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 ("Key MARLAP Concepts and Terminology") and the Glossary and discusses assessment in Section 8.2 ("Data Assessment Process").

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, 2000a and b; 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 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

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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.

9.2 Assessment Phase

The assessment phase is discussed in Section 8.2. This present section provides a brief overview of the individual assessment processes, their distinctions, and how they interrelate.

"Data verification" generally evaluates compliance of the analytical process with project-plan and other project-requirement documents, and the statement of work (SOW), and documents compliance and noncompliance in a data verification report. Data verification is a separate activity in addition to the checks and review done by field and laboratory personnel during implementation. Documentation generated during the implementation phase will be used to determine if the proper procedures were employed and to determine compliance with project plan documents (e.g., QAPP), contract-specified requirements, and measurement quality objectives (MQOs). Any data associated with noncompliance will be identified as an "exception," which should elicit further investigation during data validation.

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

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

While both data validation and DQA processes address usability, the processes address usability from different perspectives. "Data validation" attempts to interpret the *impacts of exceptions*

identified during verification and the impact of project activities on the usability of an individual datum. In contrast, "data quality assessment" considers the *results of data validation* while evaluating the usability of the entire data set.

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

In summary, data validation is a transition from the compliance testing of data verification to usability determinations. The results of data validation, as captured in the qualified data and validation reports, will greatly influence the decisions made during the final assessment process, which is discussed in Section 9.6 ("Data Quality Assessment Process).

9.3 Graded Approach to Assessment

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

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

9.4 The Data Quality Assessment Team

The project planning team is responsible for ensuring that its decisions are scientifically sound and comply with the tolerable decision-error rates established during planning. MARLAP recommends the involvement of the data assessment specialist(s) on the project planning team

during the directed planning process. This should result in a more efficient assessment plan and should increase the likelihood that flaws in the design of the assessment processes will be detected and corrected during planning. Section 2.4 ("The Project Planning Team") notes that it is important to have an integrated team of operational and technical experts. The data assessment specialist(s) who participated as members of the planning team need not be the final assessors. However, using the same assessors who participated in the directed planning process is advantageous, since they will be aware of the complexities of the project's goals and activities.

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

9.5 Data Quality Assessment Plan

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

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

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

The DQA plan should contain the following information:

- A short summary and citation to the project documentation that provides sufficient detail about the project objectives (DQOs), sample and analyte lists, required detection limit, action level, and level of acceptable uncertainty on a sample- or analyte-specific basis;

- Specification of the necessary sampling and analytical assessment criteria (typically expressed as MQOs for selected parameters such as method uncertainty) that are appropriate for measuring the achievement of project objectives and constitute a basis for usability decisions;

- Identification of the actual assessors or the required qualifications and expertise that are required for the assessment team performing the DQA (Section 9.4);

- A description of the steps and procedures (including statistical tests) that will constitute the DQA, from reviewing plans and implementation to authoring a DQA report;

- Specification of the documentation and information to be collected during the project's implementation;

- A description for any project-specific notification or procedures for documenting the usability or non-usability of data for the project's decisionmaking;

- A description of the content of the DQA report;

- A list of recipients for the DQA report; and

- 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, 2000a and b; 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	• 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 • DQOs (as established for assessment) if a clear description of the DQOs does not exist
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 (b) SOPs for sampling (c) Sample handing and preservation requirements of the analytical protocol specifications	• Documentation of all assumptions as potential limitations and, if possible, a description of their associated ramifications • Determination of whether the design resulted in a representative sampling of the population of interest • Determination of whether the sampling locations introduced bias • Determination of whether the sampling equipment used, as described in the sampling procedures, was capable of extracting a representative set of samples from the material of interest • 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

DQA PROCESS	Input	Output for DQA Report
3. Are the Data Accurate?	The project plan documents (or a cited stand-alone document) which address: (a) The analysis portion of the Sampling and Analysis Plan (b) Analytical protocol specifications, including quality control requirements and MQOs (c) SOW (d) The selected analytical protocols and other SOPs (e) Ongoing evaluations of performance (f) Data Verification and Validation plans and reports	• Determination of whether the selected methods were appropriate for the intended applications • Identification of any potential sources of inaccuracy • Assessment of whether the sample analyses were implemented according to the analysis plan • Evaluation of the impact of any deviations from the analysis plan on the usability of the data set
4. Can a Decision be Made?	The project plan document (or a cited stand-alone document) that addresses: (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 tolerable decision error rates were met • Final determination of whether the data are suitable for decisionmaking, estimating, or answering questions within the levels of certainty specified during planning

