DEVELOPMENT OF DATA QUALITY OBJECTIVES

FOR MARINE CORP AIR STATION

EL TORO

U.S. Navy, Southwest Division
Naval Facilities Engineering Command
San Diego, California

November 18-20, 1992

Viar & company

DATA QUALITY OBJECTIVES FOR MARINE CORP AIR STATION

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Environmental data are collected for making and defending many environmental and policy decisions. Using the Data Quality Objective (DQO) process to plan new data collection activities helps ensure that the right type and quality of information will be collected and that the study design developed will efficiently address the decision. The implementation of the DQO process can help improve the effectiveness, efficiency, and defensibility of decision making.

The DQO process is a Total Quality Management (TQM) tool to facilitate the planning of data collection activities. It requires that environmental scientists, site managers, and regulators focus their planning efforts by specifying the use of data (the decision), the decision criteria, and the probability they can accept of making an incorrect decision based on the data. The process is structured to encourage the sequential consideration of relevant planning issues and it is anticipated that the DQO process, in conjunction with the observational approach, will be used during all DOD site remediation projects.

If you wish to discuss any aspects of this process, please call:

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Measures of Success for the DQO Workshop

- Develop an understanding of the DQO process
- Develop procedures to resolve issues at EL TORO
- Obtain consensus of DQOs for an EL TORO site

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Participants Have Different Agendas

Navy:
- Get on with business
- Design criteria, WP, SAP, etc.
- Start work

EPA:
- Define a yardstick
- Desires an acceptable measurement of success
- National criteria

State:
- Protect state interests/concerns
- Desires an acceptable measurement of success

Overall:
- Concerns for performance measures
- Nobody contests the decisions/results

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Streamlined Approach For Environmental Restoration

A93-012

Why Consider Streamlining Processes?

- Environmental restoration requires decision making under uncertainty
- Traditional approaches can be very time-consuming and can apply resources inefficiently
- EPA experience indicates a strong need for streamlining
- DoD site investigations remediation faces additional complexity with large sites and compliance agreements

Objectives of SAFER

- Enhance focus on planning/scoping
- Link data collection directly to decision-making needs
- Recognize & manage uncertainty explicitly
- Learn as planning & investigations proceed—apply what you have learned directly and efficiently
- Converge early on a remedy (bias for action)
- Assure participation & consensus from key stakeholders

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Safer Framework

Planning:
(OA)
- Site characterization/models

Decision Process:
(OA, DQOs)
- Develop decisions for probable conditions
- Determine possible deviations
- Prepare basic contingencies

Assessment:
(OA, DQOs)
- Evaluate designs and data
- Refine designs, deviations, and contingencies

Implementation:
(OA)
- Implementation of removal, risk assessment, or remedy
- Final contingency evaluation

Streamlining Approach

Combining elements of the DQO process and Observational Approach to help plan and conduct efficient and effective investigations

DQO process

establishes THE problem and action requiring attention, defines the quality and quantity of data needed for problem resolution

Observational Approach

operational framework for managing uncertainty and planning decision-making

↓

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Data Quality Objectives as a Resource Management Tool

Data Quality Objectives (DQOs)

DQOs are an

- Integrated planning methodology for
- Developing consensus-based performance standards to
- Support regulatory compliance decisions, which will be made
- On the basis of environmental data

Data Quality Objectives (DQOs)

- Regulator endorsed
- Directly compatible with the observational approach
- Proven applications for PA/SI –> RI/FS –> RD/RA

Why Do We Need DQOs?

Answer: So everybody can be more effective

- Environmental restoration requires planning
- Traditional approaches may be ineffective
- ***Everybody*** wants to streamline
- Need for planning increases with site complexity
- Improve customer-supplier communications

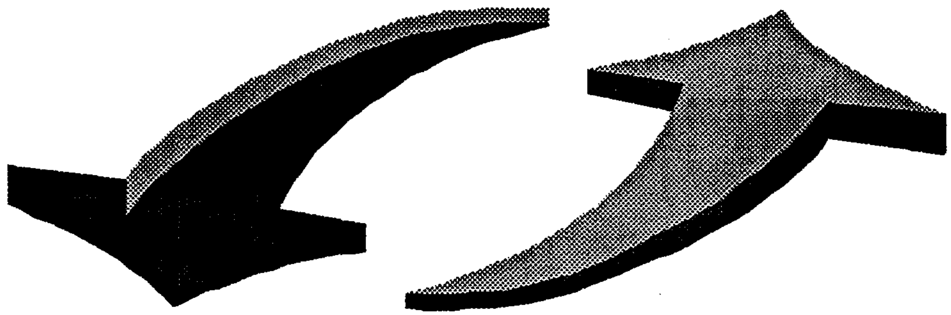
Benefits

Application of the DQO methodology will:

- Control costs
- Expedite restoration and compliance
- Limit and quantify liability
- Improve communication with public interest groups
- Decision makers “own” the planning and design
- Direct link between site/risk assessments and remedial action

DQO Product

Specifications needed to design a study



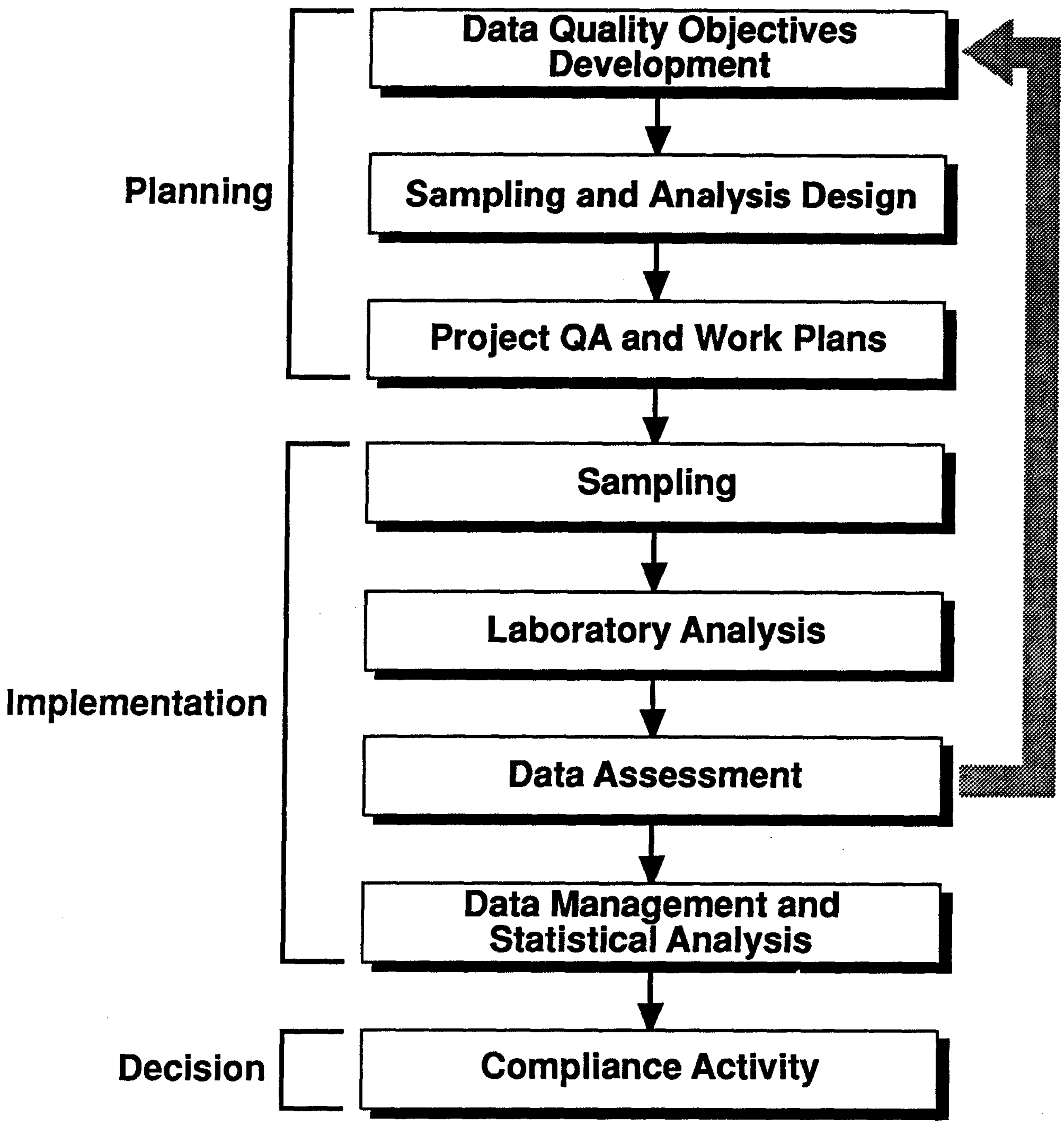
Specifications of acceptable uncertainty

DQO Product (cont'd)

Specifications:

- What is the decision?
- What data?
- When and where?
- How are the data to be used?
- How good are the data?
- How much time and money?
- What level of uncertainty?

Decision-Making Process



Issues to Consider during DQO Development

- Definitions
- Historical/current data sources
- Data collection evaluation
- Identifying chemicals of potential concern (and TBC)
- Exposure assumptions - time, people

Issues to Consider during DQO Development (cont'd)

- ARARs and Risk-based PRGs
- Potential deviations
- Use and interpretation of data
  - Population of interest, averaging considerations
- "Hotspot" identifications
- Combining data from other sources

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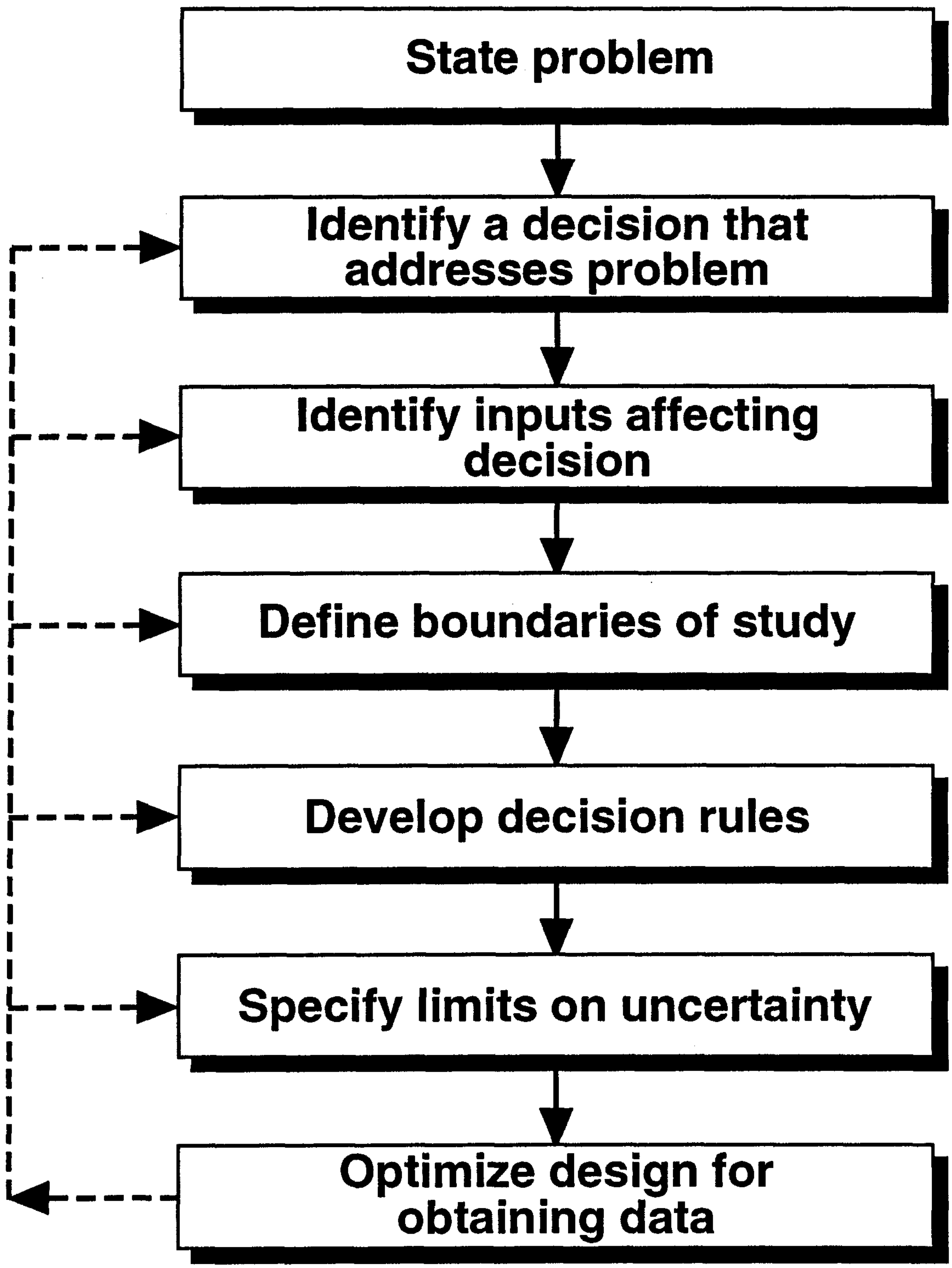
DQO Process



