



## U.S. Navy Human Health Risk Assessment Guidance

# Chapter 6 – Data Quality Objectives for Risk Assessment

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## 6.0 Introduction

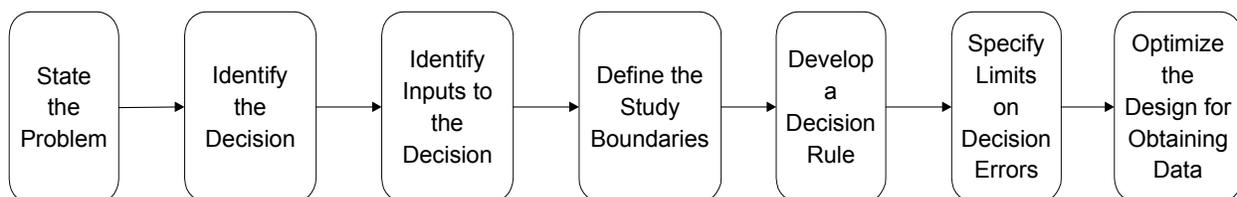
This chapter presents the approach for using Data Quality Objectives (DQOs) as strategic planning tools that can be used to ensure that the type, amount, and quality of the data collected is appropriate to meet project objectives. This issue is particularly important since the analytical data collected during environmental investigations typically serve numerous purposes (e.g., site characterization, risk assessment, design of remedial alternatives, etc.). [Figure 6.1](#) presents an overview of the DQO process.

One important benefit of the DQO process is that it provides investigators with a reliable approach for clarifying how decisions about a site will be supported by environmental data and for establishing site-specific performance criteria for these decisions. In general, the DQO process also:

- ◆ increases efficiency by generating the appropriate type (i.e., using appropriate data collection and analysis methods) and appropriate amount of data necessary to answer site-specific, study questions;
- ◆ improves the application and interpretation of sampling designs by using statistical and scientific principles for optimization;
- ◆ addresses the right questions early in the investigation by obtaining better knowledge of the chemicals involved;
- ◆ helps investigators conserve resources by determining which data-collection and analysis methods are most appropriate for the data quality needs of the study; and
- ◆ provides investigators with cutoff criteria – a way for the planning team to determine when enough data of sufficient quality have been collected to make site decisions with the desired level of confidence (USEPA, 2000).

The following sections describe the purpose of DQOs and how DQOs are considered as part of sampling methods, sample analysis issues, risk-based detection limits, data validation procedures, and data management.

**Figure 6.1 – Overview of the Data Quality Objectives Process**



## 6.1 Purpose and Objectives

DQOs are qualitative and quantitative statements established prior to data-collection, which specify the quality and quantity of the data required to support decisions during remedial response activities. The DQOs for a particular site vary according to the end-use of the data (USEPA, 1989). While DQOs should be identified for every project, the need for formal DQO planning sessions varies based on project needs and project complexity. In some cases the project objectives and data needs are so clear (or so prescriptive) that the DQOs are easily established by the Remedial Project Manager (RPM) alone, and the documentation for the DQO process fits on a single sheet of paper. In other cases, the DQO process may require a considerable investment of time and resources, as well as input from technical experts (e.g., risk assessors, geologists, and engineers).



United States Environmental Protection Agency (USEPA) Guidance defines the DQO Process as a seven-step iterative planning approach for environmental data-collection activities. It provides a systematic approach for defining the criteria that a data-collection design should satisfy, including when, where, and how to collect samples or measurements; determination of tolerable decision error rates; and the number of samples or measurements that should be collected (USEPA, 2000 & USEPA, 1999a). The key steps in the process, as identified by the USEPA, are presented in Table 6.1.

