CHAPTER 1
Introduction

1.1. Purpose. This document is intended to serve as a guide to project team members for the use of statistics in environmental decision-making.

1.2. Applicability. The U.S. Army Corps of Engineers (USACE) developed this document within the broader scope of Technical Project Planning (TPP), recognizing that understanding statistical evaluations can improve project planning and implementation at hazardous, toxic, and radioactive waste (HTRW) sites.

1.3. Distribution Statement. Approved for public release; distribution unlimited.

1.4. References. References are contained in Appendix A.

1.5. Introduction. This Manual's primary objective is to improve a decision-maker's understanding of common environmental statistical evaluations. The applicability of statistical tests and considerations is presented in the context of a typical environmental project life cycle. This document should serve as a first step in explaining statistical concepts and their application at HTRW sites. It is not intended to replace more robust statistical texts or electronic statistical software.

1.5.1. Statistics are applicable to environmental projects throughout their entire life cycle and yield defensible, cost-effective solutions to environmental questions. Statistics can be used to guide the selection of sampling locations, analyze large data sets, and verify that project objectives have been met. Statistics are of particular importance for quantifying the power and limitations of environmental data, specifically because these data are usually limited. It is not possible to collect and analyze every bit of an environmental medium (for example, soil, sediment, groundwater, or surface water) at a site; instead, a set of sample data is used to characterize the environmental medium as a whole.

1.5.2. This Manual is organized into four major Chapters, each associated with a stage in a typical Superfund project life cycle. These Chapters are supported by Appendices that provide detailed statistical or technical explanations of concepts or techniques used within the main sections.

1.5.3. The document is organized as follows:

Chapter 1	Introduction
Chapter 2	Preliminary Assessment (PA)/Site Investigation (SI)
Chapter 3	Remedial Investigation/Feasibility Study (RI/FS)
Chapter 4	Remedial Design (RD)/Remedial Action (RA)

Appendix A References
Appendix B Statistical Tables
Appendix C Sampling Strategies
Appendix D Descriptive Statistics
Appendix E Assumptions of Distribution
Appendix F Testing for Normality
Appendix G Detection Limits and Quantitation Limits
Appendix H Censored Data
Appendix I Identification and Handling of Outliers
Appendix J Graphical Tools
Appendix K Intervals and Limits
Appendix L Hypothesis Testing—Simple Cases
Appendix M Hypothesis Testing—Two-Population and General Cases
Appendix N Hypothesis Testing—Tests of Dispersion
Appendix O Measures of Correlation
Appendix P Comparing Laboratory and Field Data
Appendix Q Trend Analysis
Appendix R Geostatistics
Appendix S Geochemical Trend Analysis
Glossary

1.5.4. Statistical terms unfamiliar to some readers may be used in the four main chapters. When used for the first time, these terms will be printed in italics and footnoted. The footnote will direct the reader to the appropriate Appendix for a detailed explanation of the term. To demonstrate the types of statistical concepts necessary for the planning stages of environmental projects, concepts are presented in the context of *Comprehensive Emergency Response, Compensation, and Liability Act* (CERCLA) projects. The material is applicable to *Resource Conservation and Recovery Act* (RCRA) projects as well. The steps involved in the two programs are similar except for the use of different terminology and the applicable regulations. Table 1-1 presents a terminology crosswalk for the stages of CERCLA and RCRA investigations.

1.5.5. In the following Chapters of this document, major stages that require data gathering and evaluation are presented, and to the extent that statistical processes are applicable, examples are provided from case studies illustrating the application of those statistical processes. Some statistical elements may apply in more than one phase of the project life cycle. The Appendices provide detailed instructions on implementing the statistical processes.

1.5.6. The CERCLA project life cycle is not always linear. As information regarding a given site is gathered, additional questions may be raised about a previously unrecognized threat to human health or the environment. In that case, the process can repeat in whole or in part, creating a series of loops to previous portions of the cycle. In addition, at any point in the process, emergency activities (e.g., “time critical” remedial actions) may occur at earlier or later times in

the cycle. Finally, the process can terminate at the end of any given phase in a "no further action" determination.

Table 1-1.
Project Phase Crosswalk between CERCLA and RCRA

CERCLA Project Phase	RCRA Project Phase
Discovery and Notification	Permit Application
Preliminary Assessment	RCRA Facility Assessment
Site Investigation	Site Inspection
Hazard Ranking	Administrative Order
Remedial Investigation	RCRA Facility Investigation
Feasibility Study	Corrective Measures Study
Proposed Plan	Statement of Basis
Record of Decision	RCRA Permit
Remedial Design	Remedy Design
Remedial Action	Corrective Measures Implementation
Five Year Review	Monitoring/Annual Report
Closeout	Closure

1.5.7. The remedial action process under CERCLA is necessarily iterative and the same statistical tools can be employed repeatedly to address the original problem or newly identified issues at the site. For purposes of this text, however, we will assume a linear progression through an idealized project life cycle, consistent with the instructions contained in EM 200-1-2.

1.5.8. In the *Technical Project Planning Process*, the user is encouraged to identify the appropriate project phase for a given segment of work, then reference matching portions of this Manual for statistical guidance and methods appropriate to that phase.