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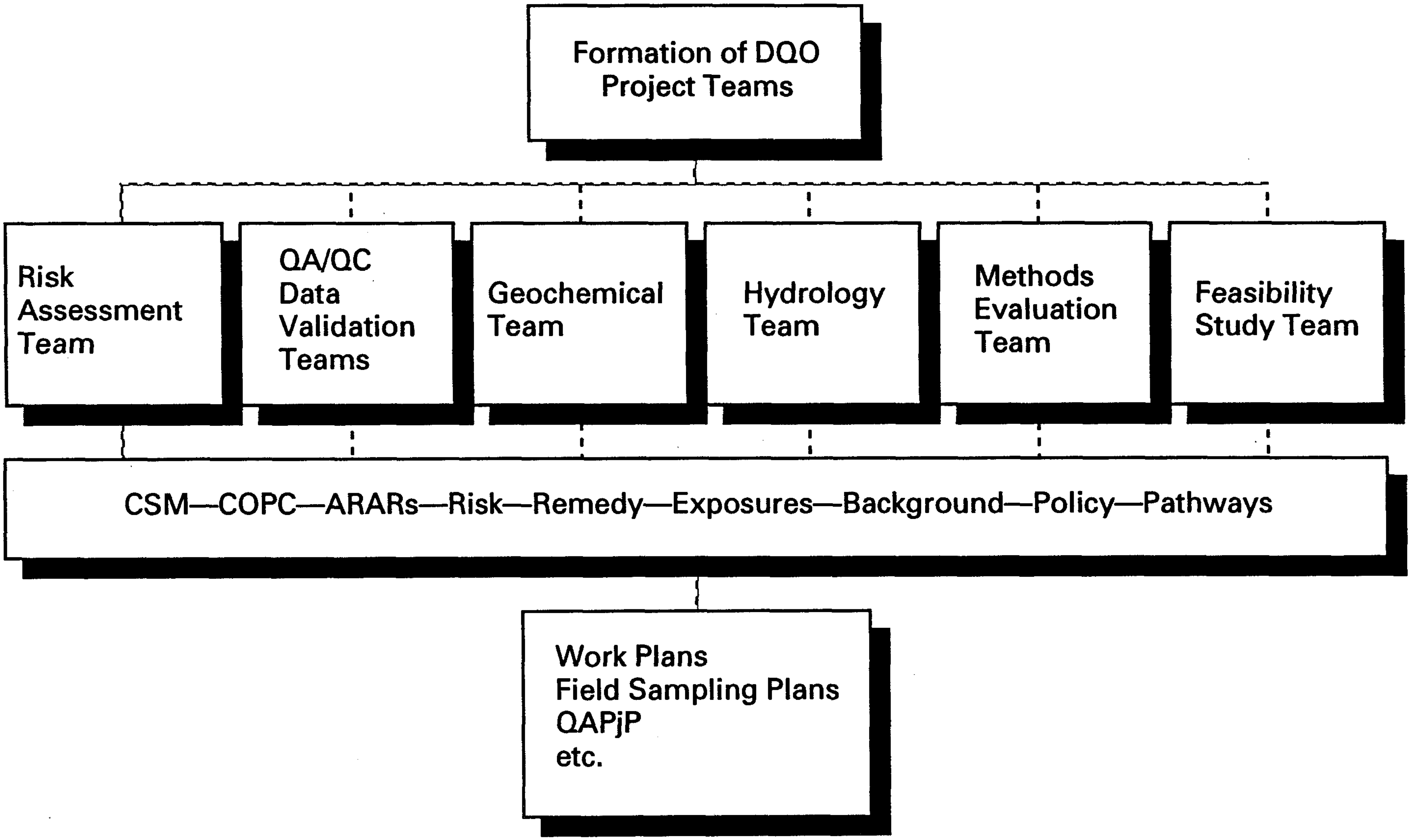
DQO Planning Process



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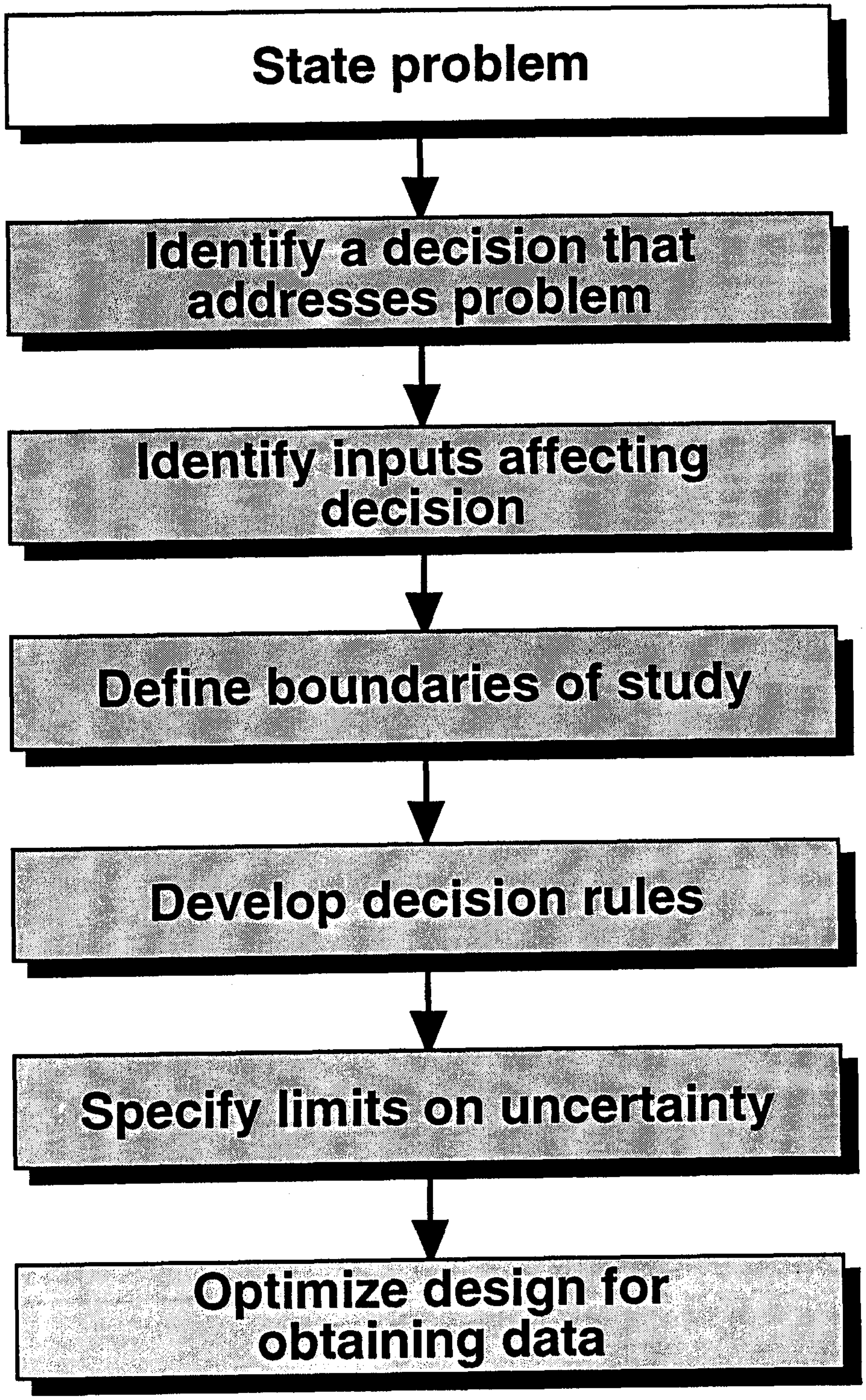
Data Quality Objective Process



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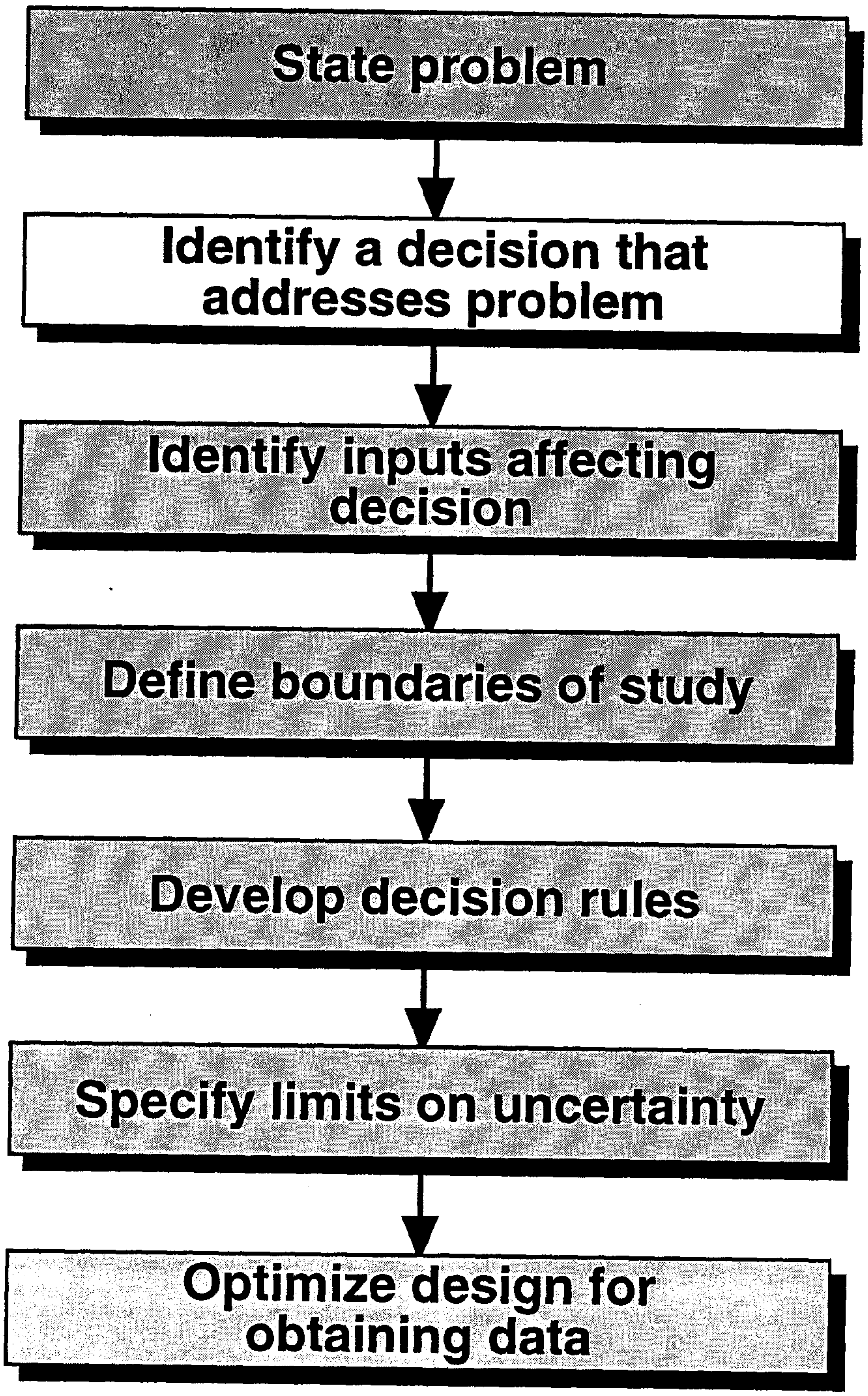
State the Problem to be Resolved

- What is known or expected? How known?
- What approaches are under consideration?
- What courses of action could be taken to address the problem?
- Resource requirements & availability
  - Budget
  - Time
  - Personnel
- Are there any practical constraints?
- Who should be involved in planning?

