PROTOCOL FOR VOC-ARID ID REMEDIATION PERFORMANCE
CHARACTERIZATION

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SUMMARY

The Volatile Organic Compound-Arid Integrated Demonstration (VOC-Arid ID) is a technology development program sponsored by the U.S. Department of Energy's Office of Technology Development that is targeted to acquire, develop, demonstrate, and deploy new technologies for the remediation of VOC contaminants in the soils and groundwaters of arid DOE sites. Technologies cannot be adequately evaluated unless sufficient site characterization and technology performance data have been collection and analyzed. The responsibility for identifying these data needs has been placed largely on the Principal Investigators (PIs) developing the remediation technology, who usually are not experts in site characterization or in identification of appropriate sampling, analysis, and monitoring techniques to support the field testing.

This document provides a protocol for planning the collection of data before, during, and after a test of a new technology. This generic protocol provides the PIs and project managers with a set of steps to follow. The protocol is based on a data collection planning process called the Data Quality Objectives (DQO) process, which was originally developed by the U.S. Environmental Protection Agency and has been expanded by DOE to support site cleanup decisions. The DQO process focuses on the quality and quantity of data required to make decisions. Stakeholders to the decisions must negotiate such key inputs to the process as the decision rules that will be used and the acceptable probabilities of making decision errors.

Benefits to be gained from this protocol are that stakeholders must be identified and involved in the decision making process. It forces the criteria for a successful test to be quantified before any data are collected. It forces the PIs to justify data quality and quantity to be collected. It forces PIs, project managers, and stakeholders to acknowledge that decision errors exist and must be traded-off against increased sampling and analysis costs. Finally, following the protocol should result in defensible Sampling and Analysis Plans, which are part of the Integrated Test Plans.

This document summarizes the steps in the generic protocol and provides lessons learned from applications of the protocol to three technology demonstrations in the VOC-Arid ID program.

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1.0 INTRODUCTION

1.1 PURPOSE

This document provides general guidance on the application of the Data Quality Objectives (DQO) process to direct the data collection planning activities for demonstrations of emerging technologies to be implemented under the Volatile Organic Compound-Arid Integrated Demonstration (VOC-Arid ID). This guidance is intended for use by the Principal Investigator (PI) and others and is designed to satisfy the needs of both the PI and the VOC-Arid ID Management Team (Jensen et al. 1994). Guidance is needed to ensure adequate planning in advance of field demonstrations such that sufficient site characterization and test performance data will be collected to measure the successfulness of the demonstration.

The VOC-Arid ID is conducted by the Office of Demonstration, Testing, and Evaluation under the U.S. Department of Energy (DOE) Office of Technology Development (OTD). The OTD is charged with developing emerging technologies that are better, faster, safer, and cheaper than current methods (DOE 1994). The principal objective of the VOC-Arid ID is to identify, develop, and demonstrate new and innovative technologies for environmental restoration at arid or semiarid sites containing volatile organic compounds with or without associated contamination (e.g., radionuclides and metals) (Jensen et al. 1994). Candidate technologies are being demonstrated in the areas of site characterization; performance prediction, monitoring, and evaluation; contaminant extraction and ex-situ treatment; in-situ remediation; and site closure and monitoring (Figure 1).

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FIGURE 1. Overview of the Volatile Organic Compound - Arid Integrated Demonstrations

1.2 SCOPE

This document provides a protocol for characterizing the performance of in-situ restoration, removal, and/or containment technologies for the VOC-Arid ID. It represents the next level of detail required to transition between the more general test objectives that PIs must develop for the Conceptual Test Plans, to the detailed identification of test parameters and sampling and analytical procedures that must be part of the Integrated Test Plans and Performance Evaluation Reports that must be written (Jensen et al. 1994). The protocol will guide data collection efforts before, during, and after the demonstration.

The 15 evaluation criteria presented by Jensen et al. (1994) and summarized in Table 1 are broad categories of concern that should be considered in formulating demonstration objectives. Some of these criteria suggest the type of data to be collected before, during, and after the test. The criteria were developed from two sources: workshops where PIs and stakeholders developed consensus issues of concern in the technology evaluation process and CERCLA Evaluation Criteria defined in EPA (1987).

In addition to evaluating a new technology on its own merits, it is important to compare a new technology to a baseline technology to determine if the new technology is better, faster, safer, and/or cheaper, and thus, could replace the baseline as the technology of choice.

The protocol presented here focuses on the data required to evaluate criteria 1-4 (Table 1) and the "better and faster" comparative criteria. The technologies currently planned for demonstration are in-well vapor stripping, bioremediation, and passive vapor extraction. Because work plans have been completed for several of these tests (Gilmore and Koegler 1994a,b), this document provides a protocol for developing future work plans and reviewing

TABLE 1. VOC-Arid ID Demonstration Test Objectives Evaluation Criteria

1. Technology Performance: Remaining Contamination
 - Type and amount of contaminated materials destroyed or treated
 - Type and amount of residual contamination remaining after treatment
 - Reduction of mobility of the contaminants
 - Reduction of toxicity of the contaminants
 - Degree to which treatment is irreversible
2. Technology Performance: Process Waste
 - Type and amount of process waste or emissions generated by treatment
3. Implementability and Practicality of Technology
 - Nature and extent of any operational problems
 - Ease of use
 - Versatility of technology in addressing other types of contamination
4. Does the Technology Function as Intended?
 - How well the technology performs its intended functions
5. Cost
6. Time
7. Worker Health and Safety
8. Public Health and Safety
9. Environmental Impacts
10. Technology Reputation/Familiarity to Public
11. Future Land Uses/Tribal Rights
12. Socioeconomic Impacts
13. Regulatory Infrastructure Requirements
14. Compliance with Regulatory Requirements
15. Overall Protection of Human Health and the Environment

progress and lessons learned on in-process work plans. Although omitted from this document, the same general DQO guidance can be applied to other technology areas (e.g., characterization and monitoring) and other criteria (e.g., cost, speed, and safety).

Efforts for specifying data collection requirements and data analysis methods for criteria not covered in this report are ongoing at various sites. Staff working on the Cost Analysis Task at Los Alamos National Laboratory are performing cost evaluations and comparisons. Staff working on the Institutional Assessment Task are looking at regulatory requirements. Individual Technical Support Groups (TSGs) for each technology, working with the PIs, are specifying and reviewing detailed technical performance evaluation criteria.

This protocol uses the DQO process to guide the determination of the amount of data to collect and the quality of data required for decision making. Inputs to the DQO process must come from the decisionmakers responsible for making trade-offs between increased sampling costs and increased decision errors. This document intends to

- discuss unique issues in applying the DQO process for new remediation technology performance characterization
- discuss lessons learned, adjustments, and options that are available for DQO applications
- present a protocol for remediation performance characterization that is based on the DQO process (EPA 1993a) and Observational Approach (Smyth et al. 1992) and that incorporates unique aspects for emerging technology demonstrations.

This document is not a step-by-step guidance document because such formalism is not feasible at this phase of the development and application of the DQO process and the Observational Approach. [See Appendix A for a discussion of the DQO process, the Observational Approach, and the combined

process called SAFER (DOE 1993)]. Applications of the protocol to planned remediation demonstrations are in their initial phases. In its current form, the protocol is a compilation of general steps that can be worked through to guide data collection. The steps in this protocol should enable PIs to suggest and defend the sample sizes and sample types proposed in Sampling and Analysis Plans that become part of Conceptual Test Plans and Integrated Test Plans.