1.6. Technical Project Planning and the Project Life Cycle. EPA QA/G-4 states, "EPA Order 5360.1 A2 [requires that] all EPA organizations (and organizations with extramural agreements with EPA) follow a systematic planning process to develop acceptance or performance criteria for the collection, evaluation, or use of environmental data." Similarly, ER 5-1-11 states, "Requirements for quality must be addressed during the planning phase of a project's life cycle, rather than waiting until the review or inspection stage." Thus, a systematic planning process of some sort is *required* for all HTRW projects involving the collection of data.

1.6.1. The EPA approach to systematic planning is described in detail in EPA QA/G-4 and is called the Data Quality Objectives (DQO) process. It is a seven-step process, which has as its goal the design of legally and scientifically defensible sampling strategies. The DQO guidance generally assumes that decision-making requires a probabilistic approach. Fundamental to the DQO process is identifying some statistic describing an environmental site that is compared via a statistical process to either a fixed threshold or risk-based value, or a statistical comparison of

some descriptive measure of data for two or more variables. The DQO process also incorporates statistical tools for estimating such things as the number of samples required to measure a site characteristic, spacing of sampling locations, and frequency of sampling. This permits data users to make decisions with specific degrees of statistical confidence.

1.6.2. The USACE TPP process is broader in scope, with the EPA's DQO process as one step within it, to the extent that probabilistic decision-making is appropriate to the goals of the project. The intent of the TPP process is to "get to closure" and to provide documentation of project decisions and project performance. The TPP process is useful for all sites, regardless of whether probabilistic decision-making is involved. It is highly flexible and promotes an approach that balances the size and complexity of a given site or problem with the level of effort involved in the planning process.

1.6.3. As described in EM 200-1-2, there are four phases to the TPP process, as follows.

1.6.3.1. *Identify the Current Project Phase.* The project manager establishes a project team to encompass all of the perspectives and skills required to take the project from beginning to end. The project manager briefs the team on client goals and existing site information and develops a conceptual model for the site. A broad, overall approach to the work is agreed upon, including an assessment of the most likely remedies or outcomes for the site. The work is broken down into clearly defined executable stages and the current stage of work is identified.

1.6.3.2. *Determine Data Needs.* Allowing all perspectives to be addressed, the team identifies the data required for each data user type (e.g., hydrogeologic, chemical, health and safety, risk assessment, engineering, etc.). The team reviews sources of existing information for availability, quality, and applicability to the current stage of work, and identifies data gaps that only new data can fill.

1.6.3.3. *Develop Data Collection Options.* With their respective needs defined, the team members decide on the best approach to obtain the required data. Usually, the team assesses a number of differing approaches and selects the approach that provides all of the requisite data with the best balance of available resources, measurement quality, and client risk tolerance. The TPP process clearly defines three data collection options: basic, optimum, and excessive. A basic sampling approach provides data applicable only to the current stage of work, whereas an optimum approach addresses both current data needs and anticipated future needs as well. An approach not focused on the specific data required to "get to closure" is excessive and should be avoided.

1.6.3.4. *Finalize the Data Collection Program.* At this point, the team encourages clients, regulators, the public, and in some cases other parties, to take part in the decision-making process. Specific DQO statements are prepared for each data user and data type and, to the extent that probabilistic decision-making is appropriate, the EPA's DQO guidance document (EPA

QA/G-4) is used and applied to these statements. From these DQO statements, scopes of work and other project controlling documents (PCDs) such as work plans, quality assurance (QA)/quality control (QC) plans, field sampling plans (FSPs), etc., are derived and cost estimates generated.

1.6.4. Table 1-2 provides a crosswalk between the EPA DQO Process and the USACE TPP process.

Table 1-2.
Crosswalk Between the TPP and DQO Processes

EPA's DQO Process		USACE TPP Process			
		Phase I	Phase II	Phase III	Phase IV
Step 1 **State the Problem**		Identify the Current Project	Determine Data Needs	Develop Data Collection Options	Finalize Data Collection Program
Step 2 **Identify the Decision**					
Step 3 **Identify Inputs to the Decision**				Develop Data Collection Options	
Step 4 **Define the Study Boundaries**					
Step 5 **Develop a Decision Rule**		Identify the Current Project			
Step 6 **Specify Limits on Decision Error**					
Step 7 **Optimize the Design**					Finalize Data Collection Program

1.6.5. Failure to apply, or to apply properly, the TPP process can result in a variety of negative consequences. Failure to properly plan for data collection may require more time and money to implement the work. Lack of planning may extend the time it takes to validate work because both objectives and verification methods may be unclear. Poor planning may create the need for extensive rework or remobilization. Finally, lack of advance planning can cause increases in legal risk to the client and to the USACE by increasing the potential for decision error. On the other hand, too great an emphasis on planning extends the planning cycle and the checking cycle, depleting the available resources.