Data Quality Objective Process



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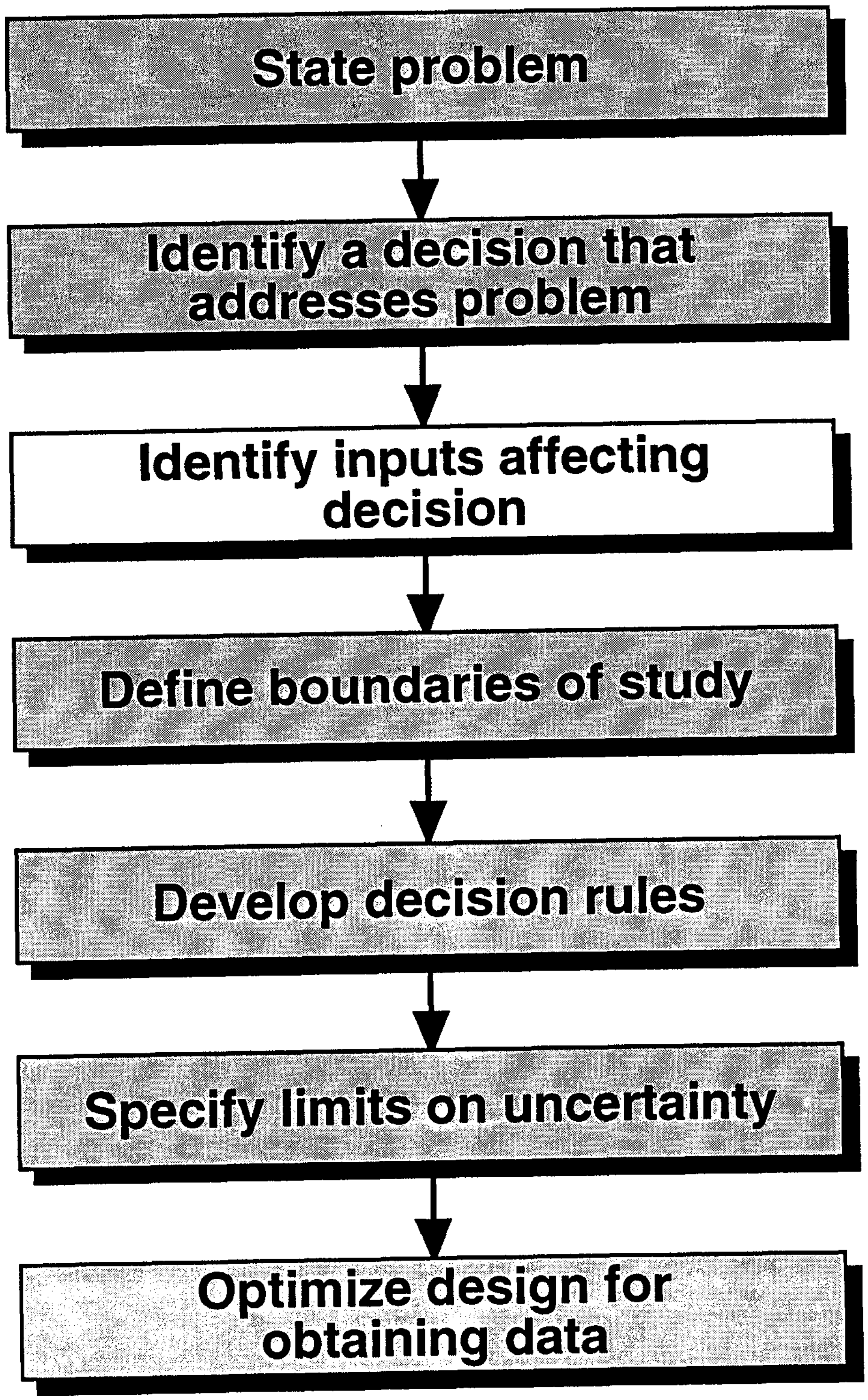
Identify the Decision

- What actions might address the problem?
- What are the range of actions which might be taken?
- What is the decision? (state as whether to take action)

Data Quality Objective Process



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Identify the Inputs

- Variables? (chemicals of potential concern)
  - Statistical measures of the variables ($\overline{x}$, cv, etc.)?
- Criteria for taking different actions?
- Information from other studies?
  - Need for pilot study?

Identifying Chemicals of Potential Concern

"Full" characterization is not practical in the real world

Proposal

- Use "expanded" list of COCs, available from another site and add any new currently identified compounds
- Reduce the list as needed based upon extensive record and document review
- Utilize any available toxicological information
- Include consideration of available analytical methods

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Surrogates for the Coefficient of Variation

- Data from similar sites
- Historical data
- Pilots
- Models

SD = √CV

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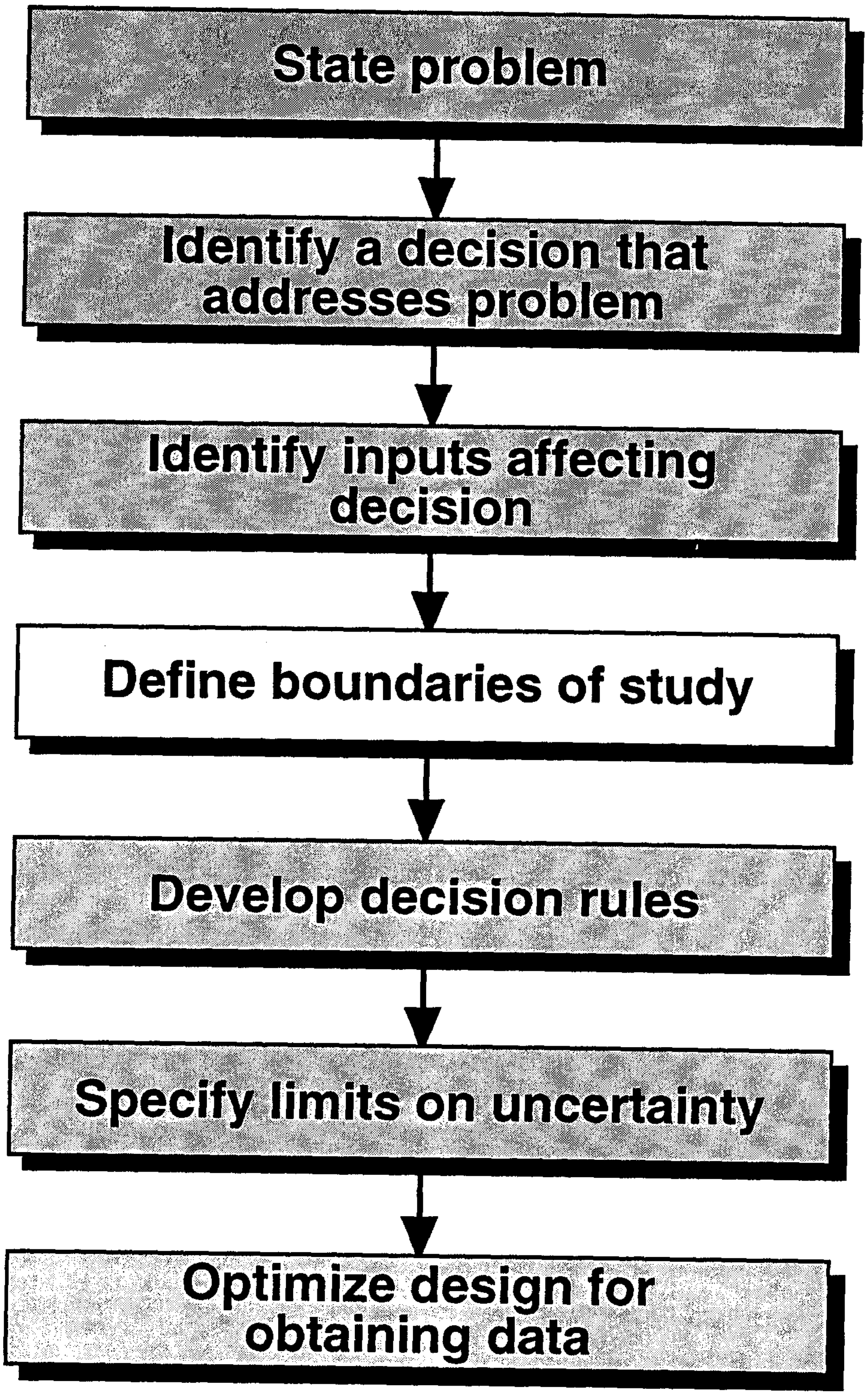
Data Quality Objective Process



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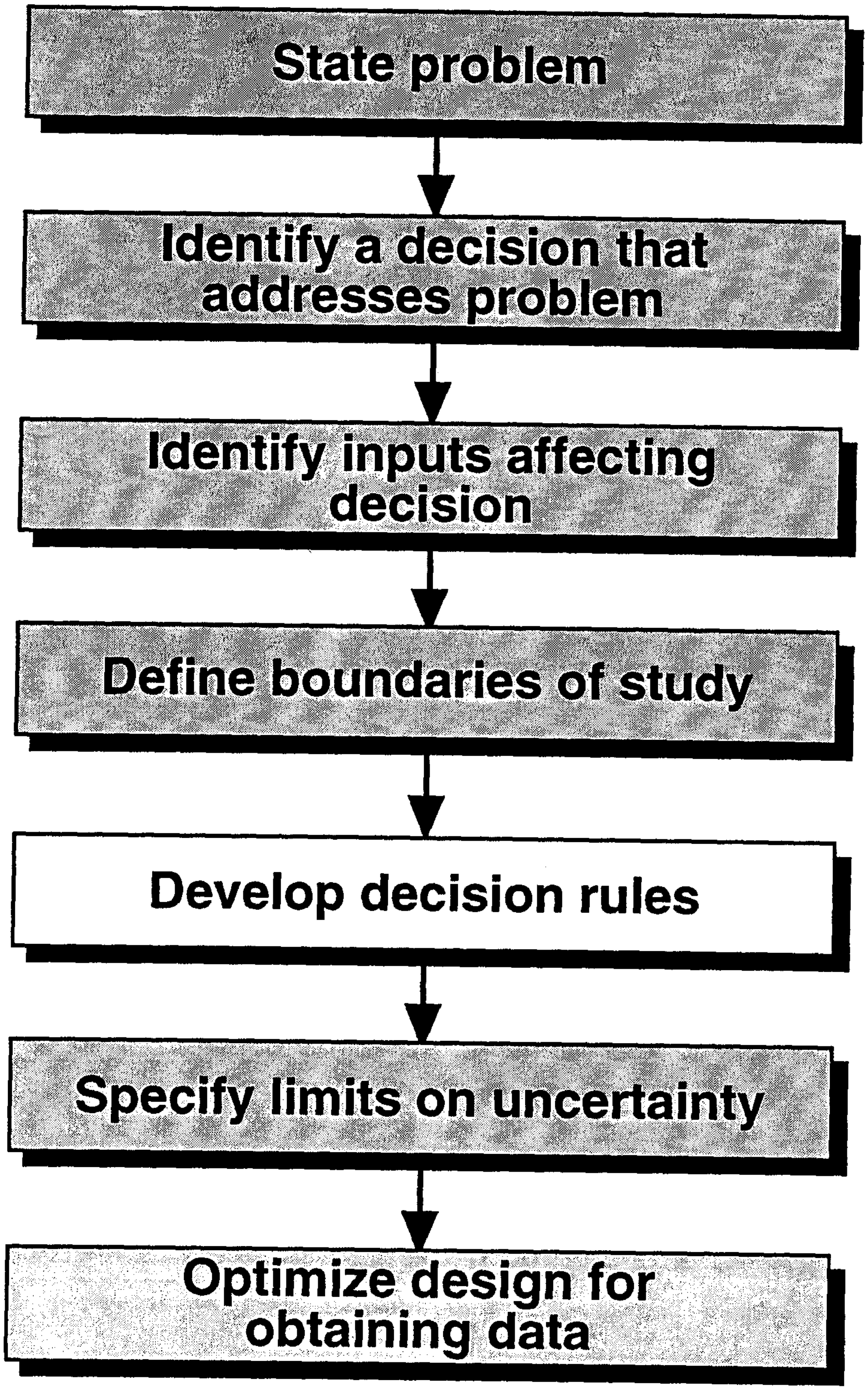
Define the Boundaries of the Study

- How would you describe:
  - The population and any distinguishing characteristics? Future use of land.
  - Spatial boundaries?
  - Temporal boundaries?
- What is the smallest sub-population of interest?