2.0 BACKGROUND

2.1 SITE DESCRIPTION

The initial host site for the VOC-Arid ID is an area of carbon tetrachloride (CCl_4) contamination in the 200-West Area of DOE's Hanford Site (Figure 2). Between 1955 and 1973, a total of 363,000 to 580,000 liters (95,832 to 153,120 gallons) of liquid CCl_4 , in mixtures with other organic and aqueous, actinide-bearing fluids, were discharged to the soil column at three disposal facilities near the center of 200-West Area. In the mid-1980s, CCl_4 was found in the aquifer beneath the disposal facilities. In late 1990, the U.S. Environmental Protection Agency (EPA) and the Washington State Department of Ecology requested that the DOE proceed with planning and implementing an expedited response action to minimize additional CCl_4 contamination of the groundwater. In February 1992, a soil-vapor extraction system began to recover CCl_4 from the unsaturated zone beneath these disposal facilities. As of May 1994, a total of 10,560 liters (2787 gallons) of CCl_4 had been removed, amounting to an estimated 2 percent of the original discharge.

Site investigations conducted in support of both the EPA Superfund Expedited Response Action (ERA) initiated at the site and the VOC-Arid ID have been fully integrated because of their shared primary objective to refine the conceptual model of the site and to promote efficiency. Rohay, Swett, and Last (1994) present the most recent refinement of the conceptual model.

Three in-situ remediation and/or removal technologies are currently planned for demonstration at the Hanford Site. Two of these technologies, in-situ bioremediation and in-well vapor stripping, are designed for in-situ remediation of groundwater contamination. A third, barometric pumping, is designed for removal of unsaturated zone contamination. A fourth remediation

FIGURE 2. The Initial Host Site for the VOC-Arid ID in the 200-West Area of the Hanford Site

technology, Electrical Remediation at Contaminated Environments (ERACE), was planned for demonstration at the 300 Area of the Hanford Site in FY93 and was later demonstrated at the Savannah River Site.

The flow chart in Figure 3 provides a graphic representation of the VOC-Arid ID evaluation process. The process can be partitioned into three stages: the Planning Stage, the Baseline Stage, and the Implementation Stage. Individual steps within the Planning Stage correspond to the seven-step DQO process.

2.1.1 Planning Stage

The DQO process is used to plan data collection activities resulting in a decision that explicitly incorporates the acceptable limits on decision errors of the stakeholders. The benefit of using the DQO process is to ensure that the final set of data quality objectives (e.g., amount and quality of data to be collected) provide a defensible basis for all participants for the decisions to be made.

2.1.2 Baseline Stage

Two types of baselines must be established in a technology demonstration: beginning environmental conditions and performance parameters for the comparison technology.

1. Pretest or initial environmental conditions, especially beginning levels of contamination present in the target medium, are called baseline conditions. Beginning levels of contaminants and co-contaminants, and beginning environmental conditions need to be established for later post-test comparisons.
2. Performance parameters for a known, recognized technology, which will be used as the baseline technology, must be established because they will be used in a comparison with the performance parameters estimated from the new technology demonstration data. If there is no baseline technology

FIGURE 3. VOC-Arid ID Project Evaluation Process

for the type of contamination and environmental conditions for the current test, the new technology must be evaluated on the basis of its individual evaluation criteria (see Table 1).

2.1.3 Implementation Stage

Once the actual field demonstration has begun, data are collected at specified locations and intervals to characterize and monitor the areal extent and speed of cleanup. Additional information needed for the final performance evaluation includes process wastes generated, amount of contaminants removed and processed through a treatment system, and levels of co-contaminants and newly introduced contamination (e.g., the technology had secondary effects that were harmful to the environment or caused new contamination).

In addition to environmental sampling and process operation data, technology demonstrations often use computer models to assess performance. Computer models currently under development (Bergsman et al. 1993) are being used to calculate predicted volumes and rates of organic constituent removal during test demonstrations. Examples of models currently used or considered for use follow:

- TOUGH2, a numerical model for water movement in porous media (Pruess 1991).
- MSTS, a multiphase subsurface transport model for both the saturated and unsaturated zones involving a single contaminant (Nichols and White 1993; White and Nichols (1993).
- STOMP Engineering Simulator, a newly developed multiphase, subsurface-transport simulator for specifically analyzing remediation techniques associated with arid sites contaminated with organic compounds and radionuclides (White et al. 1992).

Numerical simulations, combined with experimental results, can greatly enhance the value of limited sampling data. Combining simulation results with sampling data in an iterative fashion, where new sampling results are used to validate model predictions and update model parameters, is a very cost-effective way to determine when test objectives are met. Thus, performance decisions can be made with a minimal amount of sample data.

The Implementation Stage generally ends when a decision can be made as to whether the test objectives were met. The estimated error tolerances associated with the decision (from estimated sampling error, estimated model error, and estimated analytical lab and instrument error) are compared to acceptable error tolerances. If acceptable error tolerances cannot be met, more samples must be taken, more accurate equipment used, and/or additional instruments acquired to measure uncertain parameters. The results of the demonstration and the performance decisions are documented in a final report [the Remediation Performance Evaluation Report (Jensen et al. 1994)].

3.0 ISSUES FOR DEVELOPING DATA REQUIREMENTS FOR A REMEDIATION DEMONSTRATION

This section discusses several issues affecting the selection of parameters to be measured for a new technology performance evaluation. These issues should be considered before working through the protocol steps provided in Section 4.0.

3.1 DATA QUALITY OBJECTIVES COMPARED WITH TRADITIONAL EPA PARAMETERS

Most developers of new remediation technologies are not familiar with the data quality terms and conventions that have been promulgated by the EPA over the years. Therefore, this section provides insight into the dual use of the term data quality objectives.

In support of sampling and analysis for such activities as Superfund cleanup actions (e.g., remediation investigation/feasibility studies), risk assessments, and environmental impact statements, EPA has introduced the convention of assessing data quality in terms of the PARCC parameters (precision, accuracy, representativeness, comparability, completeness). Guidance from the EPA on analytical methods to be used, instrument capability, technical judgement, and negotiations with regulators has been used to set quantitative levels for these PARCC parameters. For example, precision and accuracy quantitative goals might depend on the types of samples to be collected (baseline/characterization, monitoring confirmation by mobile lab analysis, confirmation of field screening), identified EPA Analytical Level, and the capability of the selected analytical analyses to be performed. These pre-specified quantitative levels have been referred to by some as the "DQO values" and are included in the Quality Assurance Project Plan (QAPjP) for a Work Plan.

The DQO process described here takes a more comprehensive approach to data quality. Rather than ask "how good does this individual piece of data have to be?," the DQO process asks "how good does this decision have to be?" The DQO process requires a consensus among stakeholders on acceptable decision errors before sampling can begin. Selecting a quantitative level for the PARCC parameters and selecting a sample size and sampling plan without first going through the DQO process can result in overly conservative and expensive analytical method selections that waste project resources. Conversely, the selected levels could result in inadequate sampling and analysis methods that do not protect against unacceptably large decision errors. The DQO process provides a defensible basis for selecting PARCC parameter levels and selecting sample sizes and sampling designs.