9.6.1 Review of Project Documents

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

9.6.1.1 The Project DQOs and MQOs

Since the usability of data is measured in terms of the project DQOs, the first step in the DQA process is to acquire a thorough understanding of the DQOs. If the DQA will be performed by more than one assessor, it is essential that the assessment team shares a common understanding

of the project DQOs and tolerable decision error rates. The assessment team will refer to these DQOs continually as they make determinations about data usability. The results of the directed planning process should have been documented in the project plan documents. The project plan documents, at a minimum, should describe the DQOs and MQOs clearly and in enough detail that they are not subject to misinterpretation or debate at this last phase of the project.

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

9.6.1.2 The DQA Plan

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

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

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

9.6.1.3 Summary of the DQA Review

The review of project documents should result in:

- An identification and understanding of project plan documents, including any changes made to them and any problems encountered with them;

- A clear understanding of the DQOs for the project. If a clear description of the DQOs does not exist, the assessment team should reach consensus on the DQOs prior to commencing the DQA and record the DQOs (as they were established for assessment) as part of the DQA report; and

- A clear understanding of the terminology, procedures, and criteria for the DQA process.

9.6.2 Sample Representativeness

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

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

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

9.6.2.1 Review of the Sampling Plan

The sampling plan and its ability to generate representative samples are assessed in terms of the project DQOs. The assessors review the project plan with a focus on the approach to sample collection, including sample preservation, shipping and subsampling in the field and laboratory, and sampling standard operating procedures (SOPs). Ideally the assessors would have been involved in the planning process and would be familiar with the DQOs and MQOs and the decisions made during the selection of the sampling and analysis design. If the assessors were part of the project planning team, this review to become familiar with the project plan will go

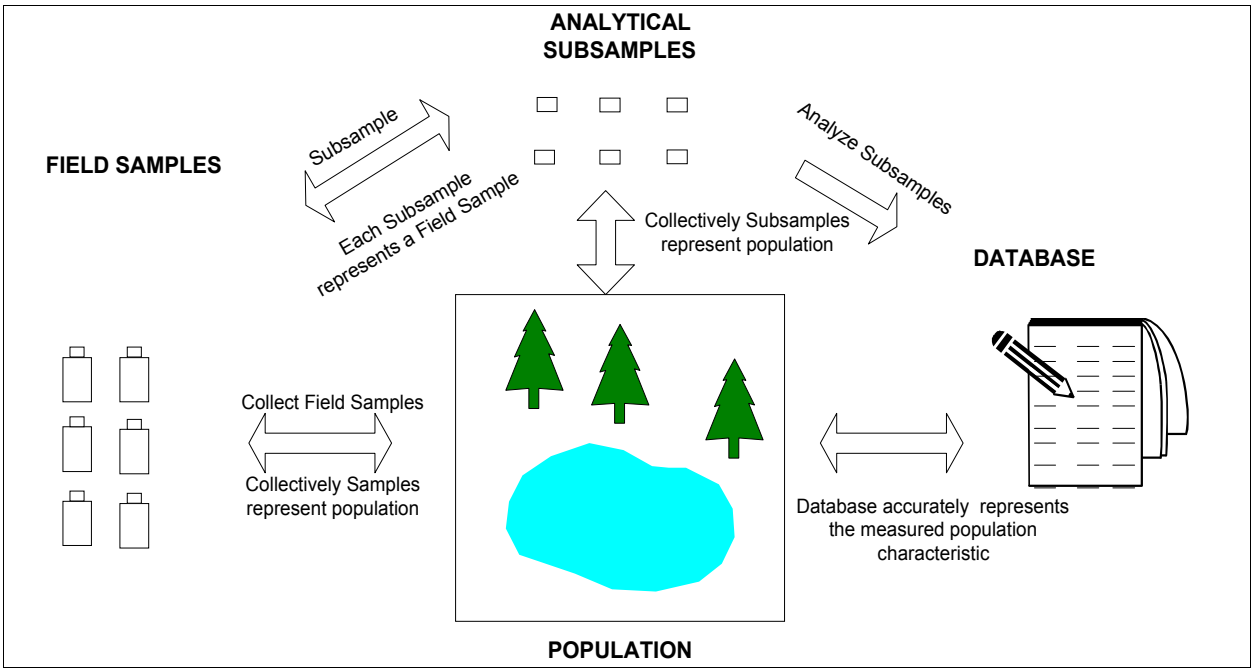

FIGURE 9.1 — Using physical samples to measure a characteristic of the population representatively.

quickly, and the team can focus on deviations from the plan that will introduce unanticipated imprecision or bias (Section 9.6.2.2).

