan will be encountered commonly and the assessment team will evaluate
567 the impact of these deviations upon the accuracy of the analytical data. The deviations and the
568 assessment team's related findings should be detailed in the data quality assessment report.

569 The prior verification and validation processes and the prior DQA steps involving the evaluation
570 of sampling are all an attempt to define the quality of data by (1) discovering sources of bias,
571 quantifying their impact, and correcting the reported data; and (2) identifying and quantifying
572 data imprecision. The products of this step are a set of findings regarding the analytical process
573 and their impact on data usability. Some findings may be so significant (e.g., the wrong analytical
574 method was employed) that the associated data cannot be used, and as a result, the DQA need not
575 progress any further. Typically, findings will be subject to interpretation and a final
576 determination as to the impacts will have to wait until the data has been subjected to evaluations
577 described in Section 9.6.4.

578 After reviewing the verification and validation reports, the outputs of the analytical data
579 evaluation are:

- 580 • A determination of whether the selected analytical protocols and analytical performance
581 specifications were appropriate for the intended application;
- 582 • An identification of any potential sources of inaccuracy; and
- 583 • A determination of whether sample analyses were implemented according to the analysis plan
584 and the overall impact of any deviations on the usability of the data set.

585 **9.6.4 Decisions and Tolerable Error Rates**

586 A goal of DQA is to avoid making a decision based on inaccurate data generated by analytical
587 protocols found to be out of control or on data generated from samples found to be nonrepresentative,
588 and to avoid making decisions based on data of unknown quality. Preferably, a decision
589 should be made with data of known quality (i.e., with data of known accuracy from samples of
590 known representativeness) and within the degree of confidence specified during the planning
591 phase.

592 This section focuses on the final determination by the assessment team, who uses the information
593 taken from the previous assessment processes and statistics to make a final determination of
594 whether the data are suitable for decision-making, estimating, or answering questions within the
595 levels of certainty specified during planning.

596 9.6.4.1 Statistical Evaluation of Data

597 Statistics are used for the collection, presentation, analysis, and interpretation of data. The two
598 major branches of statistics, “descriptive statistics” and “inferential statistics,” are applicable to
599 data collection activities. “Descriptive statistics” are those methods that describe populations of
600 data. For example, descriptive statistics include the mean, mode, median, variance, and
601 correlations between variables, tables, and graphs to describe a set of data. “Inferential statistics”
602 use data taken from population samples to make estimates about the whole population
603 (“inferential estimations”) and to make decisions (“hypothesis testing”). Descriptive statistics is
604 an important tool for managing and investigating data in order that their implications and
605 significance to the project goals can be understood.

606 Sampling and inferential statistics have identical goals—to use samples to make inferences about
607 a population of interest and to use sample data to make defensible decisions. This similarity is
608 the reason why planning processes, such as those described in Chapter 2, couple sample
609 collection activities with statistical techniques to maximize the representativeness of samples, the
610 accuracy of data, and the certainty of decisions.

611 Due to the complexity of some population distributions (Appendix 19A) and the complex
612 mathematics needed to treat these distributions and associated data, it is often best to consult
613 with someone familiar with statistics to ensure that statistical issues have been addressed
614 properly. However, it is critical for the non-statistician to realize that statistics has its limitations.
615 The following statistical limitations should be considered when assessment teams and the project
616 planning team are planning the assessment phase and making decisions:

- 617 • Statistics are used to measure precision and, when true or reference values are known,
618 statistics can be applied to imprecise data to determine if a bias exists. Statistics do not
619 address all types of sampling or measurement bias directly.

- 620 • If the characteristic of interest in a sample is more similar to that of samples adjacent to it than
621 to samples that are further removed, the samples are deemed to be “correlated” and are not
622 independent of each other (i.e., there is a serial correlation such that samples collected close in
623 time or space have more similar concentrations than those samples further removed).

624 Conventional parametric and non-parametric statistics require that samples be independent
625 and are not applicable to populations that have significantly correlated concentrations.