3.2 ESTIMATION VERSUS THRESHOLD DETECTION PROBLEM

Data that are collected can be used in two ways: 1) to estimate the performance parameters of the technology (called the estimation problem data-use requirement), and 2) to make a decision about the technology. If this decision is binary (e.g., the technology did or did not work), it is called a "threshold detection" problem. The threshold value defines the dividing point between the two decisions. The DQO process focuses on the threshold detection problem, but can be modified to fit an estimation problem. Table 2 lists key considerations for both types of problems.

3.3 IDENTIFICATION OF CAUSAL FACTOR: THE NEED FOR SECONDARY TEST PARAMETERS

Planning data collection in support of a new technology demonstration should include developing a range of outcomes to account for possible environmental and test conditions. A list of secondary variables or test

TABLE 2. Key Considerations in Collecting Data for Estimation and Threshold Detection Problems

Key Considerations	Estimation Problem	Threshold Detection Problem
Use of data	Estimate a test parameter to within $\pm D$ with a stated confidence level	Make a decision with stated levels for decision errors
Example of test objectives	What is the amount of contaminant removed per hour and per dollar?	Is amount of contaminant removed per hour greater than X? Is amount of contaminant removed per hour greater than baseline technology?
	What is the percent of contaminant removed or the percent remaining?	Is percent removed greater than X% or percent remaining greater than Y%? Is percent removed or percent remaining greater than with baseline technology?
Impact on data collection	Expected data values don't affect data collection efforts	If expected data values are far away from decision threshold, planned data collection efforts can be reduced because the same decision will be made.
Inputs required from stakeholders	Acceptable or accurate estimate?	Consequences of alternative decision errors Acceptable levels for two types of decision errors.

parameters that may provide insight on the demonstration results should be developed. Numerical models and simulations can help evaluate "what if" scenarios and may provide insight when used at the completion of the demonstration to provide causal relationships among the environmental variables and the operating conditions and parameters.

The guidance provided in this document does not directly address data collection when the emphasis is on providing a causal explanation for a variety of possible test outcomes. The use of the Observational Approach (Smyth et al. 1992), listing secondary data requirements during the Planning Stage, using sequential sampling during the Implementation Stage, and the concurrent and iterative use of sample collection and model prediction data are some suggested techniques for dealing with this problem.

3.4 ROLE OF VARIABILITY ON DECISION ERROR

Variability is the key driver for increased sampling costs and increased decision error. The source of the variability is important because some sources are more easily controlled than others. More accurate sample collection, laboratory methods, and analytical laboratory equipment can be purchased and thus reduce measurement error. Some studies estimate that natural variability and sample error (e.g., spatial and temporal variability) account for over 90% of total sample error. This may not be the case when the contaminants of concern are volatile organic compounds that can easily be lost during the process of sample collection and analysis. Natural variability cannot be controlled. However, certain sampling designs are more efficient than others at obtaining unbiased estimates under highly variable conditions. Examples of such sampling designs are stratified sampling, composite sampling, and

adaptive sampling. Variability, both sample and measurement, drives up sample number, which includes sampling frequency, number of sampling locations, and volume of sample.

Not only is variability a key driver for sample size, it is also the most difficult to estimate compared to an average or a total. The estimate for natural variability should be based on sample data that are of the same scale as that on which the decision will be based. In the case of the technology demonstrations, variability estimates are required for contaminant (VOCs) concentration and for soil and groundwater properties spatially, especially at the depth where the equipment will be operating. In addition to obtaining estimates of the various components of variance, it is necessary to develop a model that describes the components of error in the measured value, and the relationship of the measured value to the true value. This model should indicate whether the components are additive or multiplicative, correlated or uncorrelated.

Figure 4 shows what happens when natural pre-test concentration ranges overlap post-test removal concentration ranges. It is impossible to differentiate between real contaminant reduction caused by a successful test and lower post-test sample concentration values caused by sampling variability. In the case shown, a post-test sample reading of 30 ppb could be indicative of an unremediated aquifer, a successful test with true contaminant removal of 90%, or a successful test with true contaminant removal of 99%. Such natural variability has been seen at several of the VOC-Arid ID test locations (Brouns et al. 1990) where contaminant concentration spans several orders of magnitude within a very small area. Add the instrument and sampling equipment error to the natural variability and definitive test results are elusive. When success criteria are in the single order of magnitude range (i.e., 90 percent

FIGURE 4. Comparison of Natural Variability Range with Success Criteria Range

reduction), and total sample collection and analysis variability span several orders of magnitude, good experimental design must be instituted if significant results are to be obtained.

The ERACE demonstration was able to control for environmental variability by energizing the soil-heating electrodes after a vapor extraction system had been operating for a period of time. The opportunity to have a true side-by-side comparison of the new technology to the baseline technology is rare. The usual case is that environmental conditions cannot be controlled, and the differences in the two technologies must be assessed using statistical sampling design and post-test analysis of variance methods for identifying significant differences.

4.0 PROTOCOL FOR REMEDIATION PERFORMANCE CHARACTERIZATION

This protocol is based on the DQO process, variants of the DQO process, the Observational Approach (Symth et al. 1992), and lessons learned from working through the DQO process for several VOC-Arid ID remediation technology demonstrations. The DQO process is a series of planning steps that is designed to ensure that the type, quantity, and quality of data used in decision making are appropriate for the intended application. The term "DQOs" refers to the qualitative and quantitative statements derived from the outputs of each step of the DQO process. One of the primary benefits of working through the DQO process is that it requires all stakeholders involved in the decision-making process to be involved in each step. It also documents the consensus conclusions and assumptions of each step. The seven steps are shown in Figure 5.

The shaded areas of Figure 5 show the steps that have been completed thus far for the in-well vapor stripping and ERACE demonstrations. Experience with these two DQO applications have shown that it is difficult to get stakeholders to specify or agree to acceptable limits on decision errors. Because the objective of the DQO process is to produce decisions with stated acceptable decision error limits, the process is not complete when these limits have not been determined by the stakeholders as part of the planning process. Without stated acceptable decision error limits, there is no specific target to guide staff trying to design a data collection system. As a word of caution, at a minimum, it is critical that the stakeholders be informed of the decision error rates that are likely to be encountered given the final Sampling and Analysis Plan that they consent to before work proceeds.

The first six protocol steps should have direct involvement/input from the stakeholders. The seventh step, determining an optimal sampling design plan, is the output of the DQO process. This output will specify both the number of samples required and the quality of data (accuracy, precision, completeness, representativeness) required. The DQO process is iterative;

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FIGURE 5. The Seven-Step Protocol Derived from the Data Quality Objectives Process

the outputs from one step are used in future steps but may also influence prior steps and cause them to be redefined.

4.1 STEP 1: STATE THE PROBLEM

Concisely describe the problem to be studied. Review prior studies and existing information to gain an acceptable understanding of the problem. There may be several problems or a hierarchy of problems. In that case, the DQO

process should be repeated several times. Integrating the data needs from several problems is done only after each individual problem is addressed.

