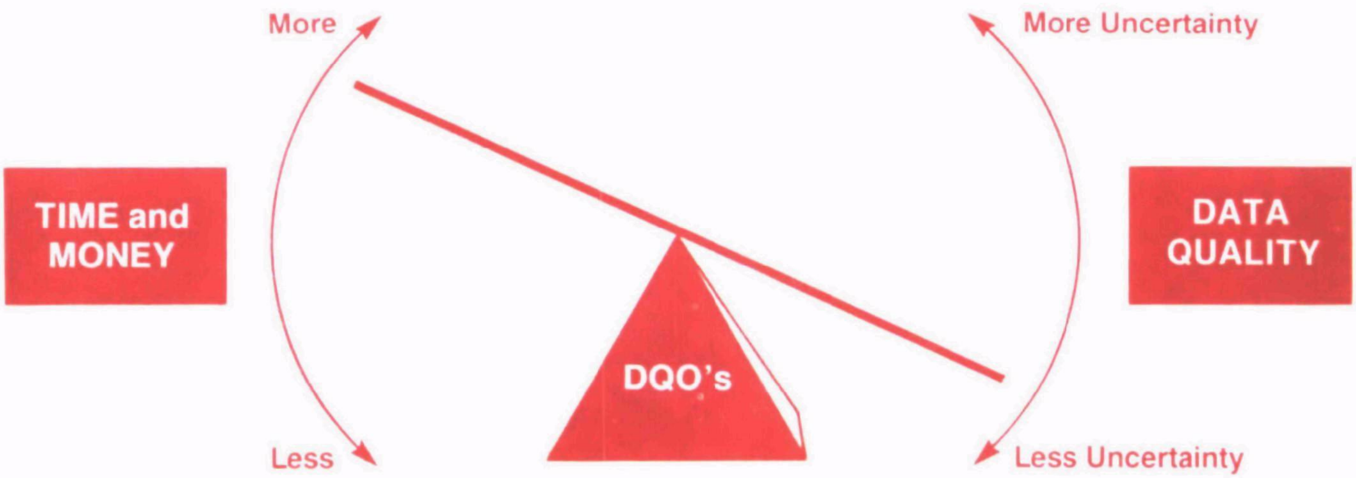
DATA QUALITY OBJECTIVES WORKSHOP



U.S. ENVIRONMENTAL PROTECTION AGENCY
QUALITY ASSURANCE MANAGEMENT STAFF

DATE: April 15, 1987

SUBJECT: DQO Workshop Handouts

FROM: Kevin Hull
Quality Assurance Management Staff (RD-680)

TO: DQO Workshop Participants

Thank you for your decision to participate in the April 17 presentation of the Data Quality Objectives (DQO's) workshop. In order to prepare you for this session, I am providing you with:

1. the workshop agenda, and

2. a document summarizing key points of the DQO concept and process.

A brief review of these materials should help to focus your initial impressions of DQO's and make your participation in the workshop a more rewarding experience.

As the attachment indicates, QAMS conceives of DQO development as a three-stage process. The April 17 workshop will deal primarily with Stages I and II of the process. Our primary aim is to enhance your understanding of and sensitivity to the management issues associated with these stages.

I look forward to working with you beginning at 9:00 a.m. on Friday, April 17.

Attachments

DQO WORKSHOP AGENDA

9:00	Initial Discussion - Introduction of course participants - Initial impressions of DQO's	K. Hull
9:15	Course introduction - Background/purpose of DQO training efforts - Preview of course content, format, logistics	K. Hull
9:25	Presentation on DQO's as management and communications tool (LECTURE 1) - Purpose/value of the DQO concept - Overview of the DQO process - Status of QAMS' support efforts	D. Neptune
10:00	BREAK	
10:15	Open discussion -- do participants face real-world situations where the DQO process could help?	K. Hull
10:35	Presentation on DQO's as a quantitative tool (LECTURE 2) - What are performance criteria? - How are they developed?	G. Brantly
11:30	LUNCH	
12:30	DQO exercise #1 (WORK SHEETS)	D. Michael
1:10	DQO exercise #2 (GROUP EXERCISE)	D. Michael
2:20	BREAK	
2:35	DQO exercise #2 (comparison of small group results)	D. Michael
3:15	Presentation on how performance criteria are used in the design of data collection programs	G. Brantly
3:30	Open discussion -- have the participants' perspectives on DQO's changed?	K. Hull
3:45	Complete workshop evaluation form	
4:00	ADJOURN	