Data Quality Objective Process



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Develop a Decision Rule

- How will environmental data be summarized and used to make the decision?
- What are the quantitative criteria for determining what action to take?

If —

Then —

What is Unacceptable?

- Concentration of a single carcinogenic COC exceeds risk-based criterion for that COC
- Ratios (concentration of carcinogenic COC/risk-based criterion for that COC), when summed over all major carcinogenic COCs, and divided by the number of carcinogenic COCs, exceeds 1.0

  $\frac{1.2 + .8 + 1.4}{3} > 1$
- Exposure level for a single noncarcinogenic COC exceeds 1.0 for the reference dose (RfD)
- Ratios (exposure level of noncarcinogenic COC)/(RfD for that COC), when summed over all major noncarcinogenic COC, exceeds 1.0
- Concentration of a single COC, whether carcinogenic or not, exceeds its ARAR

Deviation and Contingency

Expected Condition:	No "hit" outside of lagoon
Potential Deviation:	Find "hit" outside of lagoon
Mechanism to Identify:	Analysis of data
Contingency:	Determine if sampling outside of lagoon is adequate for "probablistic target model"
Probability of Occurrence:	Low

Deviation and Contingency (cont'd)

Expected Condition: Find [COCs] that permit use of DURA

Data Usability for Risk Assessment EPA guidance

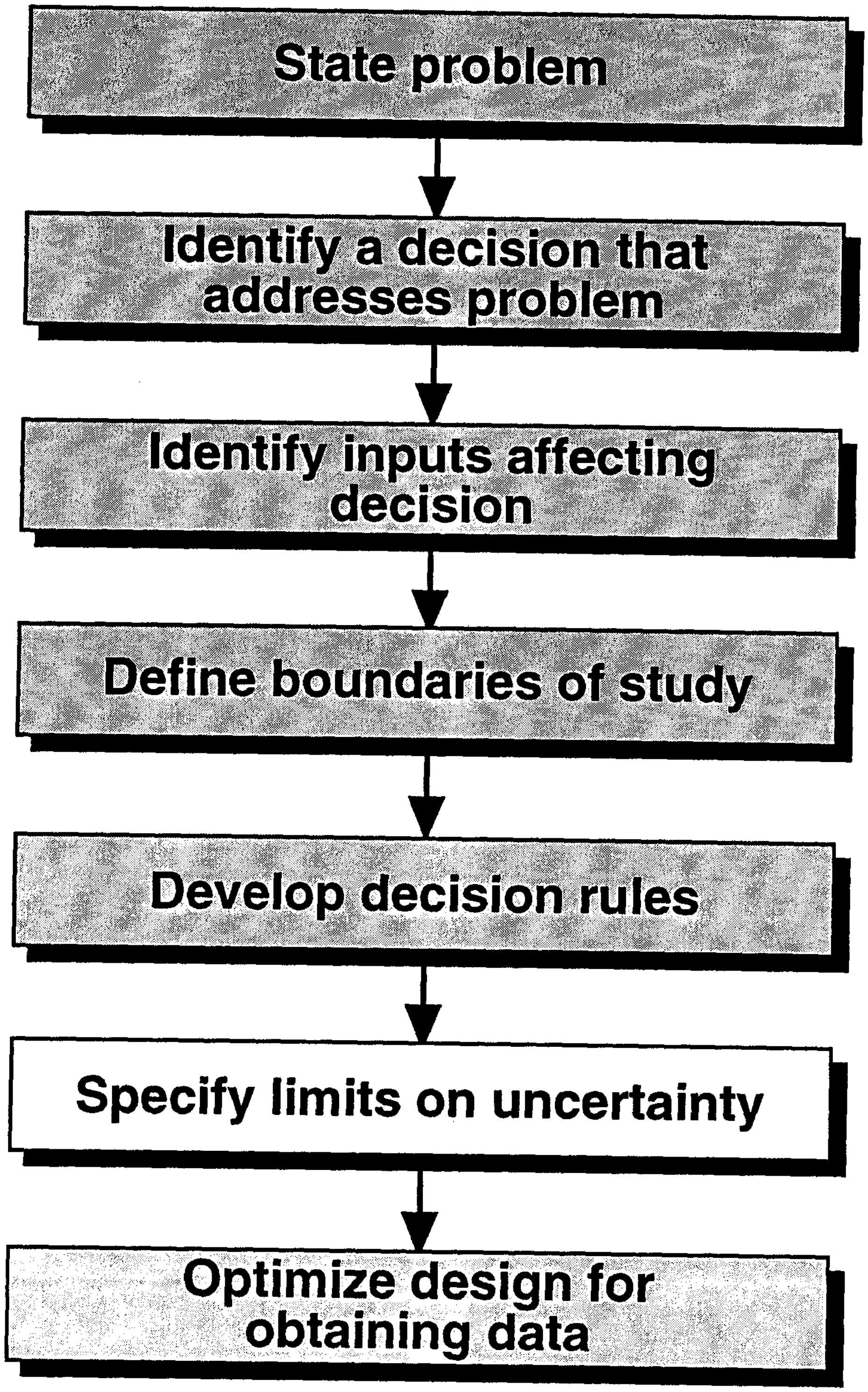
Potential Deviation: All samples are LOD

Mechanism to Identify: Analysis of data

Contingency: Use "binomial hit model"

Probability of Occurrence: Medium

Data Quality Objective Process



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Develop Limits on Uncertainty
Identify Decision Errors and Consequences

Exposure unit

Deciding an EU is a problem when it is not a problem

- Consequences:
  - Unnecessary further study performed in the EU
  - Wasted $ and time

Deciding an EU is not a problem when it is a problem

- Consequences:
  - An EU that poses an unacceptable risk is not remediatied, resulting in human health and/or environmental risk
  - Future health costs or cancer deaths

Note: This error type is of greater concern

Specify Limits on Uncertainty

- What are F(+) and F(-) decision errors?
- Under what circumstances might these occur?
- What consequences would result and how concerned would you be?
  - Costs
  - Health risks
  - Ecological risks
  - Political/credibility
  - Social
- What are acceptable frequencies for these decision errors?

Alternative Responses to Uncertainty

- Determine and design for average conditions
  - Leads to high risk of failure
- Determine and design for worst conditions
  - Leads to high cost
- Determine and design for most probable conditions
  - Prepare contingencies
  - Leads to reasonable costs and risks

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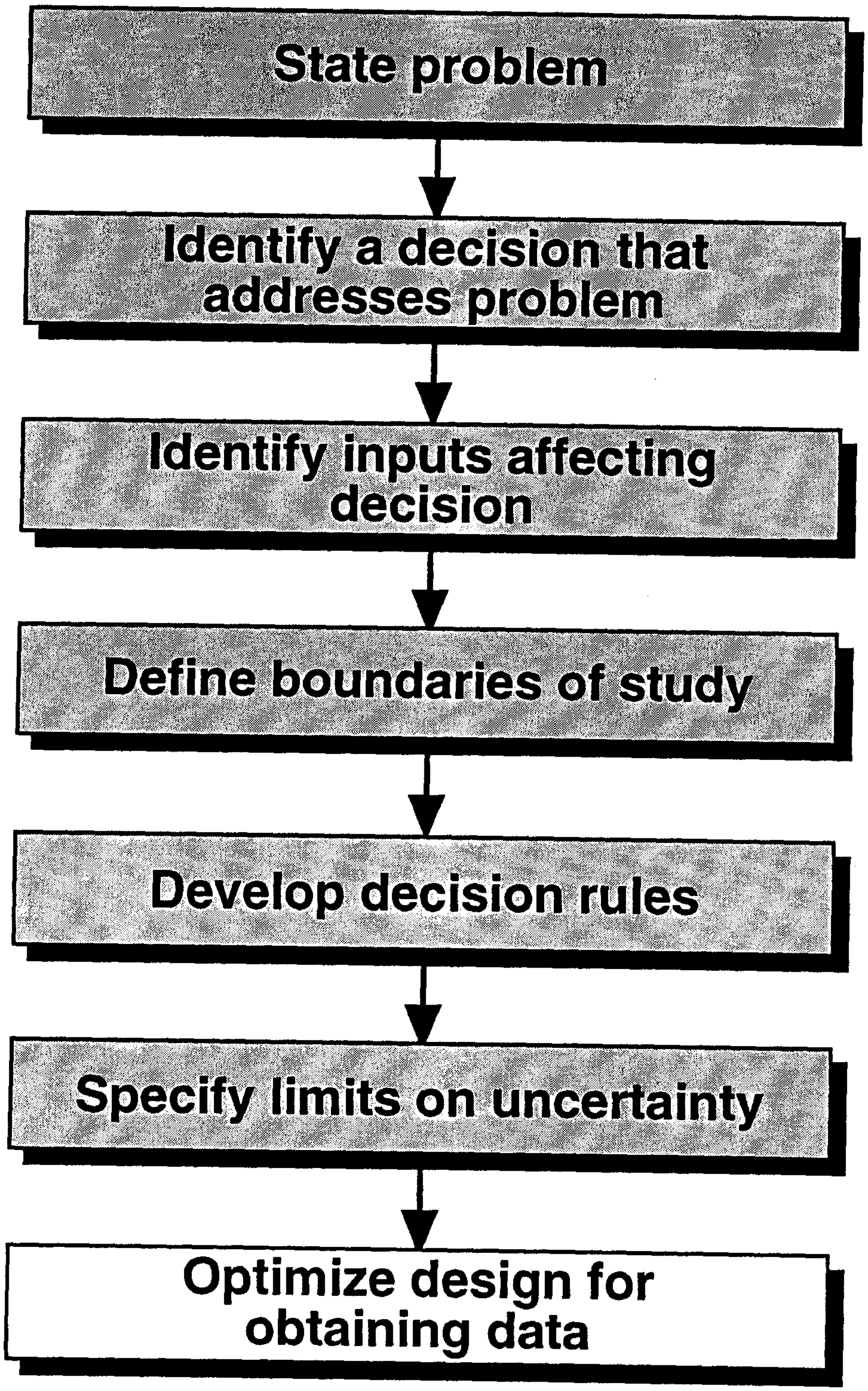
Data Quality Objective Process



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Optimize Design

- Goal: Lowest cost design that will achieve desired limits on uncertainty
- Considerations
  - Data from historical or pilot studies
  - Statistical design options
  - Number of samples/experimental trials
  - Sampling & analytical methodologies
  - Limiting error source(s)
  - Practical constraints

Design Optimization for Resource Management

- Analytical considerations
- Sampling and analysis alternatives
- Cleanup strategies

Design Optimization

Sampling and Analysis Alternative

Number Analyses per EU	Number scoops/ analysis	Cost/EU ($)	Probability of Error	Total Site Cost (S&A)
2	5	2,400	.20	$48,000
2	4	2,240	.27	$44,800
3	5	3,600	.11	$72,000
3	4	3,360	.18	$67,200
4	1	3,520	.53	$70,400
4	4	5,200	.12	$89,600
5	3	5,200	.15	$104,000
8	1	7,040	.20	$140,800

Note: Adopted from Neptune, et al. "Quantitative Decision Making in Superfund: A Data Quality Objectives Case Study." 1990. HMC, May,June, p. 19-27.