1.7. Data Quality Objectives, Data Quality Indicators, and Measurement Quality Objectives. This paragraph provides a conceptual understanding of DQOs in the context of project planning for environmental investigations and remediations. The terminology is less important than the underlying concepts that support the decision-making process, as long as all parties possess a common understanding of that process. Project planners derive DQOs from scientific objectives, as well as social and economic objectives and the regulatory objectives of the environmental program under which the project is implemented. DQOs are technical, goal-oriented, qualitative, and quantitative statements derived from the planning process that clarify

study objectives, define the appropriate type of data, and specify tolerable levels of potential decision error. The DQO process typically uses statistics and is the basis for establishing the quality and quantity of data needed to support decisions. The DQO process does not establish specifications for data quality—called measurement quality objectives (MQOs)—or the mechanisms for measuring conformance to those specifications—called data quality indicators (DQIs). MQOs and DQIs are discussed in additional detail below.

1.7.1. *Data Quality*. Data quality depends on the integrity of each element in a series of events. It is critical to collect samples that are representative of the features of the environmental population being investigated in the study area. Representativeness depends on factors such as sample frequency, location, time of collection, and the nature of the sampled medium. Pretesting factors include sample containerization, preservation, transportation, and storage. Sample analysis factors generally include sample homogenization, sub-sampling, sample preparation (such as extraction and cleanup), as well as the instrumental analysis of the sample. The final steps of the process include data generation, reduction, and review.

1.7.1.1. Historically, attention has been focused primarily on the analytical component of data quality rather than on "total measurement system quality." Environmental decision-makers and practitioners tend to assume that data quality is primarily determined by the analytical methodology. For example, as fixed laboratory methods tend to be superior to field methods in terms of analytical uncertainty, data produced from field methods have been viewed to be too uncertain to support critical project decisions. However, defensible decisions are possible only when data quality encompasses total uncertainty rather than the uncertainty associated with only the analytical portion of the investigation. The value of data is limited less by the analytical procedures than by the quality of the *sampling design*[*] and the inherent variability of the environmental population of interest or condition being measured (the "field" component of variability). Because analytical uncertainty is typically small relative to field uncertainty, data quality usually depends more on sampling design than the quality of the individual test methods.

1.7.1.2. Table 1-3 summarizes sources or components of variability for environmental studies and how they are measured and controlled.

1.7.1.3. Regulators have also historically insisted on adhering to pre-approved analytical methods because of a perception that this ensures defensible data and that definitive data will be produced when EPA-approved analytical methods and QA/QC requirements are used. Though adequate data quality is often achieved using EPA-approved analytical methods, they are insufficient to ensure data of high quality. Efforts to improve data quality have primarily focused upon increasing laboratory oversight, rather than on developing mechanisms to manage the largest sources of uncertainty in data, which are issues related to sampling. Furthermore, prescriptive methods are scientifically feasible only when the sample matrices do not vary in any manner that

[*] Appendix C.

will affect the reliability of the analyses. As all analytical methods are potentially subject to chemical and physical interferences, given the variability and complexity of environmental matrices, it is unlikely that "one-size-fits-all" analytical methodologies are viable for all projects.

Table 1-3.
Variability in Environmental Studies

Source of Variability	Measurement Method	Control Methods
Analytical Variability		
Analytical instrumentation	Replicate measurements of instrumental standards (most common for inorganic analysis)	Regular preventive maintenance
Analytical method	Duplicate analytical spikes, lab-blind field duplicate samples	Use of standard methods documented as standard operating procedures; control of standards and reagents; control of instrument conditions
Sample preparation method	Duplicate control samples and matrix spike/matrix spike duplicates	Use of standard methods documented as standard operating procedures; control of standards and reagents; regular, close supervision
Analyst	Analyst demonstration of capability, blank spikes/performance evaluation (PE) samples	Inter-laboratory comparison studies; internal PE and auditing programs; analyst training; regular, close supervision
Field Variability		
Sampling equipment	Field blanks	Routine inspection and preventive maintenance; decontamination; selection of appropriate equipment for representative samples
Sampling method	Method-specific standard deviation of field duplicate results	Selection of appropriate methods for representative samples
Sampler	Inter- and intra sampler standard deviation of field replicate results	Independent auditing program; training; regular, close supervision
Matrix heterogeneity	Field duplicates or replicates, matrix specific standard deviation of field replicates, matrix spike duplicates	Effective field mixing of sample components; compositing
Sample selection	Site-wide or stratum-specific standard deviation of field replicate results	Representative sampling plan; sufficient number of samples; statistically-based sampling design

Note: Duplicates are separate aliquots of the same sample; replicates are a second sample from the same location.

1.7.1.4. The EPA has recently clarified its intended meaning of the term "data quality" in its broadest sense by defining it as "the totality of features and characteristics of data that bear on its ability to meet the stated or implied needs and expectations of the client." One must know how a data set is to be used to establish a relevant benchmark for judging whether the data qual-

ity is adequate. Linking data quality directly to their intended use provides a firm foundation for building a vocabulary that distinguishes the individual components of overall data quality.

1.7.2. *Data Quality Indicators*. DQIs are qualitative and quantitative descriptions of data quality attributes: the various properties of analytical data historically expressed as precision, accuracy, representativeness, comparability, and completeness. Collectively, these factors are called the PARCC parameters. These are discussed in detail in EPA guidance documentation. Because it is evaluated at the same time, an additional parameter often combined with the PARCC parameters is sensitivity, which is the ability of an analytical method or technology to reliably identify a compound in the sample medium.