**Table 6.1 – USEPA DQO Process, Activities and Outcomes (USEPA, 2000 & USEPA, 1999a)**

Description	Activities	Outcomes
<b>1. State the Problem</b>		
<ul style="list-style-type: none"> <li>Define the problem; identify the planning team.</li> <li>Develop conceptual site model.</li> <li>Examine budget, schedule.</li> </ul>	<ul style="list-style-type: none"> <li>Identify members of the planning team.</li> <li>Develop/refine the conceptual site model.</li> <li>Define the exposure scenarios.</li> <li>Specify the available resources and constraints.</li> </ul>	<ul style="list-style-type: none"> <li>Description of the contamination problem with its regulatory and programmatic context.</li> <li>A CSM.</li> <li>Estimate of the budget, schedule, and personnel necessary to implement the appropriate response for the site.</li> </ul>
<b>2. Identify the Decision</b>		
<ul style="list-style-type: none"> <li>State decision.</li> <li>Identify study question.</li> <li>Define alternative actions.</li> </ul>	<ul style="list-style-type: none"> <li>Identify the principal study question.</li> <li>Define the alternative actions that could result from the resolution of the principal study question.</li> <li>Combine the principal study question and the alternative actions into a decision statement.</li> <li>Organize multiple decisions.</li> </ul>	<ul style="list-style-type: none"> <li>A decision statement or set of statements that link the principal study question to possible or potential actions that will resolve the problem.</li> </ul>
<b>3. Identify Inputs to the Decision</b>		
<ul style="list-style-type: none"> <li>Identify information needed for the decision (information sources, basis for Action Level, sampling/analysis method).</li> </ul>	<ul style="list-style-type: none"> <li>Identify the information that will be required to resolve the decision statement.</li> <li>Determine the sources for each item of information identified.</li> <li>Identify the information needed to establish the action level.</li> <li>Confirm that appropriate analytical methods exist to provide the necessary data.</li> </ul>	<ul style="list-style-type: none"> <li>A list of informational inputs needed to resolve the decision statement and the sources of that information, including new environmental measurements.</li> </ul>
<b>4. Define the Study Boundaries</b>		
<ul style="list-style-type: none"> <li>Specify sample characteristics.</li> <li>Define spatial/temporal limits, units of decision-making.</li> </ul>	<ul style="list-style-type: none"> <li>Define the geographic area to which the decision statement applies.</li> <li>Specify the characteristics that define the population of interest.</li> <li>When appropriate, divide the population into strata that have relatively homogenous characteristics.</li> <li>Define the scale of decision-making.</li> <li>Identify any practical constraints on data collection.</li> <li>Determine the time frame to which the decision applies.</li> <li>Determine when to collect data.</li> </ul>	<ul style="list-style-type: none"> <li>A detailed description of the characteristics that define the population of interest.</li> <li>A detailed description and illustration of the geographic limits of each environmental medium (e.g., soil, water, air) within which the field investigation will be carried out.</li> <li>The time period in which samples will be taken and to which decisions will apply.</li> <li>The most appropriate scale of decision making for each medium of concern.</li> <li>A description of practical constraints that may impede sampling.</li> </ul>
<b>5. Develop a Decision Rule</b>		
<ul style="list-style-type: none"> <li>Define statistical parameter (mean, median).</li> <li>Specify Action Level.</li> <li>Develop logic for action.</li> </ul>	<ul style="list-style-type: none"> <li>Specify the action level for the decision.</li> <li>Specify the statistical parameter (such as mean, median, maximum, or proportion) that characterizes the population of interest.</li> <li>Combine the outputs from the previous DQO steps and develop a decision rule.</li> <li>Confirm that measurement detection limits will allow reliable comparisons with action level.</li> </ul>	<ul style="list-style-type: none"> <li>The output of this step is the "if...then..." decision rules that capture the decision rule logic.</li> </ul>



Table 6.1 – USEPA DQO Process, Activities and Outcomes (USEPA, 2000 & USEPA, 1999a)

Description	Activities	Outcomes
<b>6. Specify Limits on Decision Errors</b>		
<ul style="list-style-type: none"> <li>Specify the decision maker's acceptable limits on decision errors, which are used to establish performance goals for limiting uncertainty in the data.</li> </ul>	<ul style="list-style-type: none"> <li>Determine the possible range of the parameter of interest.</li> <li>Specify a range of possible parameter values where the consequences of a false negative decision error are relatively minor (gray region).</li> <li>Assign probability values to points above and below the action level that reflect the tolerable probability for the occurrence of decision errors.</li> <li>Define both types of decision errors and their potential consequences and select the baseline condition.</li> </ul>	<ul style="list-style-type: none"> <li>The site manager's tolerable decision limits based on a consideration of the consequences of making an incorrect decision.</li> </ul>
<b>7. Optimize the Design for Obtaining Data</b>		
<ul style="list-style-type: none"> <li>Select resource-effective sampling and analysis plan that meets the performance criteria.</li> </ul>	<ul style="list-style-type: none"> <li>Review the DQO outputs and existing environmental data.</li> <li>Develop general data-collection design alternatives.</li> <li>Formulate the mathematical expressions necessary for each design alternative.</li> <li>Select the most resource-effective design that satisfies all DQOs.</li> <li>Document the operational details and theoretical assumptions of the selected design in the Quality Assurance Project Plan (QAPP).</li> <li>Select the sample size that satisfies the DQOs for each design alternative.</li> </ul>	<ul style="list-style-type: none"> <li>The outputs for this step include the optimal (most resource-effective) data-collection design for the field investigation.</li> <li>Documentation of the key assumptions underlying the design.</li> </ul>