93-003-13

Introduction

- Selecting Chemicals and Methods
- Tentatively Identified Compounds
- Detection Limits
- Data Review

Selecting Potential Chemicals of Concern

- Historical Analytical Data
- Manifests and Site Activity
- Risk Assessor Input
- ARARs and Other Benchmarks and Standards
- Age of Site - Breakdown products
  - volatiles in hot, dry environment

Select Appropriate Methods

- Based on Chemical and Medium
- Detection Limits
- Known Interferences - ex: metals
- Methods Acceptable to Regulatory Agencies

Tradeoffs

- Turnaround Time
- Sensitivity
- Availability of Trained Resources
- Cost

TIC (LSC)

Definition:

A compound not associated with the Toxic Compound List which has been identified through the library search on CLP GC/MS.

TIC (LSC) (cont.)

- Tentative Identification
- Use - Expand Knowledge of COCs
- Additional Data Need
  - Interpretation
  - Quantitation
  - Standards

Detection Limits

Method Detection Limit   Sample Quantitation Limit

- MDLs vs. SQLs
- Lower Than Concentration of Concern (MDL ≤ 20% of COC) according to DURA
- Human Health, Ecological Risk and Aquatic Life May Be Different

Data Review

Purpose:

To provide the data user with easy access to summary data along with information based on ***professional judgement*** about the limitations of the data from a technical standpoint.

El Toro used a method - not prof. judgement.

Data Quality

Definition of Qualified Data (CLP)

Data for which control limit windows are exceeded as judged by QC results.*

Data Quality
Measures of Quality

- Laboratory Quality Control
  - Blanks, spikes, calibrations, etc.
- Quality Assurance Programs
  - Error tracking systems

Use of Qualified Data

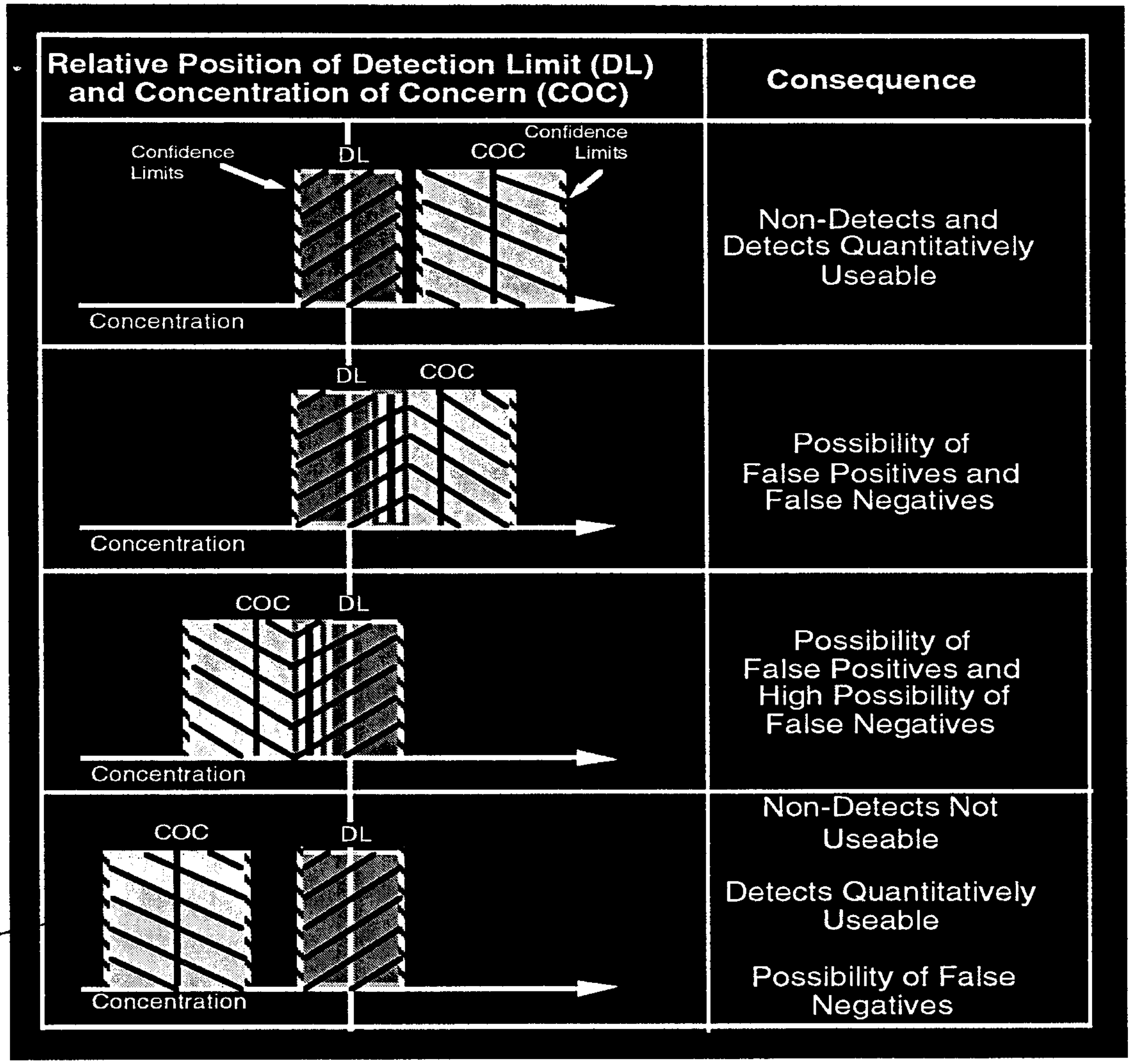
Rules of Thumb

- Qualified data are not unuseable data.
- Data quality must support the decision to be made.
- Error (statistical) is always present.

Use of Qualified Data Implications

- False positives
  - Overestimation of contamination
  - Increased cost
- False negatives
  - Underestimation of contamination
  - Increased risk

Use of Qualified Data Risk Assessment



regulators then agree to have COC ≥ DL

Data Quality

QUALITY CONTROL CRITERION	EFFECT ON IDENTIFICATION WHEN CRITERION IS NOT MET	QUANTITATIVE BIAS	USE
Spikes (High Recovery)	-	High	Use data as upper limit.
Spikes (Low Recovery)	False Negative[1]	Low	Use data as lower limit.
Duplicates	None, unless analyte found in one duplicate and not the other. Then either false positive or negative.	High or Low[2]	Use data as estimate - poor precision.
Blanks	False Positive	High	Set confidence level 5x blank. Use data above confidence level. Use data below confidence level as estimate.

1 False negative only likely if recovery is near zero.
2 Effect on bias determined by examination of data for each individual analyte.
3 Includes surrogates and system monitoring compounds.

Data Quality (cont'd)

QUALITY CONTROL CRITERION	EFFECT ON IDENTIFICATION WHEN CRITERION IS NOT MET	QUANTITATIVE BIAS	USE
Calibration	-	High or Low [2]	Use data as estimate unless problem is extreme.
Tune	False Negative	-	Reject data or examine raw data and use professional judgment.
Internal Standards (Reproducibility) [3]	-	-	Use data as estimate - poor precision.
Internal Standards (High Recovery)	-	Low	Use data as lower limit.
Internal Standards (Low Recovery)	False Negative [1]	High	Use data as upper limit.

1 False negative only likely if recovery is near zero.
2 Effect on bias determined by examination of data for each individual analyte.
3 Includes surrogates and system monitoring compounds.

Use of Qualified Data Alternatives

- Data of "Known Quality"
  - Data with no defects
  - Data with measurable defects
- Unreviewed (unqualified) data

Statistical Subjects
Sampling vs. Analytical Variability

Rule of Thumb:

The component of total variability attributable to sampling far outweighs that attributable to analytical measurement.

Data Quality Objectives

A Forward Retrospective Technique!

At some point in the future . . .

I will make a **decision**
with an accepted level of **uncertainty**
based on an affordable **quality** of data

B93-013

Samples Are Like Potato Chips

- You're never satisfied with just one
- Every one you take makes you want more
- You're never sure you've had enough until you've had too many

Points to Remember About Sampling Strategies

- Sampling strategies must be consistent with study objectives
- Large sample sizes will not compensate for an inappropriate strategy
- Excellent planning will not compensate for inconsistent implementation
- The interpretation of a descriptive (or inferential) statistic will depend on the sampling strategy

Sample Size

Related to the objective of the study

- Identifying targets
- Describing data
- Detecting differences
- Evaluating trends

Can be estimated using:

- Calculations
- Rules of thumb
- Iterative approaches

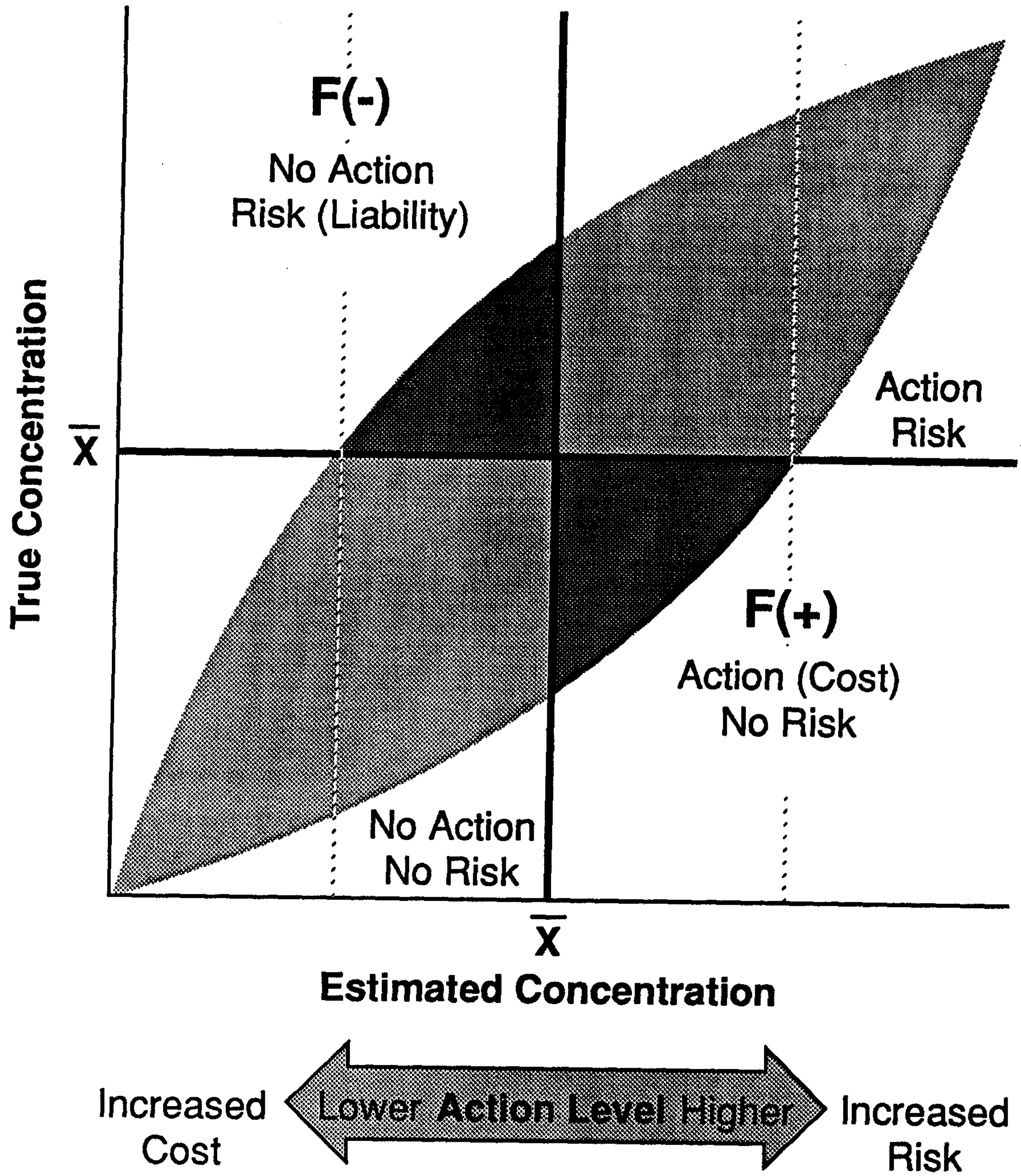
Depends on how certain (precise and accurate) the answer needs to be