APPROACH TO SAMPLE COLLECTION

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

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

Optimizing the data collection activity (Section 2.5.4 and Appendix B3.8) involves a number of assumptions. These assumptions are generally employed to manage a logistical, budgetary, or other type of constraint, and are used instead of additional sampling or investigations. The

assessment team needs to understand these assumptions in order to fulfill its responsibility to review and evaluate their continued validity based on the project's implementation. The assessment team should review the bases for the assumptions made by the planning team because they can result in biased samples and incorrect conclusions. For example, if samples are collected from the perimeter of a lagoon to characterize the contents of the lagoon, the planning team's assumption was that the waste at the lagoon perimeter has the same composition as that waste located in the less-accessible center of the lagoon. In this example, there should be information to support the assumption, such as historical data, indicating that the waste is relatively homogenous and well-mixed. Some assumptions will be stated clearly in project plan documents. Others may only come to light after a detailed review. The assessment team should review assumptions for their scientific soundness and potential impact on the representativeness of the samples.

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

SAMPLING SOPS

Standard operating procedures for sampling should be assessed for their appropriateness and scientific soundness. The assessment team should assess 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. The team also should assess whether the equipment's composition was compatible with the analyte of interest. At this stage, the assessment team assumes the sampling device was employed according to the appropriate SOP. Section 9.6.2.2 discusses implementation and deviations from the protocols.

In summary, the assessment team should investigate whether:

- The sampling device was compatible with the material being sampled and with the analytes of interest;
- The sampling device accommodated all particle sizes and did not discriminate against portions of the material being sampled;
- The sampling device avoided contamination or loss of sample components;
- The sampling device allowed access to all portions of the material of interest;

- The sample handling, preparation, and preservation procedures maintained sample integrity; and

- The field and laboratory subsampling procedures resulted in a subsample that accurately represents the contents of the original sample.

These findings should be detailed in the DQA report.

9.6.2.2 Sampling Plan Implementation

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

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

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

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

9.6.2.3 Data Considerations

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

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

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

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

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

- An identification of any assumptions that present limitations and, if possible, a description of their associated ramifications;
- A determination of whether the design resulted in a representative sampling of the population of interest;
- A determination of whether the specified sampling locations, or alternate locations as reported, introduced bias;
- A determination of whether the sampling equipment used, as described in the sampling procedures or as implemented, was capable of extracting a representative set of samples from the material of interest; and
- An evaluation of the necessary deviations from the plan, as well as those deviations resulting from misunderstanding or error, and a determination of their impact on the representativeness of the affected samples.

The product of this step is a set of findings regarding the impact of representativeness—or the lack thereof—that affects data usability. Findings and determinations regarding representativeness will impact the usability of the resulting data to varying degrees. Some findings may be so significant (e.g., the wrong waste stream was sampled) that the samples can be determined to be non-representative and the associated data cannot be used; as a result, the DQA need not progress any further. Typically, findings will be subject to interpretation, and the impacts on representativeness will have to be evaluated in light of other DQA findings to determine the usability of data.

9.6.3 Data Accuracy

The next step in the DQA process is the evaluation of the analysis process and accuracy of the resulting data. The term "accuracy" describes the closeness of the result of a measurement to the true value of the quantity being measured. The accuracy of results may be affected by both imprecision and bias in the measurement process, and by blunders and loss of statistical control (see Chapter 19, *Measurement Uncertainty*).

Since MARLAP uses "accuracy" only as a qualitative concept, in accordance with the *International Vocabulary of Basic and General Terms in Metrology* (ISO, 1993), the agreement between measured results and true values is evaluated quantitatively in terms of the "precision" and "bias" of the measurement process. "Precision" usually is expressed as a standard deviation, which measures the dispersion of results about their mean. "Bias" is a persistent deviation of results from the true value (see Section 6.5.5.7, "Bias Considerations").