The outputs of the DQO Process are qualitative and quantitative statements that are developed in the first six steps of the DQO Process. DQOs define the purpose of the data-collection effort, clarify what the data should represent to satisfy this purpose, and specify the performance requirements for the quality of information to be obtained from the data. These outputs are then used in the seventh and final step of the DQO Process to develop a data-collection design that meets all performance criteria and other design requirements and constraints. The DQO Process is iterative and is allowed to terminate when the DQO outputs are acceptable to the decision-maker with respect to potential decision error rates and expenditure of resources. Numerous USEPA data quality objective procedural and guidance documents can be found at [http://www.epa.gov/quality1/qa\\_docs.html](http://www.epa.gov/quality1/qa_docs.html).

*Note: The data generated during site investigations serve as the foundation for all of the decisions that are made concerning the site. Data management though, is often an overlooked or de-emphasized aspect of environmental investigations. It is important to have a data management plan that results in a logical and systematic approach for electronic data-collection. The data management plan should take into account what information the end users need, how the users will retrieve the information, and how to ensure and to document the accuracy of the data management system. The data management plan should encompass the activities from sample collection through data validation and use of the data by risk assessors and others. Involving a data manager early in the process will ensure that electronic data of known quality are readily available which will reduce the level of effort for the rest of the project team.*

## 6.2 Sampling Methods

### 6.2.1 SAMPLING DATA QUALITY OBJECTIVES

In general, there is a limited budget and different objectives being pursued by the project team, regulators, and other stakeholders. These differences typically result in negotiations that shape the resulting sampling plans. Consequently, it is important to include regulators and stakeholders in the sampling design process. The following considerations should be taken into account when developing DQOs for sampling plans:



- ♦ objectives of the study;
- ♦ cost-effectiveness of alternative sampling designs;
- ♦ patterns of environmental contamination and variability; and
- ♦ practical considerations – such as convenience, site accessibility and availability, security of sampling equipment, and political considerations (Gilbert, 1997).

While it is important to carefully consider all four criteria when developing sampling plans for sites, risk assessors are primarily focused on patterns of environmental contamination and variability.

The primary DQO for environmental sampling, from a risk assessment point of view, is to determine exposure point concentrations for chemicals of potential concern (COPC) that are representative of conditions that people encounter. Usually site sampling plans focus on primary and secondary source areas, modes of contaminant transport, and potential human exposure points as identified in the CSM. In other cases, sites are subdivided first – based on exposure scenario (e.g., industrial area vs. open space), and then data are gathered or grouped together accordingly.

## 6.2.2 SAMPLING METHODOLOGIES

There are a number of different ways to collect samples at sites – including the purposive, systematic, and random sampling methodologies that are summarized below:

- ♦ **Purposive** sampling involves using knowledge about a site such as historical information, contamination information, or disposal practices to select sample locations. Purposive sampling might be undertaken in an area where the maximum impacts at a site might be expected (e.g., immediately adjacent to a spill area) to provide initial information on the nature and extent of contamination;
- ♦ **Systematic** sampling consists of collecting samples at locations and times according to spatial or temporal patterns. The most common systematic sampling approach is to overlay a grid on an area and then collect a sample at each grid node; and
- ♦ **Random** sampling involves collecting samples from locations at a site in manner such that each location has an equal probability of being sampled (Gilbert, 1997).

In some cases these approaches may be combined. For example, a systematic grid might be developed and then samples could be randomly collected within each grid cell.

## 6.2.3 DISCRETE VS. COMPOSITE SAMPLES

A discrete sample, or grab sample, is a single sample obtained from a single location and time. A composite sample represents the mixing of two or more discrete samples. Composite samples may introduce sampling errors through inadequate mixing, and provide less information about the nature and extent of contamination than discrete samples. If extreme values are a concern, compositing may result in diluting the higher samples (e.g., combining one high sample with four low samples) and masking the presence of a hotspot. The degree that samples are diluted depends on how many discrete samples are included in the composite sample.

In general, discrete samples are preferable because they provide more information about the nature (including variability) and extent of contamination. In addition, these data can be combined in order to determine an average concentration.