Applicability of Sampling Strategies

Objective of Sampling

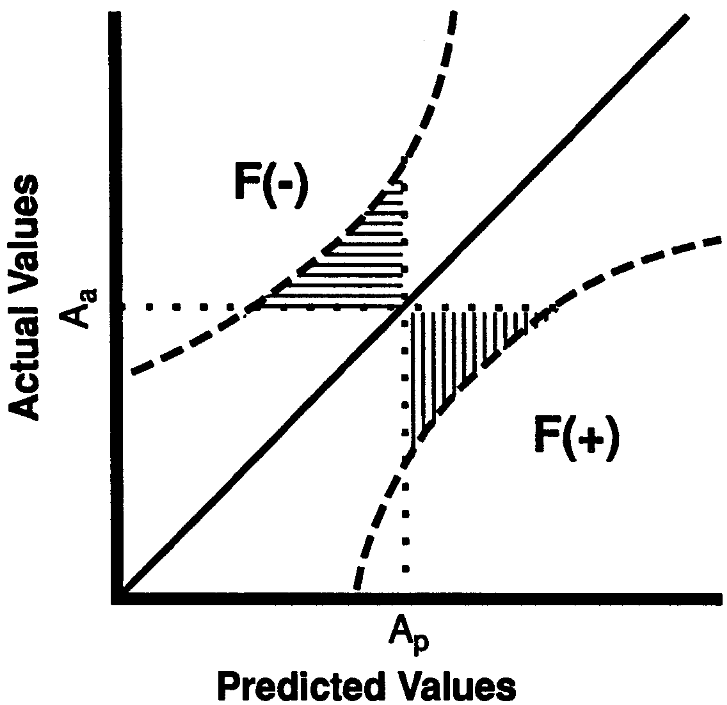
Strategy	Estimate Population	Evaluate Trends	Identify Targets
Judgement	No	Maybe	Maybe
Random	Yes	Yes	No
Stratified:			
Random	Yes	Yes	Maybe
Systematic	Maybe	Yes	Maybe
Cluster	Yes	No	No
Composite	Maybe	No	Maybe
Systematic			
Random	Maybe	Yes	Maybe
Grid	No	Yes	Yes
Search	No	No	Yes
Surrogate	No	Yes	Maybe
Phased	No	Maybe	Yes
Geostatistical	Yes	Yes	Yes

Effects of Error on Compliance Decisions

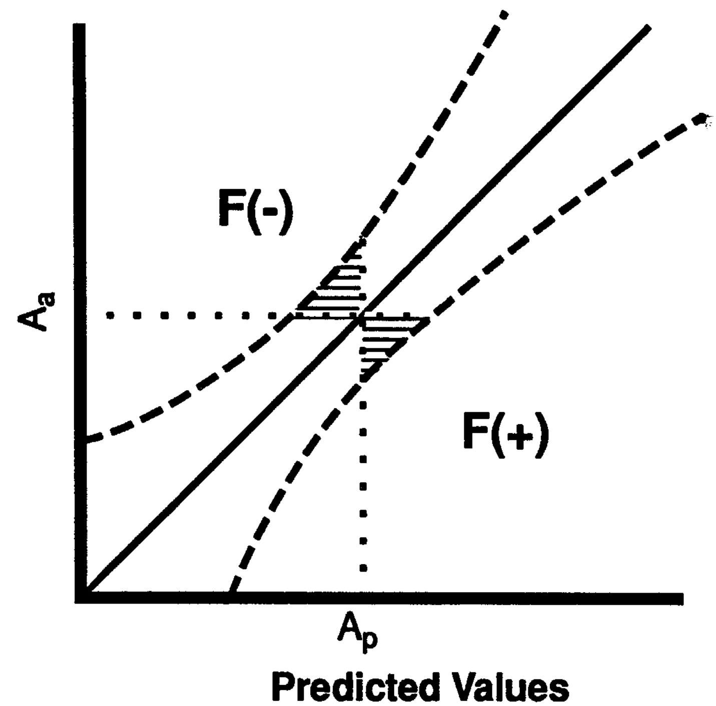


Error Reduction Sampling

First Sampling Round



Second Sampling Round



A_a=Actual Action Limit
A_p =Predicted Action Limit

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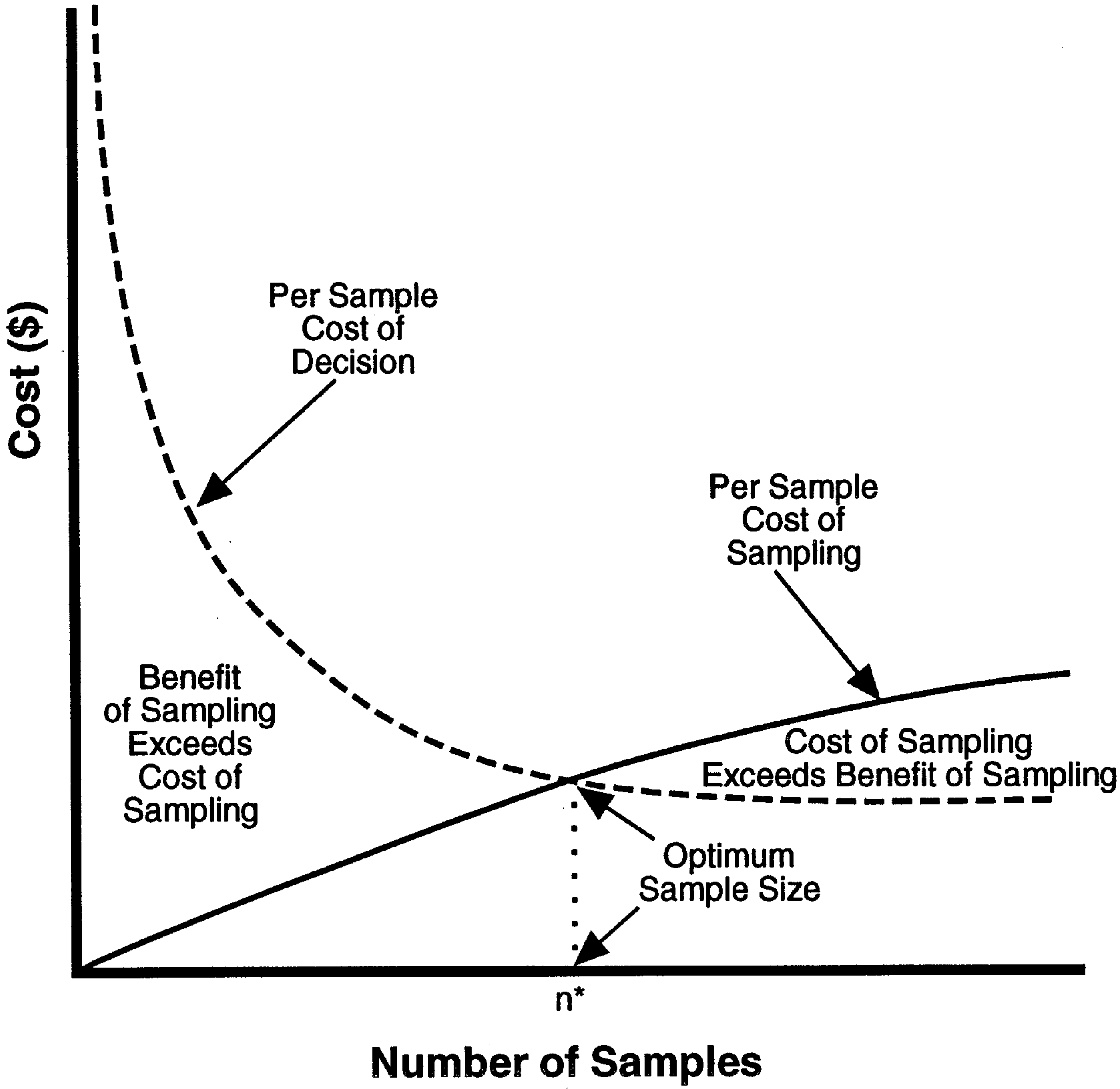
Cost Optimization Sampling



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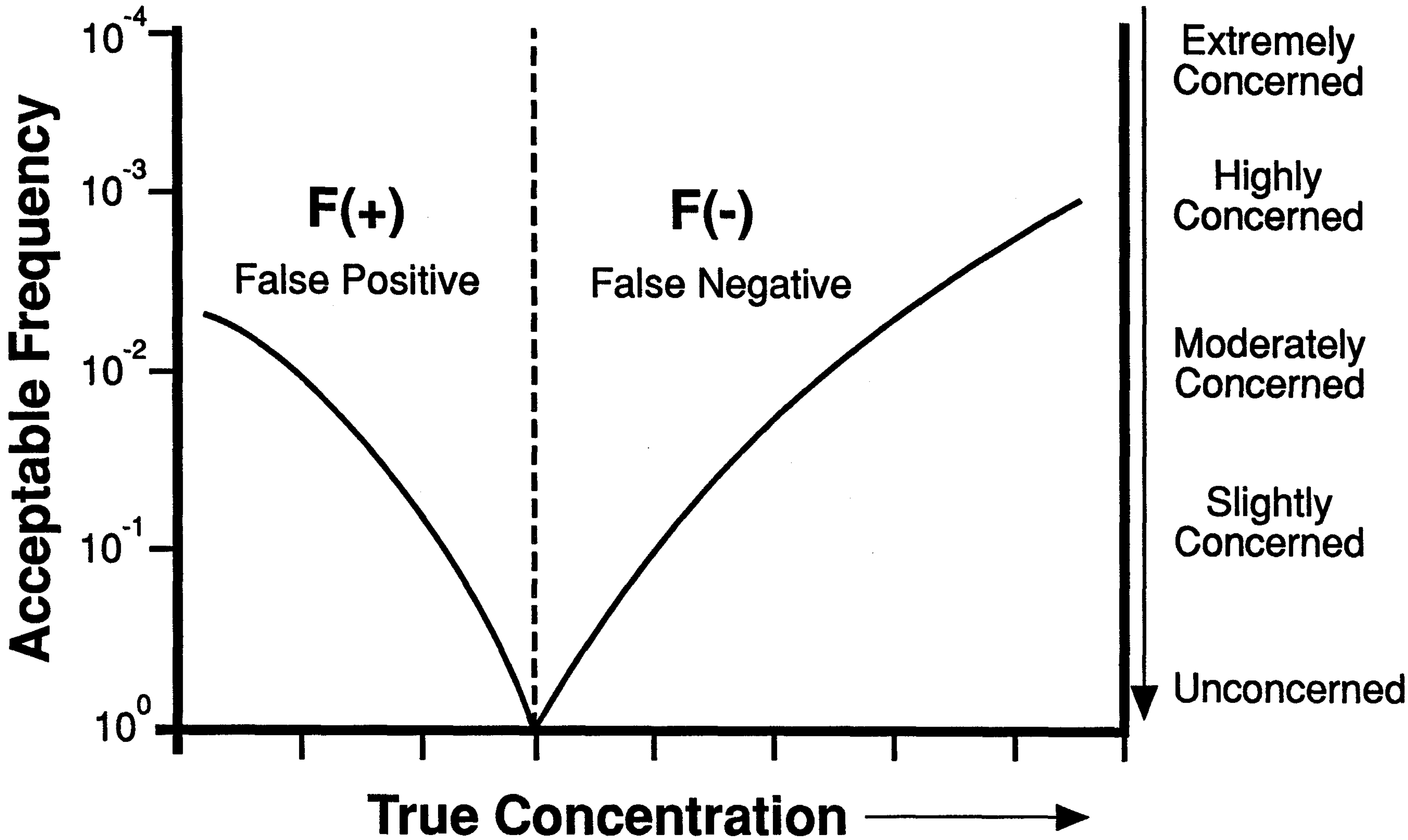
Discomfort Curve