1.7.2.1. Precision, accuracy, and sensitivity are quantitative properties of data directly measured through an appropriate analytical QC program. Representativeness is primarily a qualitative data quality indicator that is a function of the adequacy of the sampling design (for example, the number of samples and the manner in which samples were collected). Representativeness, in the context of an analytical measurement, can be inferred by examining factors such as duplicates/replicates, blanks, and sample collection procedures. Comparability is a qualitative measure that is critically important when *hypothesis testing*[*] involves comparing different populations, disparate in either space or time.

1.7.2.2. Completeness has been assigned an arbitrary goal of 80 to 100% based on the premise that decisions are still possible if a limited portion of the data are discarded (for example, because of quality control problems). However, the goal is based primarily on practical experience and is not mathematically based. Completeness should be evaluated in the context of project objectives.

1.7.2.3. In addition to these, selectivity is also a data quality indicator. “Selectivity” is the ability of an analytical method to identify the analyte of concern, e.g., the existence of other analytes in a sample or other interferences may mask the presence of the target analyte.

1.7.2.4. There may be more than one DQI for a single data quality attribute. For example, sensitivity is generally thought of in terms of detection, quantitation, or reporting limits, i.e., the lowest value that an analytical method can reliably detect or report. However, another important element of sensitivity is discrimination, the ability to distinguish between values to a given degree of precision. In other words, can the method tell the difference between values of 1 and 2 units, or only differences between 10 and 20 units? When developing DQIs, it is important to define them in terms of all the important attributes and assign specific numeric values to them as often as practicable.

[*] Appendices O and P.

1.7.3. *Measurement Quality Objectives.* MQOs are project-specific values assigned to DQIs derived from project-specific DQOs. MQOs are acceptance criteria for the DQIs and are derived by considering the level of measurement system performance needed to actually achieve project goals. MQOs are not intended to be technology- or method-specific. As with DQOs, MQOs specify *what* the level of data performance should be, but not *how* that level of data performance is to be achieved. A large part of the variability in environmental data stems from sampling considerations. MQOs should balance the relative contributions from analytical uncertainties and from sampling uncertainties. In many environmental media, matrix heterogeneity causes sampling variability to overwhelm analytical variability. Historically, the term MQO was restricted to the analytical side of the measurement process, but the broader concept of DQO (or decision confidence objectives) requires that sampling considerations be included. The importance of including both the sampling and analytical component of MQOs when assessing overall data quality cannot be overemphasized.

1.7.4. *Relationships Among Decision Goals, DQOs, MQOs, and QC Protocols.* During project planning, there should be a logical conceptual progression in the development of decision goals, DQOs, MQOs, and QC acceptance criteria. However, in practice, this will be a non-linear process.

1.7.4.1. As project planning develops, the following should be clearly presented:

1.7.4.1.1. General decision goals.

1.7.4.1.2. Technically expressed project goals (DQOs), and decision rules that will guide project decision-making.

1.7.4.1.3. Tolerable uncertainties for decisions.

1.7.4.1.4. Uncertainties that create decision errors.

1.7.4.1.5. Strategies for managing the uncertainties to achieve the desired tolerances for decision errors.

1.7.4.2. In the beginning of the project, program managers often set broad, non-technical goals. The next step is to translate these broad, non-technical goals into more technically oriented goals that can address specific considerations such as the following.

1.7.4.2.1. Regulations—what are the applicable environmental regulations?

1.7.4.2.2. Confidence in the outcome—how certain do we need to be by the end of the project that we have achieved goals such as risk reduction or regulatory compliance?

1.7.4.2.3. What are the constraints that need to be accommodated?

1.7.4.3. The next level of technical detail for data collection involves identifying DQIs and assigning to them project-specific MQOs that will be needed to achieve the project DQOs. At this point, the project team begins to consider in detail the options available for acquiring the needed measurements and selecting those that best meet the needs of the program. These decisions are documented in sampling and QC plans that specify the controls that will be used to ensure that MQOs are met and that any deviations are appropriately addressed.

1.7.4.4. Because sampling design and analytical strategy interact to influence the statistical confidence in final decisions, interaction among a statistician, a sampling expert, and an analytical chemist is critical for selecting a final strategy that can achieve project goals cost-effectively. The statistician is concerned with managing the overall variability of data, and with interpreting data with respect to the decisions being made. A statistician is a person having adequate familiarity with statistical concepts to correctly apply the required tests; this does not necessarily require a degree in statistics. The field sampling expert is responsible for implementing the sampling design while managing contributions to the sampling variability as actual sample locations are selected and as specimens are collected. The chemist is responsible for managing components of variability that stem from the analytical effort.

1.7.4.5. In summary, the conceptual progression starts with the project-specific decision goals, and then moves from broader, higher-level goals to narrow, more technically detailed articulations of data quality needs. Project decisions are translated into project-specific DQOs; then into project-specific MQOs; then into technology/method selection and development of a method-specific QC protocol that blends QA/QC needs of the technology with the QA/QC needs of the project. Then the process reverses. The data must be assessed against the project MQOs to document that data quality meets the decision-making needs of the project.