To make decisions on performance, information is needed regarding the environmental conditions before, during, and after the demonstration. Information about the operating conditions of the equipment is also needed, as well as information about by-products and process wastes generated by the test equipment. Sufficient site characterization data are needed to estimate parameters required to initially run a numerical model of the processes occurring during the technology demonstration.

Because the final test objectives and decision rules (which determine the test parameters to be measured and the quality of the measurements) are usually not available until well into project planning, a good practice is to start developing a data requirements matrix, such as the one shown in Table 3. List categories of data that might be of interest to either the PI, the modelers, or the project managers, along with how the data will be used and the justification for requiring the data.

The data collection method and the data quality columns will be formally determined during the DQO process. However, if any special methods or requirements for data collection and analysis have been specified, they should be identified now. Also, if only one method of known accuracy and precision is available, this can be documented in the matrix.

TABLE 3. Data Requirements Matrix

Data Category	Data Use/Justification	Standard Data Collection Method	Initial Data Quality Required
Groundwater			
Subsurface soils			
Surface soils			
Test operating conditions			
Process wastes			

Filling out a matrix such as Table 3 in final form without first going through the DQO process can result in overly conservative and expensive analytical method selections that waste project resources.

Two problems are common to most new technology demonstrations: 1) determining if the technology met the performance test objectives, and 2) finding a sufficient explanation for the test results.

Most projects associated with the VOC-Arid ID will be a combination of these threshold detection and estimation problems. Being able to explain the observed test phenomena will be most valuable when examining the proof of concept of the technology and the feasibility of improvements, and when transferring the technology to new sites or comparing test results across sites.

4.2 STEP 2: IDENTIFY THE DECISION(S)

Identify the decision(s) that will resolve the problem using new data. The decision statement is the pronouncement of what question must be resolved using the data that is collected. List the possible actions or outcomes that would result from each resolution of the decision statement.

The most obvious decision is whether to take the technology on to the next step of development and/or transfer the technology to the environmental restoration contractor. Not only does a decision have to be made on whether or not the technology met the test objectives, but whether it is *enough* better than the baseline technology to be considered a viable alternative. In the case of groundwater and vadose zone remediation technologies being tested under the VOC Arid-ID, the baseline technology is pump and treat for groundwater and soil vapor extraction for the vadose zone.

A key part of identifying the decisions to be made is to state the actions or outcomes that could result from the resolution of the decisions. The following actions derive from very different decisions:

- include or exclude the technology in the next round of demonstrations
- recommend or reject the technology for further development and funding
- recommend acceptance or rejection of the technology for use by an environmental restoration contractor.

If multiple decisions are to be made, each decision should be identified along with the sequence in which it will be resolved. If the test objectives can be formulated as a series of decisions, Step 2 of the protocol is basically filling out the Objectives Worksheet from the Conceptual Test Plan. Examples of decisions that have been considered for the VOC Arid-ID remediation technologies follow:

- Removal of a fixed mass of contaminants. A collection system such as an off-gas system could be monitored for total contaminants removed. If that total amount exceeded some threshold, the technology would be declared successful.
- Removal of a fixed percent of contaminants. The before and after conditions of the contamination would be measured. If the percent removed exceeded some threshold, the technology would be declared successful.
- Remaining level of contaminants below some threshold. The criteria for a successful demonstration would be to achieve regulatory limits at the completion of the technology test.
- Shape of contaminant reduction curve over time. The rate of removal is the critical success factor. Curves could shift up or down depending on beginning levels of contamination; therefore, making accurate beginning site characterizations is less critical. However, accurate measurements during the operation of the equipment would be important, and thus add to total sampling costs.

- Performance of new technology (removal rate, removal mass, etc.) relative to baseline technology. The new technology has a performance measure X percentage points above the same performance measure for the baseline technology.

4.3 STEP 3. IDENTIFY INPUTS TO THE DECISION

Identify the information that needs to be learned and the measurements that need to be taken in order to resolve the decision. Not all of the decision information sources need to be new data. But for new data that are required, confirm that appropriate field sampling techniques and analytical methods exist to collect and analyze the data. One of the inputs required is the action level for choosing between alternative actions. An action level can be a regulatory threshold, a technological limit, or a performance standard. The basis for a decision will be some form of comparison between observed values and an action level. In Step 5, the action level will be precisely set; here, the basis for setting the action level is identified.

The primary variables needed to measure test performance and secondary variables for explaining test results need to be identified. Step 3 of the protocol is working through the list of demonstration parameters that are required in Section 3 of the Conceptual Test Plan (Jensen et al. 1994). It must also be confirmed that appropriate field sampling techniques and analytical methods exist for their measurement. This is a preliminary assessment of methods and equipment available and may need to be revisited several times throughout the DQO process. Table 4 is a list of parameters to be measured as part of the in-well vapor stripping demonstration. Because the project is in the early planning stages (Gilmore and Koegler 1994a,b), this list is preliminary and should be used only as an example.

TABLE 4. Parameters to be Measured in the In-Well Vapor Stripping Demonstration

Category/Parameter to be Measured	Expected Range		Criteria for Successful Test	Measurements Before Test Operations
	High	Low		
Initial Environmental Conditions				
a. Lithology				
- Lithology	Gravel	Silty Clay	No consolidated media or extensive clay layer	Litho. samples taken every 5 ft caliche layer to well completion at approx 75 ft (C1) ^(a) and 45 ft (C2) ^(b) below water table. Must be able to recognize litho changes and sample at changes
- Lithology thickness	100 ft	0.2 ft	Impermeable layer (inches thick) could inhibit vertical circulation in flow cell; model to determine feasibility of flow using results of wells C1, C2.	Same as above
b. Aquifer	Multiple aquifers	Single aquifer	Single aquifer	
- Hydraulic conductivity (vertical)	1.00E-03	1.00E-07	1.0E-7 cm/sec	Aquifer tests at water table and every 10 ft to well completion (C1, C2)
- Hydraulic conductivity (horizontal)	1.00E-03	1.00E-07	1.0E-7 cm/sec	Aquifer tests at water table and every 10 ft to well completion (C1, C2)
- Hydraulic gradient (vertical)			N/A ^(c)	Water-levels
- Hydraulic gradient (horizontal)			N/A	Water-levels
- Porosity	50%	5%	<5%	Core samples every 10 ft in range; water table to 75 ft below water table, C1; 45 ft below water table, C2
- Anisotropy (Kh/Kv)	> 1:1	30:1	<30 : 1	
- Groundwater velocity			TBD ^(b) by model; downgradient well locations and monitoring frequency must be able to detect cont. concentration changes.	