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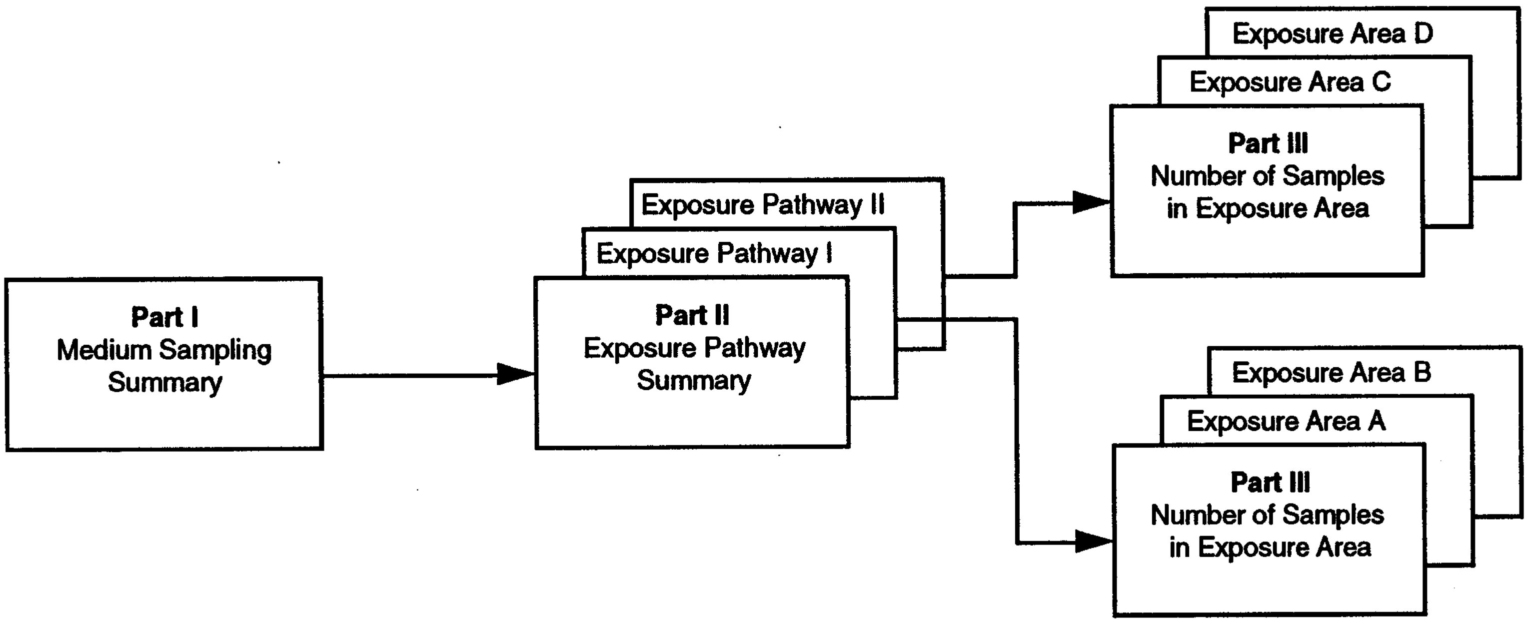
Hierarchical Structure of Sample Design Worksheet



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Part I: Media Sampling Summary
Sample Design Selection Worksheet

Medium/ Pathway Code	Exposure Pathway/ Exposure Area Name	Number of Samples from Part II					
		Judgmental/ Purposive	Back-ground	Statistical Design	Geo-metrical or Geo-statistical Design	QC	Row Total
	Column Totals:						
						Grand Total:	

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Part II: Exposure Pathway Summary Sample Design Selection Worksheet

Chemical of Potential Concern and CAS Number	Frequency of Occurrence	Estimation		CV	Background
		Arithmetic Mean	Maximum		

B93-013-2

Part III: Exposure Area Summary Sample Design Selection Worksheet

Statistical

- CV of proxy or chemical of potential concern ________
- Minimum Detectable Relative Difference (MDRD) ________ (<40% if no information exists)
- Confidence Level ________ (>80%)
- Power of Test ________ (> 90%)

Number of Samples [ ]

$$n \geq [(Z_\alpha + Z_\beta)D]^3 + 0.5Z_\alpha^3$$

$$D = MDRD/CV$$

$$MDRD = (\mu_{meas} - \mu_{loc})/\mu_{loc}$$

$$CV = \pm \sigma/\mu \times 100$$

$1-\alpha$ Confidence Level

$1-\beta$ Power

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Relationships between Measures of Statistical Performance and Number of Samples Required

Coefficient of Variation (%)	Power (%)	Confidence Level (%)	Samples Required to Meet Minimum Detectable Relative Difference 5%	10%	20%
10	95	90	36	10	3
15	95	90	78	21	6
20	95	90	138	36	10
25	95	90	216	55	15
30	95	90	310	78	21
35	95	90	421	106	28

Note: Number of samples required in a one-sided one-sample t-test to achieve a minimum detectable relative difference at confidence level and power. CV based on geometric mean for transformed data.

Source: EPA 1989c.

B93-013-4

Pilot Study CVs

OSWER Directive 9355 (1991)

Task:

Sample size in pilot study to have valid upper limit on CV

Required DQO's:

m CV order of magnitude

α Confidence level

γ Experimental design (degrees of freedom)

Assumptions:

Sample independence

Normality

Domain homogeneity

Example degrees of freedom:

Confidence Level	Criterion m Value 1.50	1.75	2.00	2.25	2.50
.995	82	44	29	22	18
.990	67	36	24	18	15
.975	46	26	17	13	11
.950	34	19	13	10	8
.900	21	12	8	6	5

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As a Resource Management Tool, The DQO Process:

- Reduces sampling and analysis costs
- Facilitates the analysis of the marginal costs
- Tradeoff analysis
- Minimizes the amount of unuseable data
- Reduces the magnitude of remedial and compliance costs

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DQOs: A Desirable Alternative

DQO Approach	Traditional Approach
• Control uncertainty to a pre-specified acceptable level	• Unknown performance/ uncertainty
• Provides quantitative criteria for "when to stop"	• Not clear when enough data have been collected
• Opportunity to optimize cost vs. uncertainty	• No objective basis for optimization of design
• Decision-makers involvement	• General absence of decision-makers input
• Link between initial site investigations and RD/RA	• Difficulty in transfering data to RD/RA stage

Planning for Data Collection

THE DATA QUALITY OBJECTIVES PROCESS FOR ENVIRONMENTAL DECISIONS

Quality Assurance Management Staff
Environmental Protection Agency
Washington, DC

INTRODUCTION

Environmental data are collected for making and defending many EPA decisions. Using the Data Quality Objectives (DQO) process to plan new data collection programs ('studies') helps ensure that the right type and quality of information will be collected and that the study design developed will efficiently address the decision. Using the DQO process can help improve the effectiveness, efficiency and defensibility of Agency decision making.

What is the DQO process? The DQO process is a Total Quality Management tool developed by EPA to facilitate the planning of data collection activities. It asks planners to focus their planning efforts by specifying the use of the data (the decision), the decision criteria, and the probability they can accept of making an incorrect decision based on the data. The process is structured to encourage the sequential consideration of relevant planning issues.

What are DQOs? DQOs are specifications needed to design a study, including the level of uncertainty that a data user is willing to accept in the decision. These specifications are the output from each step of the DQO process (see diagram on next page). DQOs specify:

- the problem to be resolved
- the decision
- the inputs to the decision
- the boundaries of the study
- the decision rule
- the limits on uncertainty

How are DQOs used? The DQOs generated from the DQO process are used to develop an efficient study design that will lead to the right type, amount and quality of data needed to make the decision with acceptable confidence. DQOs are also used to arrive at the Quality Control requirements for the study.

When are DQOs developed? DQOs are specified at the planning stage of a study, before data are collected.

What is the value of the DQO Process?

- The DQO process helps data users plan for uncertainty. By establishing DQOs, data users evaluate the potential consequences of uncertainty before they collect the data, and specify limits on the amount of uncertainty they can tolerate in the decision that will be based on the study results.
- The DQO process encourages structured communication among all those involved in planning before time and money are spent collecting data.

- The DQO process helps to focus studies by encouraging data users to narrow many vague objectives to one or a few specific decisions.
- The logical structure of the DQO process provides a convenient way to document activities and decisions that can prove useful in communicating the study design to others.
- The DQO process can save resources by making data collection operations more efficient and cost-effective.

Who participates in the DQO process? A DQO planning team consisting of senior program staff, technical experts, managers and a statistician (or someone with statistical expertise) all participate in the DQO process. It is important that all of these people, including managers, participate (or at least are kept informed) from the beginning of the DQO process so the process can proceed efficiently.

What projects require DQOs? In general, EPA's policy is that DQOs should be developed for all data collection efforts that require or result in a substantial commitment of resources. Some offices have specified which studies require DQOs in their QA Program Plan.

What projects are covered by this guidance? This guidance document is designed to provide guidance on DQO development for all efforts to collect environmental data that will be used for all Agency decisions and monitoring studies (where the results will be used to decide what action to take to address the problem). Use *The Data Quality Objectives Process for Research* if no immediate action is anticipated.

How should this guidance be used? Use this guidance document to formulate agendas and structure planning meetings. At these meetings, the DQO planning team can discuss and reach agreement on the output for each step of the process. In the course of this work, they will often be able to return to earlier steps to clarify and narrow the study, an added benefit of using the DQO process. They will often find that it is helpful to designate a facilitator to run the planning meetings to keep the meeting on track and allow all members of the planning team to fully participate.

State the Problem To Be Resolved

Product: **A description of the problem; and any resource, time, or other practical limits on the data collection.**

Background: The purpose of this step is to evaluate existing knowledge about the problem, and identify available resources.

By carefully defining the problem early in the planning process, the planning team can ultimately save time and money. In addition, refinements to the way in which the problem is stated are often made when the planning team better understands the implications of the original problem definition.

Activities: Identify the planning team, including senior program staff, technical experts, and any senior managers (decision makers) whose planning input will be needed during the process in order to ensure implementation of the study findings. A statistician (or someone with statistical expertise) should either be included in this team.

Specify any resource or time limits for this study, including the anticipated budget and the available personnel. Identify any obvious practical considerations (such as the time of year when data collection is not possible). These practical considerations will be expanded upon later in the process.

State the problem.

- Describe the problem as you currently understand it.
- Consider the importance of social and political considerations to the problem.
- Organize and review relevant information, including preliminary studies, and indicate the source and reliability of the information. Conduct literature searches and explore on-going studies to ensure that the problem has not previously been resolved.
- If it is a complex problem, then organize your understanding of it by identifying components of the problem, each of which could potentially be addressed by a separate study. Try to prioritize among these components for further planning.

Examine whether new data are critical to resolving this problem.

Identify the Decision

Product: **A statement of the decision that will be made using environmental data and the actions that will result.**

Background: The study will usually produce data that will be used to decide what action to take to address the problem. If specific actions can not be identified, then these studies fall in the category of exploratory research and the planning team should consult *The Data Quality Objectives Process for Research*. If the planning team believes actions may be taken based on the study data, but doesn't know what specific actions, then it will save time and resources to try to elicit possible actions from the decision maker so that the team understands the use of the data.

The decision should be stated as narrowly and specifically as possible. General statements of goals or objectives are not adequate.

Activities: If several separate decisions must be made to address a component of the problem, then begin by mapping out a decision or logic tree. This exercise should reveal the relationship among decisions. Then try to determine the relative importance of each decision to the overall problem. Determine which decisions require new environmental data and the importance of those data to the decision. Use the DQO process for each of the decisions that require new data starting with the most important decision. In certain cases, you may want to go back and reflect further on the problem.

State the decision so that it is clear what the role of data is in deciding what action to take.

- Describe initial ideas on approaches to resolving the problem.
- State the range of actions that might be taken based on the outcome of the study. Consider Agency policies that may influence these actions (e.g., Agency emphasis on pollution prevention rather than source containment or treatment).
- Specify the criteria for taking these actions as specific "if..., then..." scenarios, when possible. If the criteria are not known at this time, then specify how they will be established.
- State the decision as a choice among alternative courses of action that will resolve one or more components of the problem.