1.7.4.6. Figure 1-1 presents the life cycle in project planning. Figure 1-2 illustrates which guidance documents are useful in the planning phases of a project.

1.8. Statistics in Environmental Project Planning. The number of individual samples collected during a given study is called sample size and is generally designated by the statistic *n*. In order for decisions based on that sample to be meaningful in any scientific sense, the sample size has to be sufficiently large to account for the inherent variability in the characteristics measured. Sample size should be dependent on the variability in the measured condition but, in practice, is often limited by available resources.

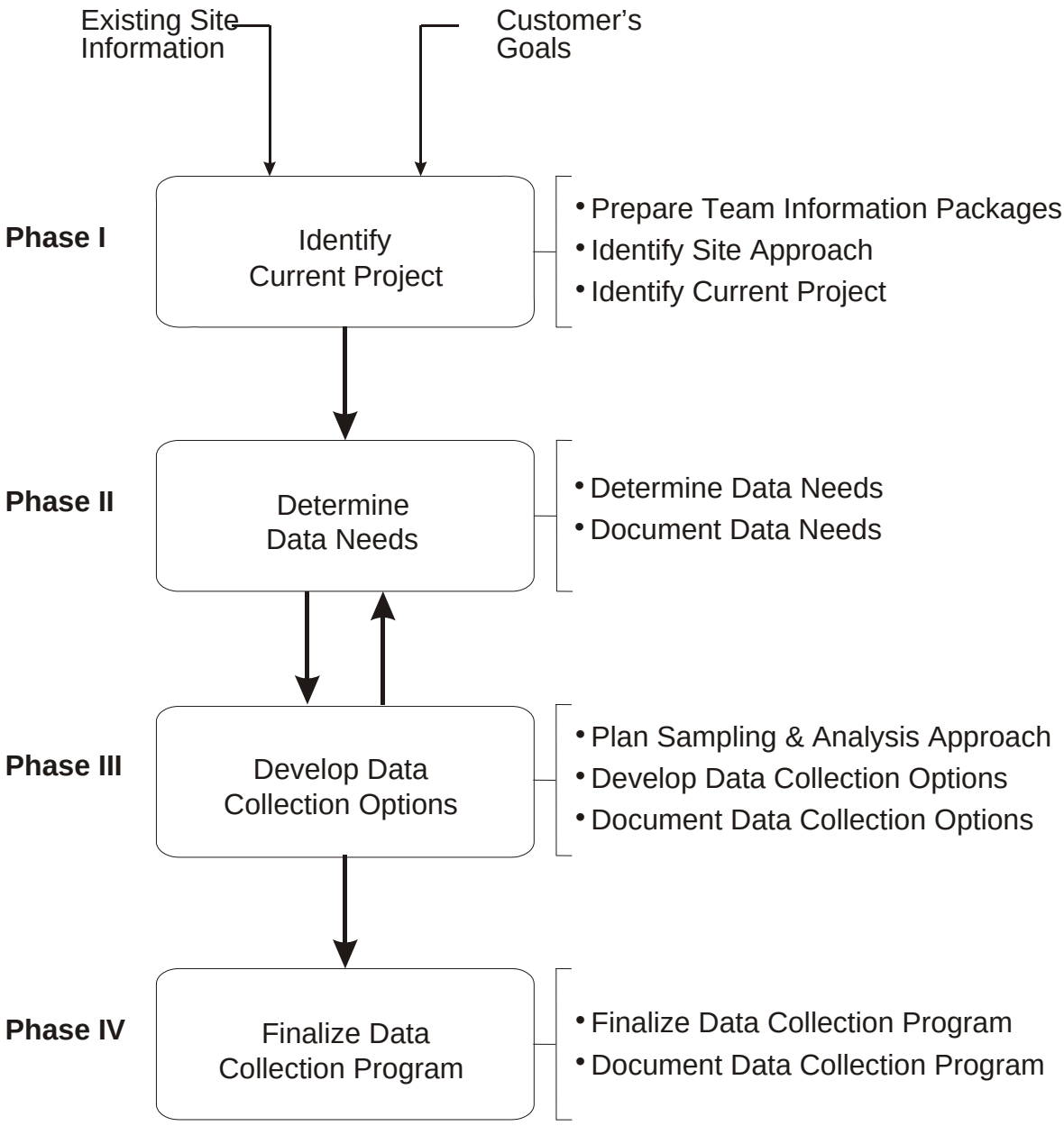

Figure 1-1. Project planning life cycle.