626 The statistical tests typically are chosen during the directed planning process and are documented
627 in the project plan documents (e.g., DQA plan, QAPP). However, there are occasions when the
628 conditions encountered during the implementation phase are different than anticipated (e.g., data
629 were collected without thorough planning, or data are being subjected to an unanticipated
630 secondary data use). Under these latter conditions, the statistical tests will be chosen following
631 data collection.

632 The statistical analysis of data consists of a number of steps. The following outline of these steps
633 is typical of the analyses that a statistician would implement in support of a data quality
634 assessment.

635 CALCULATE THE BASIC STATISTICAL PARAMETERS

636 Chapter 19 has a detailed discussion of statistical issues, so a few concepts key to understanding
637 are summarized here. Statistical “parameters” are fundamental quantities that are used to describe
638 the central tendency or dispersion of the data being assessed. The mean, median, and mode are
639 examples of statistical parameters that are used to describe the central tendency, while range,
640 variance, standard deviation, coefficient of variation, and percentiles are statistical parameters
641 used to describe the dispersion of the data. These basic parameters are used because they offer a
642 means of understanding the data, facilitating communication and data evaluation, and generally
643 are necessary for subsequent statistical tests.

644 GRAPHICAL REPRESENTATIONS

645 Graphical representations of the data are similar to basic statistical parameters in that they are a
646 means of describing and evaluating data sets. Graphical representations of QC-sample results
647 used to evaluate project-specific control limits and warning limits derived from the MQO criteria
648 are discussed in Appendix C. Graphical representations of field data over space or time have the
649 additional ability of offering insights, such as identifying temporal and spatial patterns, trends,
650 and correlations. Graphical depictions are also an excellent means of communicating and
651 archiving information.

652 REVIEW AND VERIFY TEST ASSUMPTIONS

653 Statistical tests are the mathematical structure that will be employed to evaluate the project’s data
654 in terms of the project decision, question, or parameter estimate. Statistical tests are not
655 universally applicable, and their choice and suitability are based on certain assumptions. For
656 example:

- 657 • Some tests are suitable for “normal” distributions, while others are designed for other types of
658 distributions.
- 659 • Some tests assume that the data are random and independent of each other.
- 660 • Assumptions that underlie tests for “outliers” should be understood to ensure that hot spots or
661 the high concentrations symptomatic of skewed distributions (e.g., lognormal) are not
662 incorrectly censored.
- 663 • Assumptions are made regarding the types of population distributions whenever data are
664 transformed before being subjected to a test.
- 665 • Assumptions of test robustness need to be reviewed in light of the analyte. For example,
666 radiological data require statistical tests that can accommodate positive and negative numbers.

667 It is important that a knowledgeable person identify all assumptions that underlie the chosen
668 statistical tests, and that the data are tested to ensure that the assumptions are met. If any of the
669 assumptions made during planning proved to be not true, the assessment team should evaluate
670 the appropriateness of the selected statistical tests. Any decision to change statistical tests should
671 be documented in the DQA report.

672 APPLYING STATISTICAL TESTS

673 The chosen statistical tests will be a function of the data properties, statistical parameter of
674 interest, and the specifics of the decision or question. For example, choice of the appropriate tests
675 will vary according to whether the data are continuous or discrete; whether the tests will be
676 single-tailed or double-tailed, whether a population is being compared to a standard or to a
677 second population, or whether stratified sampling or simple random sampling was employed.
678 Once the statistical tests are deemed appropriate, they should be applied to the data by an
679 assessor who is familiar with statistics. The outputs from applying the statistical tests and
680 comparisons to project DQOs are discussed in the following section.

681 9.6.4.2 Evaluation of Decision Error Rates

682 The heterogeneity of the material being sampled and the imprecision of the sampling and
683 analytical processes generate uncertainty in the reported data and in the associated decisions and
684 answers. The project planning team, having acknowledging this decision uncertainty, will have
685 chosen “tolerable decision errors rates” during the planning process, which balanced resource
686 costs against the risk of making a wrong decision or arriving at a wrong answer. During this final
687 step of DQA process, the assessment team will use the project’s tolerable levels of decision error
688 rates as a metric of success.