TABLE 4. (contd)

Category/Parameter to be Measured	Expected Range		Criteria for Successful Test	Measurements Before Test Operations
	High	Low		
- Contaminants (VOCs)			<100 x MCLs ^(d) ; if major chemical gradient, plug and isolate	Groundwater samples every 10 ft in range: water table to well completion (C1, C2)
- Co-Contaminants: metals (As, Cr); anions (NO ₃); Radionuclide (Tr); Semi-VOCs			<100 x background for metals and naturally occurring elements; 100 x MCLs for chemicals and rad.	Groundwater samples every 10 ft. in range: water table to well completion (C1, C2)
c. Sediments				
- Contaminants (VOCs)			<soil health risk standards	split spoon samples every 10 ft from caliche layer to groundwater (C1, C2)
- Co-Contaminants: metals (As, Cr); anions (NO ₃); Radionuclide (Tr); Semi-VOCs			<100 x background for metals and naturally occurring elements; 100 x soil health risk standards for chem. and rad.	split spoon samples every 10 ft from caliche layer to groundwater (C1, C2)
- Unsat. hydraulic cond. (vertical)				core samples every 10 ft
- Moisture			If find perched water, change test well design to reinject below impermeable layer.	core samples every 10 ft
- Air/water interfacial tension			TBD ^(e) by model; infiltration rates cannot exceed pumping rates	from textbook
- Water retention curves			TBD by model; reinjection and circulation flow cell must be viable	from textbook
(a) C1 = Downgradient Characterization and Monitoring Well. (b) C2 = Cross-Gradient Characterization and Monitoring Well. (c) NA = Not applicable. (d) MCL = Maximum Concentration Levels. (e) TBD = to be determined.				

The in-well vapor stripping and ERACE DQO applications were limited to partial DQO applications (see Appendix A) where initial efforts were made at developing decision rules, but all seven DQO steps were not completed. Technical judgement, standard analytical methods, innovative field test and treatment equipment, and project budgets were the primary determinants of the Sampling and Analysis Plans. In the case of the in-well vapor stripping demonstration, a matrix of parameters to be measured and an action level called a success criteria were specified for each parameter (see Table 4). The success criteria establish a cutoff level for determining whether the technology will work at this site. Technical judgement (rather than a sensitivity analysis) was used to identify primary and secondary test parameters and their success criteria. A range was also specified consisting of the minimum and maximum value expected for the parameter at the selected site for the demonstration. The methods selected for analyzing each parameter are identified in the matrix. The selection was based on a comparison of that method's limit of detection compared with the minimum value expected. Sample sizes were selected to minimize cost, but reserve samples are available if decision outcomes could be expected to be influenced by additional sample data.

Inputs to explaining why the technology did or did not work can become an extensive list. Sensitivity analysis using numerical models can identify which parameters have the most influence on the outcomes. Historical data, numerical model predictions, and technical information about equipment operations may also be inputs. Each information source should be listed and referenced with an explanation of why it is required and how it will be used.

Several other categories of inputs that are required to complete the DQO process are added during the optimization of the sampling design step (Step 7). These inputs include estimates of variability, distribution

assumptions about the populations being sampled, and assumptions on how errors are introduced and propagated throughout sample collection and sample analysis.

4.4 STEP 4: DEFINE THE STUDY BOUNDARIES

Specify the conditions (time periods, geographic area, and conditions such as contamination scenarios) to which decisions will apply and within which the data should be collected.

Defining the geographical area and time frame within which the decisions must apply is difficult when the environmental mediums of concern are groundwater and soil. The nature of the contamination changes with time and location. A key performance parameter on which the new technologies will be evaluated is the spatial extent of remediation and the pattern of change exhibited over time. When the technology itself will influence the boundaries, boundaries become one of the decision variables rather than a definition of the domain of the study. In several of the DQO applications in the VOC-Arid ID, boundaries were part of the decision rule. For example, the in-well vapor stripping technology decision rule stated that if the technology could achieve a 60 percent reduction in contamination within a circulation flow cell of X feet, after a time of Y, then it would be considered successful.

4.5 STEP 5: DEVELOP A DECISION RULE

Integrate the outputs from previous steps into an "if..then.." statement that defines the conditions that would cause the decisionmaker to choose among alternative actions. The three elements to a decision rule are the parameter of interest, the action level, and alternative actions. The chosen parameter

of interest for a population should be thought of as the true characteristic of a population. The action level should be a value for the true parameter or characteristic of the population where the decisionmaker desires a fairly high probability of taking action. This is a theoretical decision rule. Because the true population parameter will never be known (outside of a 100% sample), it can be estimated using sample data. Thus, a second operational decision rule will be defined in Step 7 that has as its elements an estimate of the parameter of interest based on summarized sample data, a trigger level (which will probably be different than the action level), and alternative actions (similar to those above).

Two DQO applications in the VOC-Arid ID (in-well vapor stripping and ERACE demonstrations) provided quantitative decision rules by using a combination of relative performance measures and values to be determined from model predictions.

- The in-well vapor stripping DQO decision rule currently states that a 60 percent reduction in contamination over a circulation flow cell of X feet in radius, over 4 circulation cycles is required to declare the technology successful. Because many subsurface environmental measurements are valid only to within an order of magnitude or so, this basically says we may not be able to distinguish natural swings in contamination levels from real decreases. The decision rule states that a model would be used to determine if real decreases have been achieved based on the calculated flow cell radius and the time for a single circulation cycle. The model would be calibrated using initial site characterization data obtained from characterization wells to be drilled at the site. The model will be recalibrated as the test progresses. Table 5 shows the complete set of preliminary decision rules planned for the in-well vapor stripping DQO application.
- The ERACE soil-heating technology decision rule used a similar approach, stating that a model would be used to calculate the X percent reduction (beginning/ending concentration levels on a relative basis) success criteria. A numerical model would calculate the spatial and temporal

TABLE 5. Primary Data Collection: Threshold Detection DQO Problem

Category	Decision Rule	Data Collection and Measurements		
		Before	During	After
1. Technology Success Criterion: Ability of air-sparging to reduce concentration of CCl_4 in groundwater at test well (location 11)	If concentration of CCl_4 in groundwater is reduced by 60% or more at test well after four circulation steps, then the technology succeeds. Note: time required for circulation step and hence primary flow cell dimensions determined from model	Concentration of CCl_4 in groundwater at inlet screen of test well. This gives beginning concentration in groundwater.	Concentration of CCl_4 in test well at time corresponding to four circulation steps. This gives ending period concentration (for specific test).	Not related to success criteria; further reduction in concentration after four circulation steps related more to cost-effectiveness of technology.
Technology Success Criterion: Ability of air-sparging to reduce concentration of CCl_4 in groundwater at down-gradient characterization/monitoring well (location 12)	If concentration of CCl_4 in groundwater is reduced by x2% or more at downgradient well after four circulation steps, then the technology succeeds. Note: x2% determined from model. If the well is outside the primary cell, expect less than one order of magnitude reduction.	Concentration of CCl_4 in groundwater at downgradient well	Concentration of CCl_4 in downgradient well at time corresponding to four circulation steps.	Not related to success criteria; further reduction in concentration after four circulation steps related more to cost-effectiveness of technology.
Technology Success Criterion: Ability of air-sparging to reduce concentration of CCl_4 in groundwater at cross-gradient monitoring well (location 13)	If concentration of CCl_4 in groundwater is reduced by x3% or more at cross-gradient well after four circulation steps, then the technology succeeds. Note: x3% determined from model.	Concentration of CCl_4 in groundwater at cross-gradient well	Concentration of CCl_4 in cross-gradient well at time corresponding to four circulation steps.	Not related to success criteria; further reduction in concentration after four circulation steps related more to cost-effectiveness of technology.
2. No Negative Secondary Effects	If no increase (<y%) in spatial distribution or concentration of CCl_4 or co-contaminants, then the technology succeeds.	Concentration of co-contaminants in groundwater and sediment at all three wells. Sediment samples from coring will give pre-test soil contamination.	Concentration of co-contaminants in groundwater in all three wells to map increasing/decreasing trends in co-contaminant concentrations.	Concentration of co-contaminants in all three wells. May need to drill (new) verification well to obtain post-test sediment samples.
3. Model Success Criterion	If model predictions of contaminant concentrations are within an order of magnitude of measured values at locations 11, 12, and 13, then the model succeeds.	Characterization well to provide lithographic and hydrogeologic parameters for input to model. Beginning concentrations used to initialize model.	Groundwater and off-gas tracked to compare to predicted values at specific points in time. Actual trends compared to model prediction trends. Model recalibrated using sample data as required.	Groundwater, off-gas, new verification core data collected at all locations and compared to model predictions.

range over which the reductions were measured. The model would be calibrated from some historical data but primarily from initial site characterization data obtained from characterization wells.