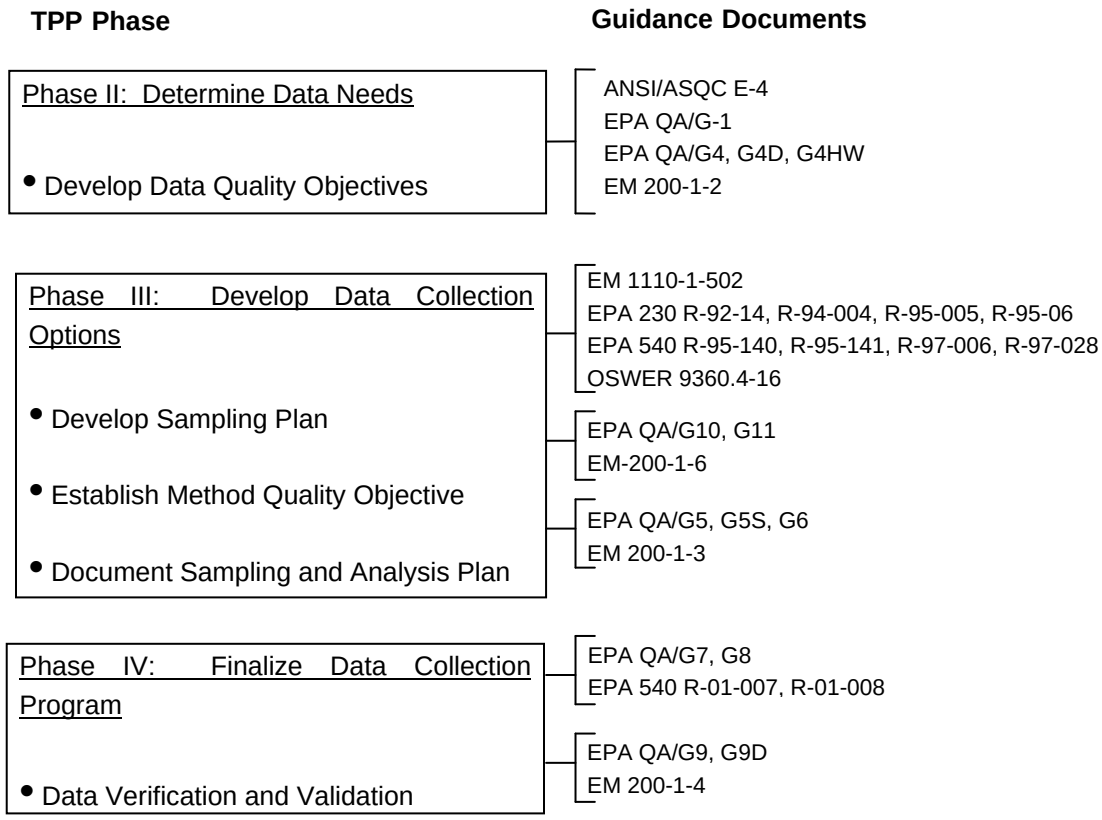

Figure 1-2. Guidance document life cycle.

1.8.1. A hypothetical illustration may be helpful in understanding this relationship. Let us suppose that a researcher wants to know the average concentration of a particular chemical constituent in the air of a sealed room. The constituent of interest is initially absent from the room and the researcher releases the chemical into the room from a port in the north wall of the room. Immediately after opening the port, a measurement taken along the south wall will not detect the presence of the chemical, while a sample taken adjacent to the port will display a high concentration. As the chemical disperses throughout the room via various physical processes, a single sample taken at any location in the room will not provide a representative value for the average concentration in the room as a whole. Even if a single sample were collected some time well after the release of the gas (i.e., after an equilibrium state of dispersion has been achieved), depending upon the physical characteristics of the chemical and the room, it may not be uniformly spread throughout the room. Thus, a sample taken at any single randomly selected location will not give a representative result for the room as a whole, or even necessarily a good approximation.

1.8.2. Only when the chemical is uniformly dispersed throughout the three dimensions of the room, and is held static in that condition, can a representative result be arrived at from a single sample. The analytical error or measurement uncertainty would also need to be negligible when analyzing the one sample. In all other cases, the true *population mean* (μ)[*] *(*the real average concentration for the room as a whole) must be approximated by averaging the results from a number of samples.

1.8.3. The greater the variability in the chemical concentration throughout the room is, the more individual samples will be required to formulate an accurate approximation of the true average. Therefore, as decision *confidence* requirements increase (i.e., as confidence increases toward 1 or 0 decision error tolerance), the number of samples required to correctly estimate any statistical parameter will also increase.

1.8.4. Variability is a measure of the degree of dispersion (or spread) for a set of values. The *sample variance*[†], s^2, and *sample standard deviation*, s, measure the spread of individual measurements or values about the *sample mean*[‡], $\bar{x}$. Some factors that may contribute to variability in environmental populations are the following.

1.8.4.1. Distance, direction, and elevation relative to point, area, or mobile population sources.

1.8.4.2. Non-uniform distribution of pollution in environmental media owing to topography, hydrogeology, meteorology, actions of tides, and biological, chemical, and physical redistribution mechanisms.

1.8.4.3. Diversity in species composition, sex, mobility, and preferred habitats of biota.

1.8.4.4. Variation in natural background levels over time and space.

1.8.4.5. Variable source emissions, flow rates, and dispersion parameters over time.

1.8.4.6. Accumulation or degradation of pollutants over time.

1.8.5. For a particular sampling plan where n measurements are taken for some contaminant of concern in a study area, a (sample) mean concentration ($\bar{x}$) and (sample) standard deviation (s) for the contaminant are calculated. The standard deviation measures the variability of the individual measurements. However, it is often the case that it is the variability of $\bar{x}$ itself that is of interest. The variability of the mean is often measured by the standard deviation of the sample

[*] Appendices C and D.
[†] Appendices D, E, and H.
[‡] Appendices C, D, E, F, G, and H.

mean, $s_{\bar{x}} = s/\sqrt{n}$. Those two sample values, $\bar{x}$ and $s_{\bar{x}}$, are used to estimate the interval (range) within which the true mean (μ) of the chemical concentration probably occurs, under the assumption that the individual concentrations exhibit a normal (bell-shaped) distribution.