The decision maker (data user) should be involved in this step and is encouraged to provide general guidance for taking action.

Identify the Inputs

Product: **The list of environmental variables or characteristics to be measured; the criteria for taking action; and other information needed in order to make the decision.**

Background: During this step the planning team should identify all variables or environmental characteristics that may be relevant to the decision, and then focus on those that must be measured in order to have the information needed to make the decision.

Activities: Develop a list of variables (or environmental characteristics) that may affect the decision and separate out those variables from the list that must be measured to make the decision (which action to take). Identify those variables that together will provide sufficient information to make the decision.

Specify the criteria for taking action. Identify information from other studies, regulations, etc. that is needed to establish the criteria for taking action.

Confirm that each variable (environmental characteristic) can be measured. If not, then determine if it is reasonable to make assumptions about the variable in order to draw conclusions without data. If the necessary assumptions can't be defended, then conduct a pilot study or select an alternative approach that involves different variables that are measurable. If no practical approach can be developed, then consider shifting the effort to develop the research tools needed to address the problem and consider not conducting the study at this time.

Define the Boundaries of the Study

Product: **A detailed description of the population for which the decision will be made, including area and time period.**

Background: The purpose of this step is to define the population for which the decision will be made (people, objects, portion of media) so that it is clear what belongs in this population, and what the boundaries on this population are (area or volume and time period).

When the population consists of people and objects, it is important to define space and time boundaries and the other characteristics that determine what belongs in and out of the population. For example, consider a study to determine the average concentration of radon in primary schools in the Midwest in the winter. The population might be all large public primary schools (objects) where the characteristics of a large primary school are defined as enrollment of more than 200 students in Kindergarten through sixth grade, or any portion thereof. The spatial boundary might be the states of Illinois, Missouri and Kansas; and the time period might be a two week period in January when the school is in session.

Alternatively, the population may consist of a continuous medium (air, water, soil). In this case, the portion of this medium that belongs in the population can usually be defined just by the spatial and temporal boundaries, although there may be other characteristics that help to define it. For example, for a survey of the toxic contaminant levels in surface waters of the Great Lakes, the population could consist of the top 10-12 meters of water (the epilimnetic waters) in each Great Lake (spatial boundary) during the months of June through August (time period). Other characteristics might include meteorological conditions (windspeeds less than 15 mph., for instance).

The study will involve sampling from this population to make inferences about the population as a whole. Sometimes we are not able to sample from the entire population. In this case, we either make inferences only to that portion of the population that can be measured, or we make assumptions that allow us to infer to the entire population.

Activities: Specify the population for which the decision will be made so that it is clear what belongs in this population.

Define the spatial and temporal boundaries of this population.

Define any additional characteristics that are needed to determine what belongs in the population.

If applicable, specify the smallest sub-population for which the decision will be made (e.g., if a decision about average radon levels will be made separately for any of the three states in the example above). The cost of the study usually increases for each sub-population because more samples are required to adequately estimate the variables within each sub-population.

Make sure that the practical considerations (identified in the Problem step) are consistent with these boundaries.

Develop a Decision Rule

Product: **A statement that defines how environmental data will be summarized and used to make the decision.**

Background: After the data for this study have been collected, they are summarized to form a result for the study, which is compared to the criteria for taking action to make the decision. The purpose of this step is to integrate the outputs from previous steps into a single statement specifying how environmental data will be summarized and used to make the decision, including quantitative criteria for determining what action to take.

It is important that someone with statistical expertise be involved in this step to be certain that the decision rule is stated in a manner that leads to an efficient design.

Activities: Describe the study result (the way in which the data will be summarized) and how the result will be calculated (e.g., mean, range, maximum).

Develop a decision rule as an "If..., then..." statement that incorporates the study result, the criteria for taking action, and the action(s) that will be taken under various possible scenarios. For example, "If the mean tail pipe emissions over two minutes exceeds X ppm, then fail that car and require corrective action." In this example, the study result is the mean emissions over two minutes, the criterion for taking action is maximum allowable emissions of X ppm, and the actions are to require corrective action if the car fails or issue an inspection sticker if the car passes.

Confirm that you will need all the data you will be collecting. If not, then define a more narrowly-focused set of input variables.

Specify Limits on Uncertainty

Product: **The decision maker's expressed desire to control decision errors, stated as limits on the acceptable probability of making an incorrect decision based on the study findings. These limits on uncertainty may be expressed as acceptable false positive and false negative error rates.**

Background: There is always some error in environmental data. As a result, some degree of uncertainty will exist in any decision based on environmental data. In this step, limits on uncertainty are established and stated as acceptable probabilities of making incorrect decisions; i.e., acceptable false positive and false negative error rates for the decision.

<u>The limits on uncertainty should be based on careful consideration of the consequences of incorrect conclusions.</u> The planning team will need to estimate the economic, health and ecological consequences of decision errors and the decision maker will also need to consider the political and social consequences when setting limits on uncertainty.

The decision maker (data user) needs to be actively involved in the specification of limits on uncertainty. In addition, the planning team should work with a statistician during this step to ensure that the limits are reasonable and complete.

There are two types of decision errors for all studies that will support a decision on whether or not to take action: false positives and false negatives. The definition of what constitutes false positive and false negative errors depends on how the decision is defined. (Consult a statistician if you have questions.) For example, consider a decision on whether to take corrective action where you presume that action will not be required and the purpose of the study is to support or refute this presumption. In this case,

- a false positive error is deciding to take corrective action when the environmental data incorrectly indicate that a problem exists; and
- a false negative error is deciding not to take corrective action when environmental data incorrectly indicate that a problem does not exist.

Limits on uncertainty for these studies can be expressed as limits on the acceptable rates of false positive and false negative errors.

The error in data and the inherent natural variability make it unreasonable (very expensive) to determine small differences in an environmental variable. As a result, when true conditions are very close to the criterion for taking action, it is difficult (if not impossible) to determine if you are above or below the criterion. To respond to this problem, you may want to consider defining a region of indifference, where either decision is acceptable. This region may be placed around, at or below the criteria for taking action, depending on the decision you are making. The width of this interval can vary, but generally, the cost of the study increases with a narrower region of indifference.

Activities: Define false positive (f(+)) and false negative (f(-)) errors for the decision (decision errors) and describe scenarios in which each type of error might take place. (Consult a statistician if you have questions.)

Order the importance of expected economic, ecological, health, political and social consequences according to the level of concern the decision maker has with each one.

Determine if false positive or false negative errors are of greater concern.

Determine if the level of concern for either type of decision error depends on the magnitude of the error (e.g., consider the case where there is a threshold below which a decision error leads to economic consequences, and above which it also leads to adverse health effects. The decision maker would be more concerned about the larger decision error that has both health and economic consequences).

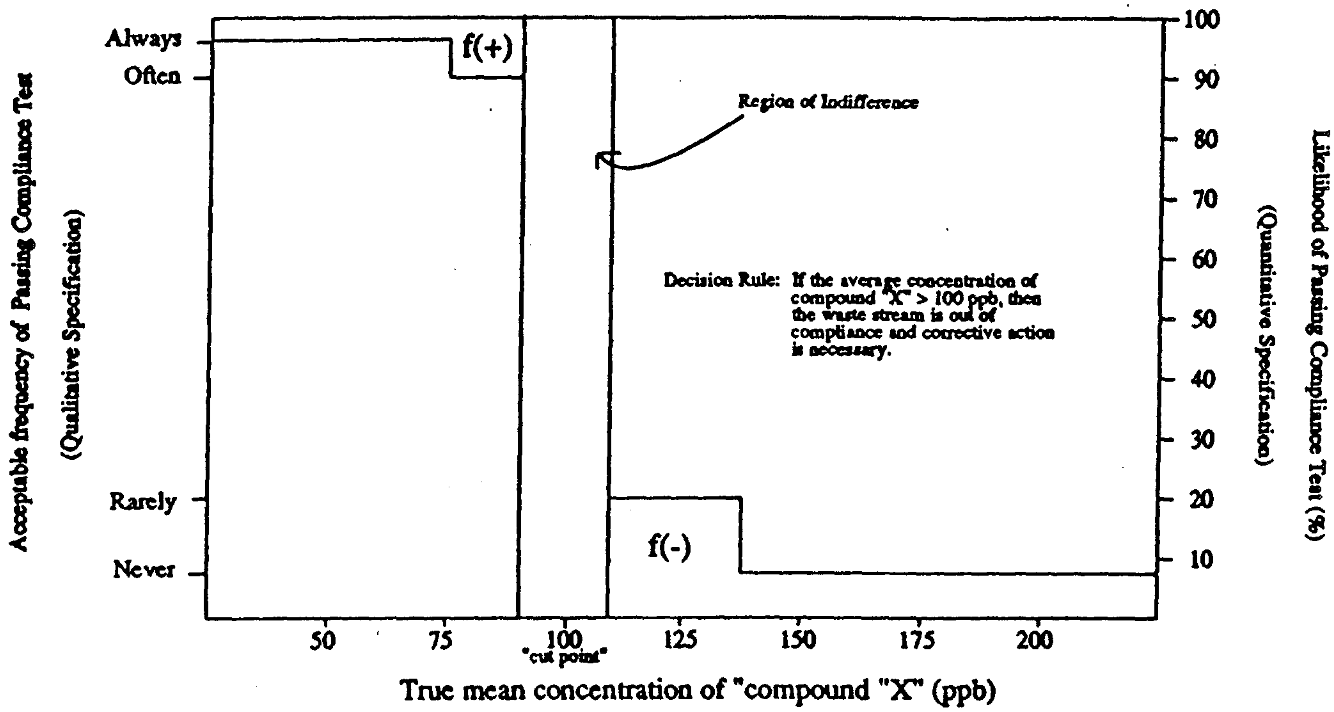
Consider the estimated magnitude of the expected consequences and decide what magnitude of false positive and false negative errors would be almost always, often, sometimes, or almost never acceptable. (Note that you may not need to assign values to all four categories.)

Establish, with statistical advice, an acceptable probability for the occurrence of each of these errors. Also, specify a region of indifference, the area in which you choose not to control the probability of an incorrect outcome because, under the stated conditions, either decision is acceptable. This region may be narrow or broad and must be acceptable to the decision maker.

Combine the probability statements into a formal statement of the levels of uncertainty that can be tolerated in the results. This formal statement may take the form of a table or a graph (see below).

One approach to developing and displaying limits on uncertainty is the use of the discomfort curve. Drawn below for a compliance testing example, the discomfort curve describes in qualitative terms, and then in quantitative terms, the acceptable level of false positive and false negative errors at different levels of the true mean concentration of the compound.

COMPLIANCE TESTING FOR COMPOUND "X"



Optimize the Design

Product: **The lowest cost design for the study (selected from a group of alternative designs) that is expected to achieve the DQOs.**

Background: The role of statistics is very important in study design and the planning team should include someone with statistical expertise.

In this step, statistical techniques are used to develop and evaluate various designs for the study that meet the specifications from the DQO process. The data collected using these designs should enable the decision to be made subject to error rates no greater than those specified in the limits on uncertainty (given that the assumptions on which the design was developed hold true).

Activities: Obtain the information needed to develop alternative designs: the limits on uncertainty from the proceeding step; any budget or time constraints; any practical considerations; cost estimates for all study activities; estimates of the inherent variability of variables or environmental characteristics to be measured; and estimates of the variability that will be introduced by the sampling and measurement process. If such information is not available, then design pilot tests to generate it, make necessary assumptions, or research improved analytical methods.

Ask a statistician or someone with statistical expertise to generate alternative designs and to estimate the cost and anticipated error rates of each design. Select the most cost-efficient design that has acceptable performance and meets all other needs of the decision maker including political and social concerns.

If there is a reasonable probability that any source of variability will be greater than estimated or assumed, evaluate the expected performance of this design under a range of alternative conditions. Confirm that the design will yield useful results, even when conditions are more adverse than those expected or assumed.

If it appears that there is no design that will meet both the limits on uncertainty and the budget constraints, then determine whether to compromise by relaxing the limits on uncertainty or other practical constraints, or by finding additional funding to achieve the desired limits on uncertainty within the specified boundaries for the study.