These decision rules focused on the amount of contaminant removed relative to the absolute amount of contamination remaining at the completion of the test. Off-gas collection systems provide a second source for determining the amount of contaminant removed. The combination of uncertain site conditions plus unknown equipment capability led to a preference for relative success criteria rather than absolute criteria. Also, current levels for VOCs in the groundwater in the areas where the in-well vapor stripping and bioremediation tests are planned are in the 4-7 parts per million range. Achieving regulatory levels, or Maximum Concentration Levels (MCLs) in the 7 parts per billion range, may not be technically feasible at this time, which further explains the preference for relative success criteria.

4.6 STEP 6: SPECIFY ACCEPTABLE LIMITS ON DECISION ERRORS

Define the acceptable decision error rates based on a consideration of the consequences of making an incorrect decision. A decision error rate is the probability of making an incorrect decision. Decision errors are unavoidable when decisions are based on data that are only a sample of the true population and thus are subject to inaccuracy, imprecision, and incompleteness. Narrow limits on decision error rates will dictate that estimates for population parameters based on sample data have very little uncertainty associated with them. Population estimates are subject to the following categories of error:

- *sampling error*, when sampling is unable to capture the complete scope of natural variability that exists in the true state of the environment
- *measurement error*, which includes errors introduced during sample collection, handling, preparation, analysis, reduction, and handling.

None of the DQO applications for the VOC-Arid ID thus far have been able to provide explicit limits on decision error probabilities. Stakeholders find it difficult to provide acceptable error probabilities (one for false positive error and another for false negative), a grey region (area of decision indifference), and possibly points in between for an entire Design Performance Goal Diagram (Appendix B). However, the error tolerances must be made by the stakeholders, who will provide input to the project management team, who will make the difficult budget choices between increased decision risk for decreased sampling costs and decreased decision risk for increased sampling costs. The two types of errors are as follows:

- The *false positive* decision error in a technology performance characterization would be to decide the technology was successful when in fact it did not achieve the success criteria set for it. Sample data could show an unrepresentative decrease in contamination levels while contamination levels remained high at unsampled locations or times. If the decision is merely to continue funding the technology, the true performance will eventually be discovered and no serious loss will result other than lost time and lost funding for the superior technology. However, if the decision is to recommend the technology for transfer and implementation by environmental restoration contractors, the consequences of a decision error could be more serious.
- The *false negative* decision error in a technology performance characterization would be to abandon the technology when in fact it is superior to the baseline technology or did in fact meet the performance criteria established for it. Unrepresentative samples or insufficient information was collected that could explain the spurious negative results. The consequence of such a decision error would be lost time and money in the abandoned technology, and lost opportunity costs if an inferior technology replaces the abandoned superior technology.

One alternative to asking stakeholders to provide decision error tolerances is to reverse the situation by having the DQO implementation team provide stakeholders with the alternative decision error probabilities that would result under various combinations of contamination scenarios, variability in the sampled population, and alternative sample sizes. Such a tactic

was used in the ERACE DQO application. This alternative scenario approach is shown in Figure 6. Using this chart, stakeholders can see that as acceptable error probabilities (shown here with both error types, false negatives and false positives are equal and referred to as decision errors) decrease, number of samples increases. For example, when total variability divided by the maximum detectable difference is 2, sample sizes of 45, 28, and 13 are required depending on whether the selected error probabilities are 5 percent, 10 percent, or 20 percent, respectively. Note that "D" refers to the maximum detectable difference, or the range of values for which the decisionmaker is indifferent between making either of the two types of errors. As relative variability decreases (i.e., the ratio of variability to maximum detectable difference decreases), sample-size requirements also decrease. Both errors cannot be simultaneously reduced without increasing sample sizes. For a more complete discussion of the relation between sample size and DQO inputs, see EPA (1993b).

It is important for stakeholders to grasp the difficulty of meeting strict decision error tolerances when sample numbers are limited, amounts of differences that are desired to be detected are small, and natural variability is large. Understanding the trade-offs will help stakeholders formalize the optimal sampling design in Step 7.

4.7 STEP 7: OPTIMIZE THE SAMPLING DESIGN

Evaluate the output from previous steps and generate alternative sampling designs. Choose the most resource-efficient design that meets (or comes closest to achieving) the DQO input from Steps 1-6. Trade-offs are required in Step 7, shown by the double arrows in Figure 5. The obvious trade-off is between decreased decision error and increased sampling and analysis costs. As trade-offs are made and prior DQO steps reiterated to try to stay within

FIGURE 6. Relationship Between the Number of Samples Required and the Error Probabilities.

budget and schedule constraints, the operational details and theoretical assumptions of the selected design are documented and form the basis for the final output, a Sampling and Analysis Plan.

Project engineers tasked with using the DQO process to design a Sampling and Analysis Plan tend to simplify the process by searching for a single formula for sample size (numbers of samples) that incorporates error tolerances and decision action levels. Such formulas are available; however, they are based on a very restrictive set of assumptions that are rarely met in the real world of environmental contamination.

A set of sample-size formulas is presented in Appendix C. They are presented not to be used out of context as an "easy fix," but rather to show the variables that affect sample size and how they affect it. Increases in terms in the numerator increase sample size; increases in terms in the denominator decrease sample size. The assumptions that are required to use these simplified sample-size formulas, the historical knowledge about expected site conditions that must be available to estimate the terms in the formulas, and the ability to translate the output of the DQO steps into formula input require statistical expertise. When the simple formulas cannot be used, implementing Step 7 can require a physical site model, a simulation model, a statistical test and power calculation module, and/or an optimization model. These models provide the tools for searching for and evaluating better sampling designs.

Selecting the appropriate sampling design that fulfills the following criteria is a formidable task.

- The sampling design meets all of the DQO input.
- The sampling design is feasible to implement (i.e., all sampling and analysis equipment is available).

- The sampling design stays within a given sampling budget and meets all scheduled milestones.

Alternative sampling strategies (random, sequential, stratified, proportional, etc.) should be evaluated and a statistical test selected. A statistical test is used to implement the operational decision rule, which is derived from the theoretical decision rule developed in Step 5.