1.8.6. The relationship among variability, available resources (expressed as sample number, *n*), and decision confidence or lack of uncertainty is fundamental to the project planning process. In general, cost increases as the desired level of confidence or lack of uncertainty increases. Thus, balancing cost and confidence is a primary objective of the planning process. As illustrated in Figure 1-3, this can be depicted as a balance between cost and level of uncertainty: reducing uncertainty increases project costs. As the number of samples increases, the uncertainty decreases but the cost increases. As depicted in Figure 1-3, project planning is the fulcrum of a seesaw balancing cost and uncertainty.

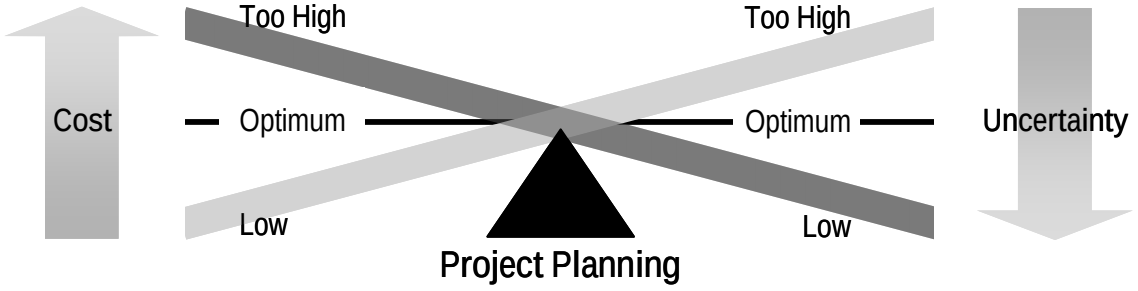

Figure 1-3. Balance between resources and certainty.

1.8.7. When dealing with regulators and clients, it is often beneficial to illustrate, in mathematical terms, the relationship among the project objectives, the desired confidence for decisions, and the cost of the project.

1.8.8. Figure 1-4 illustrates the relationship of factors that need to be considered in successful project planning.

1.8.9. The purpose of the project planning triad approach is managing total decision uncertainty. Total uncertainty may be viewed as the sum of analytical and field uncertainty. Analytical uncertainty is the portion that arises from variability and bias in the instrumental or analytical test method (as indicated in Table 1-3). Field uncertainty depends on factors such as the temporal and spatial variability of the target environmental population (Table 1-3). Field variability typically exceeds the analytical variability and primarily depends on the sampling design (e.g., the total number of samples, the sample mass, and the nature of field sampling and laboratory sub-sampling methods). In general, data produced by screening analytical methods will contain more analytical variability and bias than data produced by definitive methods. However, field analyses are less costly than laboratory analyses, so a greater number of field samples can be analyzed than laboratory samples for the same fixed cost. Thus, even though field analy-

ses typically contain higher analytical variability relative to laboratory analyses, a larger number of field samples can reduce the total variability more effectively than a smaller number of similarly collected laboratory samples. Field analytical methods should be scrutinized, however, because the total uncertainty does not depend on measurement precision (variability) alone; it also depends on a number of data quality elements such as analytical bias, sensitivity, and specificity (i.e., the ability to detect or quantify the analyte or contaminant of concern in the presence of other analytes or interferences in the sample).

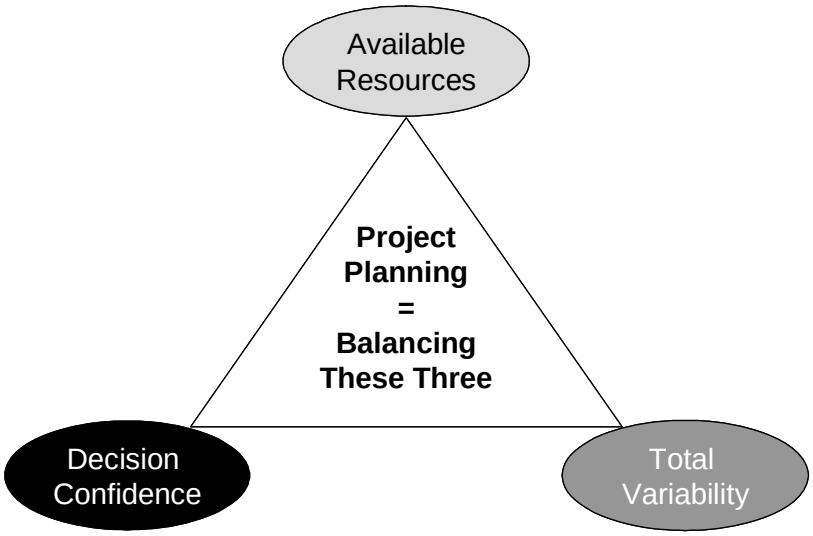

Figure 1-4. Project planning triad.