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

Bias can be identified and controlled through the application of quantitative MQOs to QC samples, such as blanks, standard reference materials, performance testing samples, calibration check standards, and spikes samples. Blunders (e.g., a method being implemented incorrectly, such as reagents being added in the incorrect order) are usually identified and controlled by well-designed plans that specify quality assurance systems that detail needed training, use of appropriate SOPs, deficiency reporting systems, assessments, and quality improvement processes.

Bias in a data set may be produced by measurement errors that occur in steps of the measurement process that are not repeated. Imprecision may be produced by errors that occur in steps that are repeated many times. The distinction between bias and imprecision is complicated by the fact that some steps, such as instrument calibration and tracer preparation and standardization, are repeated at varying frequencies. For this reason, the same source of measurement error may produce an apparent bias in a small data set and apparent imprecision in a larger data set. During data assessment, an operational definition of bias is needed. This would normally be determined by the data assessment specialist(s) on the project planning team during the directed planning process. For example, a bias may exist if results for analytical spikes (i.e., laboratory control samples, matrix spike, matrix spike duplicate), calibration checks, and performance evaluation samples associated with the data set are mostly low or mostly high, if the results of method blank analyses tend to be positive or negative, or if audits uncover certain types of biased implementation of the SOPs. At times, the imprecision of small data sets can incorrectly indicate a bias, while at other times, the presence of bias may be masked by imprecision. For example, two or three samples may be all high or all low by chance, and may be a result of imprecision rather than bias. On the other hand, it is unlikely that ten samples would all be high or low, and such an occurrence would be indicative of bias. Statistical methods can be applied to imprecise data sets and used to determine if there are statistically significant differences between data sets or between a data set and an established value. If the true value or reference value (e.g., verified concentration for a standard reference material) is known, then statistics can be used to determine whether there is a bias.

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

Each target in Figure 9.2 has an associated frequency distribution curve. Frequency curves are made by plotting a concentration value versus the frequency of occurrence for that concentration. Statisticians employ frequency plots to display the precision of a sampling and analytical event, and to identify the type of distribution. The curves show that as precision decreases the curves flatten-out and there is a greater frequency of measurements that are distant from the average value (Figures 9.2c and d). More precise measurements result in sharper curves (Figures 9.2a and b), with the majority of measurements relatively closer to the average value. The greater the bias (Figures 9.2b and d), the further the average of the measurements is shifted from the true value. The smaller the bias (Figures 9.2a and c), the closer the average of the measurements is to the true value.