It is difficult to develop a protocol for implementing Step 7. Each technology demonstration is unique. Interaction of the following variables complicates the task:

- uncertainty associated with unique site conditions
- uncertainty associated with equipment operation and performance
- compatibility or interaction of equipment operation and site conditions.

Finding a sampling design that controls for these unknowns and potential interactions so that definitive conclusions can be drawn from data collected before, during, and after the test is difficult. When faced with such complex problems and confounding variables, simple formulas (such as the sample-size formulas presented in Appendix C) are usually inappropriate to use because the assumptions on which the formulas are based are violated. The alternative is to use numerical models that simulate actual site and equipment performance conditions, and sequentially search for better sampling designs by changing some component of the sampling plan with each iteration. If uncertainty exists on site conditions and equipment operating parameters, probability distributions should be used to represent the inputs and one must search for a sampling design that has the best performance across the range of input values. Good performance of a sampling design and associated statistical test is one where the power curve most closely matches the desired Design Performance Goal Diagram (Appendix B). Computer simulations can be used to calculate

the expected performance of sampling designs and statistical tests (both parametric and non-parametric). The combination of models and simulations that provide the tools for improved decision making fall under the general category of Decision Support Systems. Several Decision Support Systems are currently being developed that address groundwater remediation and monitoring problems specifically (Bryce et al. 1994).

As discussed earlier, each of the VOC-Arid ID technology demonstrations incorporate (or plan to incorporate) the use of predictive contaminant transport and geochemical models and simulations. These models are used to predict site conditions, including contaminant concentrations at fixed time intervals and on a regular spatial grid. Initial results from the site characterization and initial monitoring results can be used to calibrate the model and verify that the model is working correctly. Using either model predictions or actual initial sampling results, alternative sampling designs can be tested for efficiency in meeting DQO objectives as the test progresses.

4.8 POST COLLECTION DATA QUALITY ASSESSMENT

The DQO process is a planning tool. Once the samples have been taken and analyzed, assumptions that went into the DQO process should be updated, and the achievable decision performance curve re-computed. Because only a sample of the population was taken, the true values for population parameters aren't known. Hence, it is unknown if decision errors were made, although the PIs will have updated information from which to re-calculate the probabilities of making decision errors and compare those results with desired levels of acceptable decision errors.

The Data Quality Assessment (DQA) process is receiving increased attention as an important activity in the overall data collection and analysis process. The feedback received from DQA is very important to future DQO

applications, especially those applications where multiple decisions need to be made. The DQA process can be combined with the post-test data analysis to provide defensible statements of test results that are included in the final Technology Evaluation Report.

5.0 CONCLUSIONS

The DQO process provides a flexible approach for designing Sampling and Analysis Plans for remediation performance characterization. Three technology demonstrations that are or were part of the VOC-Arid ID worked through many of the steps in the protocol. Lessons learned in those early applications can assist subsequent applications.

Developing an Integrated Test Plan that meets the DQO requirements requires an exchange of information from the stakeholders and to the stakeholders. Providers of input to the various DQO steps need to know what can be gained by working through the steps, relaxing error tolerances, reducing the scope of the problem, and/or increasing the sampling budget. Under what scenarios would increased sample type and quality lead to better decisions? Models that predict the response of environmental systems to changes in conditions and stressors, and simulations that test the system response over a complete range of possible values, are ideal for answering such questions. Simulations include the calculation of statistical power for the selected sampling designs and statistical tests. Optimization of sampling designs can be accomplished through sequential search techniques or formal optimization methods. Stakeholders will make better trade-off decisions if they are provided with results from models and simulations that quantify the uncertainty under alternative scenarios and assumptions.

Evaluation of linkages between the remediation performance characterization protocol and the data fusion and engineered simulator work stations has been limited because both workstations are still under development and have limited application in their current form. Future advancements and successful

demonstrations of the workstations will determine their usefulness to such data collection planning activities as the protocol presented in this document.

Full implementation of this protocol requires familiarity of the PI and stakeholders with the DQO Process. Agreement of all parties to quantitative decision rules and decision error tolerances are necessary and most difficult steps in the protocol. It is also recognized that funding and/or other constraints may lead to a shortening or omission of some steps. However, adherence to this guidance to the extent possible forces the PI to identify and involve the stakeholders, to determine the criteria to be used to define a successful test, to justify the data to be collected (how they will be used and why), to formalize the up-front planning, and to force the PI to consider trade-offs between data needs and decision errors to establish a funding level.

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APPENDIX A

ADDITIONAL INFORMATION ON THE DATA QUALITY OBJECTIVE PROCESS

APPENDIX A

ADDITIONAL INFORMATION ON THE DATA QUALITY OBJECTIVE PROCESS

A.1 BACKGROUND ON DQOs

The Data Quality Objectives Process was initially conceived by the U.S. Environmental Protection Agency (EPA) Quality Management Staff (QAMS) in 1984. The EPA was interested in redefining and expanding the role of quality assurance and quality control (QA/QC) from the traditional laboratory focus to an environmental decision focus. The EPA set out to develop a process that would generate the full set of specifications needed to design an environmental data collection study, not just the constraints on analytical imprecision and bias. The process that resulted became known as the Data Quality Objective (DQO) process. The DQO process was designed to avoid collecting data that are inconsequential to decision making.

In 1986, EPA released a draft guidance document entitled *Stages and Steps of the DQO Process, Descriptions of Stages 1 and 2*. Stage 3, the design stage, was not included, primarily because EPA thought that statisticians needed the outputs from Stages 1 and 2 rather than guidance on how to design a study using these outputs. The 1986 DQO Guidance became EPA's working document for a number of years (EPA 1987).

The Observational Approach for environmental restoration was developed by the Hazardous Site Control Division of EPA (Smyth et al. 1992a,b). The Observational Approach is a learn-as-you-go approach to data collection that does not require that every possible contingency be addressed before initial data collection. Rather, data collection is planned for expected conditions, with exceptions handled as they arise.

As part of the effort to meet the goal of the U.S. Department of Energy (DOE) to remediate DOE sites in a faster, better, safer, and cheaper way, DOE looked at combining the DQO process and the Observational Approach into a combined strategy. This strategy is identified as the Streamlined Approach for Environmental Restoration (SAFER) (DOE 1993). While it is hoped that the SAFER framework will reduce overall data collection and analysis costs, this is not a guarantee. Rather, SAFER promises to optimize the design for data collection subject to a set of goals and constraints, given there is consensus among stakeholders.

The DQO process and SAFER are being promoted by several offices within DOE including DOE-EM 26 (Analytical Support Division), DOE-EM 43 (Office of Environmental Restoration), and DOE-EH 32 (Office of Environmental Guidance). The DQO philosophy and guidance for its implementation have been described in several revised publications (EPA 1993a,b). The DQO process has been applied extensively, and reports on those applications are now available (e.g., Buck et al. 1993; O'Brien 1994). Several pilot projects to demonstrate SAFER have been initiated, and reports on those results should be available in the near future.

A.2 OPTIONS FOR APPLYING THE DQO PROCESS

What happens when the entire DQO process can't be completed? What if stakeholders cannot provide the input required? Are there any conditions when partially working through the process is an acceptable alternative? These questions have been raised and addressed by a group developing DQOs for the Hanford Tank Waste Remediation Systems (TWRS) Characterization Program (Pulsipher et al. 1994). This group has identified guidance for DQO applications when all seven steps cannot be completed. These options also address the Estimation Problem discussed in the main body of this report.