1.8.10. The triad approach also makes use of rapid turn-around times for field methods. Field methods have an advantage over laboratory methods in that they are capable of providing data to support decisions while mobilized in the field. For example, managers can modify sample locations on the basis of new information about the extent of contamination during a single mobilization. In contrast, fixed laboratory data packages are produced several weeks after sampling is complete. Remobilization may be necessary to resolve questions arising from laboratory results.

1.8.11. The triad approach is especially useful for statistical designs such as *adaptive sampling,*[*] *ranked set sampling*[*], and *systematic sampling*[*], as these designs often require larger numbers of samples. To successfully implement the approach, the capability of the field methods must be scrutinized with respect to project data quality and measurement objectives. For example, many field methods are not as sensitive or selective as laboratory methods. If the primary objective is to characterize contamination with respect to some fixed risk-based limit or cleanup goal, and the detection limit is greater than the decision limit, then comparisons of the field data

[*] Appendices C and D.

to the decision limit will not be viable. Comparisons of field and laboratory data during a pilot test phase to verify or establish correlation between two sets of results is a useful approach for evaluating and selecting field methodologies.

1.8.12. The triad approach relies on thorough, systematic planning to articulate clear project goals and encourages negotiations among stakeholders to determine the desired decision confidence. A multidisciplinary technical team then determines what information is needed to meet those goals. A key feature of this planning is identifying what uncertainties could compromise decision confidence and allowing team members with appropriate sampling and analysis expertise to explore cost-effective strategies to minimize them. Often, the most cost-effective work strategy involves the second leg of the triad, which is using a dynamic work plan to make real-time decisions in the field. The third leg of the triad uses field analytical methods to generate real-time on-site measurements that support the dynamic work plan. Projects managed using these concepts have demonstrated cost savings of up to 50% over traditional approaches.

1.8.13. The contributions to the total variability (i.e., the total precision component of the uncertainty) can be expressed as a vector sum of an analytical component and sampling component of the variability (e.g., or as a ratio of the sampling to analytical variability, say 9:1). Although the analytical variability is minimized by conventional laboratory analyses, sampling variability is often not adequately addressed. Budget constraints invariably limit the number of laboratory analyses. A combination of high laboratory analysis costs and a poor sampling design often results in a low sampling density that is not very representative of the environmental population of interest. Field studies consistently find that the sampling design, rather than analytical considerations, predominately governs the total variability.

1.8.14. When analytical costs are lower, more samples can be analyzed, yielding more confidence in the representativeness of the data set (Phase 1). This is most effective if field methods are used to generate data and a dynamic work plan rapidly resolves any uncertainty about location and volume of contamination (for example, locate and delineate hot-spots in a single field mobilization). If the analytical data quality used to manage sampling uncertainty is less than what is eventually needed to make final project decisions, such as whether the site can be declared clean, more expensive definitive analyses may be performed on samples selected to refine the feature of interest (Phase 2). However, if the initial method produces data of sufficient rigor to support defensible decision-making, then additional, expensive analyses would be redundant and unnecessary.

1.8.15. In Phase 1, analytical uncertainty (variability) increases so that unit sample costs decrease, allowing a higher sampling density than with the conventional approach. As a result, sampling uncertainty (variability) decreases, lowering the overall uncertainty in data interpretation. Sampling uncertainty is further decreased if hot-spot removal reduces the variability in contaminant concentration and if representative sampling locations for more rigorous analysis are identified based on Phase 1 information. The vector representation of uncertainty for this ap-

proach indicates that the overall uncertainty in the data set for site decision-making will be much less than the overall uncertainty in the conventional method.

1.8.16. Data quality should be judged on whether both the sampling and the analytical uncertainties in the data sets support decision-making at the desired degree of decision confidence. However, relying solely on regulator-approved, definitive analytical methods, while ignoring sampling uncertainty, easily produces uncertain decisions.

1.8.17. When field analytical methods are used, the process and resulting data are often referred to as "field screening." The term is misleading when field methods are of adequate quality to satisfy project DQOs; field analyses are not necessarily "screening" or inferior to fixed-laboratory analyses in the context of the overall end use of the data. Here, alternate terminology is proposed to reflect current EPA guidance that both sampling and analytical uncertainties must be managed to assess data quality. We consider the two terms "effective data" and "decision-quality data," to be equivalent when describing data of known quality that are effective for making defensible primary project decisions, because both sampling and analytical uncertainties have been explicitly managed to the degree necessary to meet clearly defined project goals.

1.8.18. Primary project decisions are those decisions that drive resolution of the project, such as whether or not a site is contaminated and what subsequent actions, if any, will be taken. Therefore, contaminant data are usually the data sets of interest. But data sets can interact in complex ways, and are referred to as collaborative data sets. For example, a contaminant data set considered alone might not be effective for making project decisions, yet the same data set might be more effective when combined with other data or information to manage the remaining uncertainties. Ancillary data refers to data used to support many other project decisions that fall under worker health and safety monitoring, data that help in the understanding of fate and disposition of contaminants, and data that aid in decisions about the representativeness of environmental samples.

1.8.19. This decision-making paradigm and terminology embodies the central theme of systematic project planning, the management of decision uncertainty.