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

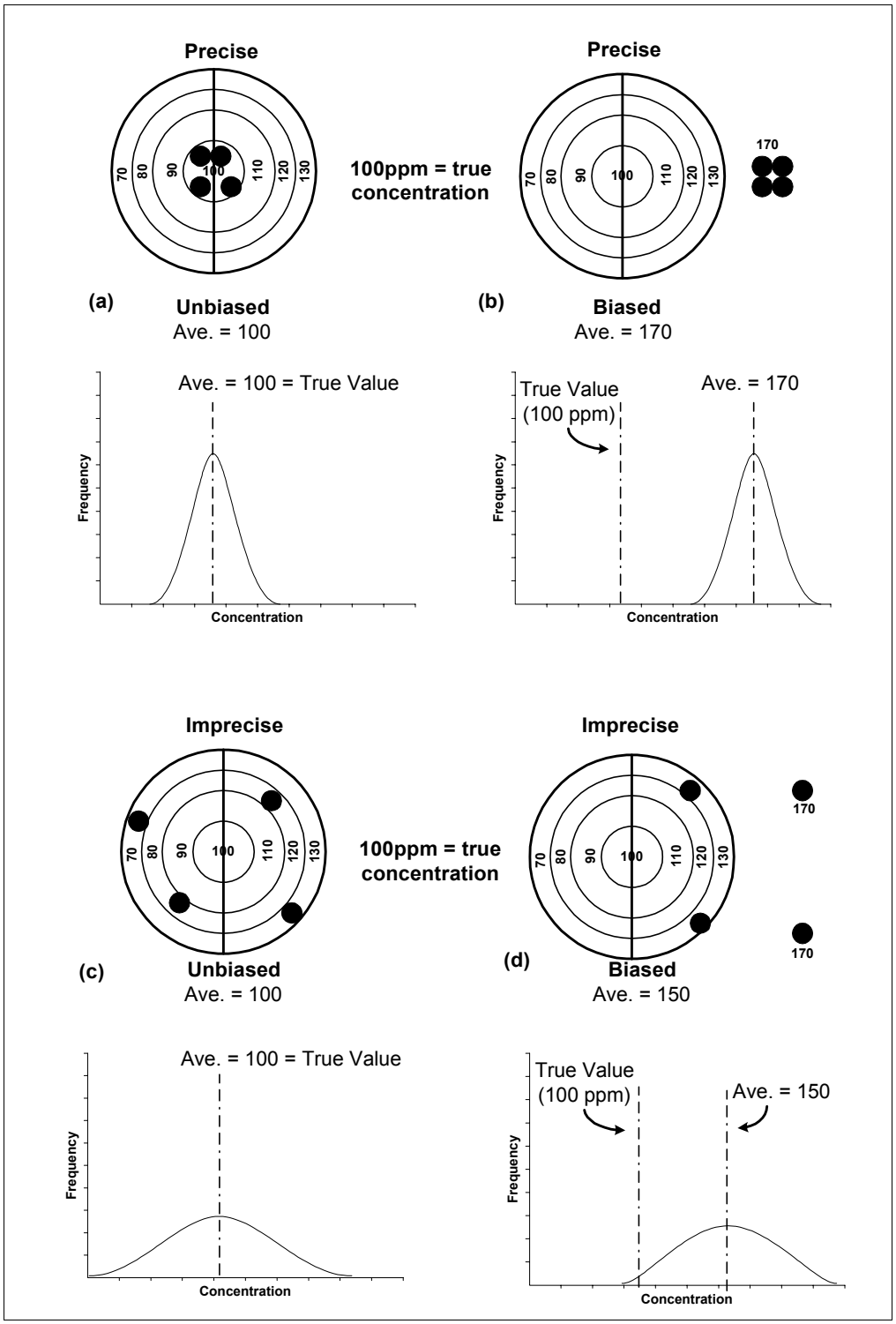

FIGURE 9.2 — Types of sampling and analytical errors.

9.6.3.1 Review of the Analytical Plan

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

REVIEW OF THE MQOS, ANALYTICAL PROTOCOL SPECIFICATIONS, AND OPTIMIZED ANALYTICAL DESIGN

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

As with the approach to sample collection, optimizing the analytical activity involved a number of assumptions. Assumptions were made when analytical issues were resolved during planning and the decisions were documented in the analytical protocol specifications (Chapter 3). It is important for the assessment team to be aware of these assumptions because they can result in biases and incorrect conclusions. Some assumptions will be clearly stated in the project plan documents. Others may only come to light after a detailed review. The assessment team should review assumptions for their scientific soundness and potential impact on the data results.

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

REVIEW OF THE ANALYTICAL PROTOCOLS

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

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

REVIEW OF VERIFICATION AND VALIDATION PLANS

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

9.6.3.2 Analytical Plan Implementation

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

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

- Laboratory subsampling procedures that resulted in the subsample that may not accurately represent the content of the original sample;
- Sample dissolution methods that may not have dissolved sample components quantitatively;
- Separation methods whose partitioning coefficients were not applicable to the sample matrix;
- Unanticipated self-absorption that biased test-source measurements;
- Non-selective detection systems that did not resolve interferences; or
- Data reduction routines that lacked needed resolution or appropriate interference corrections.

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

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

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

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

The prior verification and validation processes and the prior DQA steps involving the evaluation of sampling are all an attempt to define the quality of data by (1) discovering sources of bias, quantifying their impact, and correcting the reported data; and (2) identifying and quantifying data precision. The products of this step are a set of findings regarding the analytical process and their impact on data usability. Some findings may be so significant (e.g., the wrong analytical method was employed) that the associated data cannot be used, and as a result, the DQA need not progress any further. Typically, findings will be subject to interpretation and a final

determination as to the impacts will have to wait until the data has been subjected to evaluations described in Section 9.6.4.