From a risk assessment perspective, composite sample results are useful because, in general, people are exposed to the average concentration in an area. For example, it might make sense to take a composite sample in a relatively small, individual-exposure area (e.g., an individual residence) in order to ensure that



the average exposure point concentration is less than the site-specific project goals. Compositing samples is most useful in situations where sampling or analytical costs are high, such as when dioxins are involved.

## 6.3 Sample Analysis

### 6.3.1 SELECTION OF ANALYTICAL METHODS

An important DQO at every site is to determine which chemicals are likely to be present in the media of concern. Historical information (e.g., previous sampling results, chemical processes, disposal practices) should be used to focus the analytical program on chemicals that are known, or suspected to be present at the site. This means that not every sample should be analyzed for the full Target Compound List (TCL) and Target Analyte List (TAL). In fact, chemicals should be eliminated from consideration if there are compelling data – such as the case when chemicals have not been detected during multiple rounds of sampling. The USEPA recommends to, in general, “eliminate those chemicals that have not been detected in any samples of a particular medium (USEPA, 1989).” This principle should be applied when possible.

Reducing the number of chemicals being analyzed can have a positive impact on the budget, because potentially costly analytical methods can be eliminated from the sampling and analysis plan. This may also allow for more sampling focused on the COPCs that are likely to be responsible for the majority of the risk.

*Note: It is important that the rationale for excluding chemicals from consideration is well documented, because COPC identification is a key step in the risk assessment process and will likely be scrutinized by regulators and stakeholders.*

There are some types of data that are potentially unsuitable for a quantitative risk assessment, examples of which are presented in [Table 6.2](#). These types of data though, may be very useful for site characterization and field-screening purposes.

**Table 6.2 – Examples of the Types of Data Potentially Unsuitable for a Quantitative RA**

Analytical Instrument or Method	Purpose of Analysis	Analytical Result
HNu Organic Vapor Detector	Health and Safety, Field Screen	Total organic vapor
Organic Vapor Analyzer	Health and Safety, Field Screen	Total organic vapor
Combustible Gas Indicator	Health and Safety	Combustible vapors, oxygen-deficient atmosphere
Field Gas Chromatography <sup>(a)</sup>	Field Screen/Analytical Method	Specific volatile and semi-volatile organic chemicals

<sup>(a)</sup> Depending on the detector used, this instrument can be sufficiently sensitive to yield adequate data for use in a quantitative risk assessment; however, a confirming analysis by gas chromatography/mass spectroscopy (GC/MS) should be performed on a subset of the samples in a laboratory prior to use.

### 6.3.2 DETECTION LIMITS

Typically, one step in the risk assessment process is to compare chemical concentrations in environmental media to risk-based concentrations (RBCs), standards, or other criteria. Consequently, analytical methods should be selected so that the detection limits are less than the concentration of interest. For example, in the absence of appropriate analytical methods, non-detected data (if taken at the detection limit) may exceed the RBCs, and a chemical would be considered a COPC even though the chemical may not be present. This is especially the case for highly toxic chemicals, such as dioxins. Risk assessors should provide risk-based detection limits to the RPM during the DQO planning process in order to ensure that the appropriate analytical methods are selected.



## 6.4 Data Validation

Data validation is an important step in the data evaluation process and helps to determine whether or not the analytical DQOs have been achieved. Data validation is the process of evaluating field and laboratory data quality for precision, accuracy, representativeness, completeness, and comparability as well as overall data usability. The data validation process provides quality assurance information that is used in the data analysis steps of the risk assessment. Specifically, data validation ensures that chemicals are properly identified and quantified, and determines the overall usability of the data relative to the project objectives. Data validation consists of the following steps:

- ♦ assigning qualifiers to individual data values, based on whether the chemical in question is detected and the associated degree of variability, with consideration given to the level of deviation from performance standards;
- ♦ assessing the relevancy of certain performance criteria used to make decisions on the observed data, given information obtained during the course of the project; and
- ♦ determining whether or not the data can proceed to Data Quality Assessment (and the evaluation of whether or not DQOs were satisfied) (USEPA, 1999b).

The data validation level of effort depends on the complexity of the site and the overall project needs. In general, some percentage of the data (e.g., 5-10%) should undergo data validation (or some form of review) in order to ensure that the laboratory is correctly identifying, quantifying, and qualifying the analytical results. In special circumstances (e.g., special analytical methods, instances where there are legal concerns), it may be necessary to validate a higher percentage of the data.

*Note: USEPA Regional Guidance should be consulted to identify the data validation requirements, if any, that should be utilized to evaluate analytical data.*

## 6.5 References

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