Option 1. Estimation-Only Study or Sample Acquisition Objective

Requirement: Complete Steps 1-4 of DQO process

Optional: Evaluate acceptability of achievable delta (+ or -) on estimates for various sampling schemes.

Key attributes of the DQO process:

- Data users need only "ballpark" estimate; focus is on post-collection evaluation of how accurate and/or precise the estimate is.
- Decisions will depend on input other than this sample data; for example, results of prior experiments, historical data, process knowledge, and future sampling efforts;
- Data users will not drive sampling requirements and will have to accept the estimates and uncertainties in population estimates as reported. If appropriate and sufficient prior data are available, if the expected achievable accuracy and precision on estimates could be determined (given the recommended sampling scheme). Then the acceptable degree of uncertainty could be evaluated.
- Making incorrect decisions does not impose significant risk (safety or cost).

Option 2. Preliminary or Interim DQO Study

Requirement: Complete Steps 1-6 of DQO Process

Optional: Complete Step 7 to develop an optimal sampling scheme for estimating inherent uncertainties.

Key attributes of the DQO process:

- Decision will be based on sample results but no pertinent historical data (estimates of spatial, sampling, temporal, or analytical variations) are yet available to complete sample optimization step. Step 7 requires input or assumptions on appropriate statistical distributions for populations, quantitative estimates of variability, knowledge of performance of statistical tests, and performance characteristics of

alternative sampling designs. If any of this information is missing, Step 7 cannot be completed.

- Data users must be satisfied with the performance of judgmental sampling design because an optimized design is not available.
- The primary objective of data collection is to provide appropriate estimates of uncertainty for future data collection using the DQO process.
- Distinguished from Option 1 in that a decision(s) will be made based on the data, and there is concern about making an incorrect decision. Distinguished from Option 3 in that the probability of making decision errors is not controlled through appropriate sampling design and statistical hypothesis testing.
- Selection of data type, quality, and number are influenced by decisions that are to be made and acceptable decision error limits, but probability of making errors is not controlled by sampling design.

Option 3. Full DQO Study

Requirement: Complete Steps 1-7 of the DQO Process

Key attributes of the DQO Process:

- Health and safety risks are significant. Probability of making incorrect decisions based on sample results must be statistically controlled to acceptable levels to minimize costs and health and safety risks.
- Follow-on study after completing a preliminary (Option 2) DQO study.

For a particular DQO study, it is possible to have some combination of the three categories above. For example, some measurements may fulfill a need for "ballpark" estimates but other measurements may drive key decisions. As such, there will be primary variables and supplementary variables. The primary variables and decisions will determine the sampling design, and the supplementary variables will merely have post-collection estimates assigned to them.

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APPENDIX B

DECISION PERFORMANCE CURVES

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DECISION PERFORMANCE CURVES

The inputs that are key to the most important DQO process benefit may also be the most difficult to obtain. These inputs are the *desired* limits on false positive and false negative decision errors. The DQO process benefit is that by following the prescribed sampling plan and using the agreed-upon decision rules, decisionmakers know the *achievable* limits for errors.

One construct that has been found helpful in explaining and eliciting error tolerances from stakeholders is the Design Performance Goal Diagram (also called a Decision Performance Curve). An example diagram is shown in Figure B.1, along with a table showing the same information. The diagram breaks the steps of decision errors into smaller units. There are several good discussions of Design Performance Goal Diagrams in the EPA Guidance documents (EPA 1993). Similar concepts to the Decision Performance Curve are the payoff table and prior probabilities in decision analysis problems and the loss function in optimization problems. In all three cases, stakeholders must provide their preferences for various outcomes under alternative states of (true) nature.

The general reaction when faced with providing decision error tolerances is "I want as good a decision as possible." This can be translated into "I want as good a decision as the sampling and analysis budget allows." However, someone must set that sampling and analysis budget. The individual responsible for making budget decisions and trade-offs must be involved with setting decision error tolerances.

A second reaction when faced with providing decision error tolerances is, "I want as good a decision as needed to protect the environment and/or human health." If a safety issue is involved, there is no alternative than to provide very narrow error tolerances. In this way, stakeholders are assured that the sampling design and analysis plan selected will indeed control expected decision errors to fixed, low levels. There will always be certain non-zero probabilities of making decision errors under conditions of uncertainty. The decisionmakers can acknowledge this fact explicitly and select sample sizes and sampling designs to minimize these errors (e.g., control for decision errors), or they can ignore the issue during the planning phase and be subject to whatever decision error probabilities result based on the sample sizes and designs selected.

The benefit of completely working through all the steps in the DQO process is that the difficult aspects of decision making are worked through in a quantitative, defensible process. Assumptions and preferences are recorded and documented so that questions relating to the final performance decisions can be translated into questions relating to assumptions and preferences of the stakeholders.

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True concentration	Correct decision	Acceptable probability of making an incorrect decision (a decision error)
50 to 60 ppm	does not exceed action level	5%
60 to 80	"	10%
80 to 100	"	gray region—no probability specified
100 to 150	exceeds action level	5%
150 to 200	"	1%

FIGURE B.1. Example of Design Performance Goal Diagram and Decision Error Limits Table Corresponding to Diagram. From EPA 1993a, Pg.28

APPENDIX C

EXAMPLES OF SAMPLE-SIZE FORMULAS

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EXAMPLES OF SAMPLE-SIZE FORMULAS

The following formulas are examples of formulas that can be used to calculate the sample size required to meet certain objectives. For a complete discussion of sample-size formulas, their relation to sampling design, and their role in the estimation and threshold detection problem, see Cochran (1977).

Case 1: Estimation Problem. The objective is to estimate mean value of population to within $\pm D$ with $1-\alpha$ confidence level.

$$n = \frac{(<< t_{\alpha/2})^2 \sigma^2}{D^2}$$

where: $t_{1-\alpha/2}$ is quantile value from Student t Distribution appropriate when t test statistic is used

$1-\alpha$ is confidence level

σ^2 is estimate of total study error (natural variability + measurement error)

D is desired half-width ($\pm$ delta) for $1-\alpha$ confidence interval.

Assumptions: random sampling, estimated variability, and Normal Distribution of population being sampled.

Case 2: Threshold Detection Problem. Objective is to choose correct statement with specified limits of decision errors.

H_0 : mean concentration $\leq$ threshold, vs. H_a : mean concentration $>$ threshold

$$n = \frac{(z_{1-\alpha} + z_{1-\beta})^2 \sigma^2}{D^2} + 0.5(z_{1-\alpha})^2$$

where: $z_{1-\alpha}$, $z_{1-\beta}$ are quantiles from standard normal distribution

α , β are probabilities of Type I and Type II decision errors (false positive and false negative)

σ^2 is estimate of total study error (natural variability + measurement error)

D is the width of the "grey area" (i.e., area of indifference from Decision Performance Curve) identified by stakeholders.

Assumptions: random sampling; estimated variability; normal distribution of population being sampled; one-sided test; when H_0 is false, test statistic t follows non-central t distribution.

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