689 The DQA process typically corrects data for known biases and then subjects the data to the
690 appropriate statistical tests to make a decision, answer a question, or supply an estimate of a
691 parameter. The assessment team will compare statistical parameters—such as the sample mean
692 and sample variance estimates employed during the planning process—to those that were
693 actually obtained from sampling. If the distribution was different, if the mean is closer to the
694 action level, or if the variance is greater or less than estimated, one or all of these factors could
695 have an impact on the certainty of the decision. The assessment team also will review the results
696 of the statistical tests in light of missing data, outliers, and rejected data. The results of the
697 statistical tests are then evaluated in terms of the project’s acceptable decision error rates. The
698 assessment team determines whether a decision could or could not be made, or why the decision
699 could not be made, within the project specified decision error rates.

700 In summary, outputs from this step are:

- 701 • Generated statistical parameters;
- 702 • Graphical representations of the data set and parameters of interest;
- 703 • If new tests were selected, the rationale for selection and the reason for the inappropriateness
704 of the statistical tests selected in the DQA plan;
- 705 • Results of application of the statistical tests; and
- 706 • A final determination as to whether the data are suitable for decision making, estimating, or
707 answering questions within the levels of certainty specified during planning.

708 **9.7 Data Quality Assessment Report**

709 The DQA process concludes with the assessment team documenting the output of the statistical
710 tests and the rationale for why a decision could or could not be made, or why the decision could
711 not be made within the project specified decision error rates. The DQA report will document
712 findings and recommendations and include or reference the supporting data and information. The
713 DQA report will summarize the use of the data verification and data validation reports for data
714 sets of concern, especially if rejected for usability in the project's decision making. The report
715 also will document the answers to the three DQA questions:

- 716 • Are the samples representative?
- 717 • Are the data accurate?
- 718 • Can a decision be made?

719 Although there is little available guidance on the format for a DQA report, the report should
720 contain, at a minimum:

- 721 • An executive summary that briefly answers the three DQA questions and highlights major
722 issues, recommendations, deviations, and needed corrective actions;
- 723 • A summary of the project DQOs used to assess data usability, as well as pertinent
724 documentation such as the project plan document, contracts, and SOW;
- 725 • A listing of those people who performed the DQA;
- 726 • A summary description of the DQA process, as employed, with a discussion of any deviations
727 from the DQA plan designed during the planning process (the DQA plan should be appended
728 to the report);
- 729 • A summary of the data verification and data validation reports that highlights significant
730 findings and a discussion of their impact on data usability (the data verification and data
731 validation reports should be appended to the DQA report);
- 732 • A discussion of any missing documentation or information and the impact of their absence on
733 the DQA process and the usability of the data;

- 734 • A thorough discussion of the three DQA questions addressing the details considered in
735 Sections 9.6.2 through 9.6.4 (possible outputs to be incorporated in the report are listed at the
736 conclusion of each these section);
- 737 • A discussion of deviations, sampling, analytical and data management problems, concerns,
738 action items, and suggested corrective actions (the contents of this section should be
739 highlighted in the executive summary if the project is ongoing and corrections or changes are
740 needed to improve the quality and usability of future data); and
- 741 • A recommendation or decision on the usability of the data set for the project's decision
742 making.

743 Upon completion, the DQA report should be distributed to the appropriate personnel as specified
744 in the DQA plan and archived along with supporting information for the period of time specified
745 in the project plan document. Completion of the DQA report concludes the assessment phase and
746 brings the data life cycle to closure.

747 **Summary of Recommendations**

- 748 • MARLAP recommends that the assessment phase of a project (verification, validation, and
749 DQA processes) be designed during the directed planning process and documented in the
750 respective plans as part of the project plan documents.
- 751 • MARLAP recommends that project objectives, implementation activities, and QA/QC data
752 be well documented in project plans, reports, and records, since the success of the
753 assessment phase is highly dependent upon the availability of such information.
- 754 • MARLAP recommends the involvement of the data assessment specialist(s) on the project
755 planning team during the directed planning process.
- 756 • MARLAP recommends that the DQA process should be designed during the directed
757 planning process and documented in a DQA plan.
- 758 • MARLAP recommends that all sampling design and statistical assumptions be clearly
759 identified in project plan documents along with the rationale for their use.

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