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

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

9.6.4 Decisions and Tolerable Error Rates

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

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

9.6.4.1 Statistical Evaluation of Data

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

Sampling and inferential statistics have identical goals—to use samples to make inferences about a population of interest and to use sample data to make defensible decisions. This similarity is

the reason why planning processes, such as those described in Chapter 2, couple sample collection activities with statistical techniques to maximize the representativeness of samples, the accuracy of data, and the certainty of decisions.

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

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

- If the characteristic of interest in a sample is more similar to that of samples adjacent to it than to samples that are further removed, the samples are deemed to be "correlated" and are not independent of each other (i.e., there is a serial correlation such that samples collected close in time or space have more similar concentrations than those samples further removed). Conventional parametric and non-parametric statistics require that samples be independent and are not applicable to populations that have significantly correlated concentrations.

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

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

CALCULATE THE BASIC STATISTICAL PARAMETERS

Statistical "parameters" are fundamental quantities that are used to describe the central tendency or dispersion of the data being assessed. The mean, median, and mode are examples of statistical parameters that are used to describe the central tendency, while range, variance, standard deviation, coefficient of variation, and percentiles are statistical parameters used to describe the dispersion of the data. These basic parameters are used because they offer a means of understanding the data, facilitating communication and data evaluation, and generally are necessary for subsequent statistical tests.

GRAPHICAL REPRESENTATIONS

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

REVIEW AND VERIFY TEST ASSUMPTIONS

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

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

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

APPLYING STATISTICAL TESTS

The chosen statistical tests will be a function of the data properties, statistical parameter of interest, and the specifics of the decision or question. For example, choice of the appropriate tests

will vary according to whether the data are continuous or discrete; whether the tests will be single-tailed or double-tailed, whether a population is being compared to a standard or to a second population, or whether stratified sampling or simple random sampling was employed. Once the statistical tests are deemed appropriate, they should be applied to the data by an assessor who is familiar with statistics. The outputs from applying the statistical tests and comparisons to project DQOs are discussed in the following section. Appropriate statistical tests and guidance on their use are available from many sources, including EPA (2000b).

9.6.4.2 Evaluation of Decision Error Rates

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

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

In summary, outputs from this step are:

- Generated statistical parameters;
- Graphical representations of the data set and parameters of interest;
- If new tests were selected, the rationale for selection and the reason for the inappropriateness of the statistical tests selected in the DQA plan;
- Results of application of the statistical tests; and

- A final determination as to whether the data are suitable for decisionmaking, estimating, or answering questions within the levels of certainty specified during planning.

9.7 Data Quality Assessment Report

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

- Are the samples representative?
- Are the data accurate?
- Can a decision be made?

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

- An executive summary that briefly answers the three DQA questions and highlights major issues, recommendations, deviations, and needed corrective actions;

- A summary of the project DQOs used to assess data usability, as well as pertinent documentation such as the project plan document, contracts, and SOW;

- A listing of those people who performed the DQA;

- A summary description of the DQA process, as employed, with a discussion of any deviations from the DQA plan designed during the planning process (the DQA plan should be appended to the report);

- A summary of the data verification and data validation reports that highlights significant findings and a discussion of their impact on data usability (the data verification and data validation reports should be appended to the DQA report);

- A discussion of any missing documentation or information and the impact of their absence on the DQA process and the usability of the data;

- A thorough discussion of the three DQA questions addressing the details considered in Sections 9.6.2 through 9.6.4 (possible outputs to be incorporated in the report are listed at the conclusion of each these section);

- A discussion of deviations, sampling, analytical and data management problems, concerns, action items, and suggested corrective actions (the contents of this section should be highlighted in the executive summary if the project is ongoing and corrections or changes are needed to improve the quality and usability of future data); and

- A recommendation or decision on the usability of the data set for the project's decision-making.

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

9.8 Summary of Recommendations

- MARLAP recommends that the assessment phase of a project (verification, validation, and DQA processes) be designed during the directed planning process and documented in the respective plans as part of the project plan documents.

- MARLAP recommends that project objectives, implementation activities, and QA/QC data be well documented in project plans, reports, and records, since the success of the assessment phase is highly dependent upon the availability of such information.

- MARLAP recommends the involvement of the data assessment specialist(s) on the project planning team during the directed planning process.

- MARLAP recommends that the DQA process should be designed during the directed planning process and documented in a DQA plan.

- MARLAP recommends that all sampling design and statistical assumptions be clearly identified in project plan documents along with the rationale for their use.

9.9 References

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