INTRODUCTION TO THE DATA QUALITY OBJECTIVES CONCEPT

The critical role of environmental data in the EPA decision-making process has long been recognized. Despite this recognition, many Agency data collection programs and monitoring requirements have not adequately emphasized such key factors as the decision to be made with the collected data and the possible consequences of an incorrect decision. The historical approach used by the Agency has often been to collect the "best data possible," with the responsibility of defining the "best data possible" usually assumed by technical experts, rather than by EPA decision makers. Typically these technical experts, presented with a pre-established budget, have first identified the best available sampling and analytical methods, and then determined the number of samples and measurements that were affordable using these methods. To ward off the possibility of lawsuits, extensive negotiations with industry and environmental groups have often been conducted in order to assure that data collection requirements are defensible and appropriate.

While this traditional approach may have ensured that the best possible measurements were obtained, it has not always guaranteed that the resulting information is adequate for making a decision. Although Agency accomplishments have shown that this general approach to designing data collection activities can be successful, it can also be expensive and time-consuming, and will not necessarily lead to the selection of a data collection design likely to provide data adequate for defensible decision-making.

The Quality Assurance Management Staff (QAMS), in response to a requirement established by the Deputy Administrator in May 1984, has proposed a different approach to designing environmental data collection programs, based on the concept of Data Quality Objectives (DQO's). The DQO process does not use a pre-established budget as the sole constraint on the design of the data collection program. Rather, it also considers the quality of data needed to achieve an acceptable level of confidence in the data dependent elements that will play a role in the decision-making process. The DQO process provides a logical, objective, and quantitative framework for finding an appropriate balance between the time and resources that will be used to collect data and the quality of the data that will be needed to make the decision.

One of the important aspects of the DQO process is that decision makers must be involved. DQO's are developed using a top-down/iterative approach. The initial input and perspective of the decision maker, which can be expressed in tentative and qualitative terms, is crucial to the successful development of DQO's. Up to now, the absence of a well-defined framework for obtaining the decision maker's input and for focusing the activities of senior program staff has been a significant obstacle to the design of effective data collection programs. QAMS recognizes that the role of the decision maker may vary to some degree, from one of directly providing the information and participating in planning, to one of reacting to/concurring with options presented by key staff to the decision maker. Through their personal involvement, the decision makers can ensure that the DQO process will become a "way of life" at EPA. Systematic implementation of the DQO process will improve the probability that the quality of EPA data is compatible with the requirements of the decision-making process.

OVERVIEW OF THE DQO PROCESS

Simply stated, DQO's are statements of the level of uncertainty that a decision maker is willing to accept in results derived from environmental data, when the results are going to be used in a regulatory or programmatic decision (e.g., deciding that a new regulation is needed, setting or revising a standard, taking an enforcement action). To be complete, these statements must be accompanied by clear statements of:

- o the decision to be made;
- o why environmental data are needed and how they will be used;
- o time and dollar constraints;
- o descriptions of the environmental data to be collected;
- o specifications regarding the domain of the decision; and
- o the calculations, statistical or otherwise, that will be performed on the data in order to arrive at a result.

Developing DQO's should be the first step in initiating any significant environmental data collection program to be conducted by or for EPA. The DQO process helps data users and data generators to communicate clearly with each other about the purposes for which environmental data will be used and the design of the data collection program that will meet the decision maker's requirements. Once the qualitative and quantitative data performance requirements have been developed, a suitable design option can be selected for the data collection activity.

DQO's are used to define quality assurance (QA) and quality control (QC) programs specifically tailored to the data collection activity. Once DQO's have been established, a "QA Project Plan" is prepared, documenting all of the activities needed to assure that the data collection program will produce environmental data of the type and quality required to satisfy the DQO's. Without prior development of DQO's, a QA program can be used merely to document the quality of data obtained, rather than to assure that the quality of data obtained will be sufficient to support an Agency decision.

As envisioned by QAMS, the DQO process consists of three stages with several steps in each stage. The process described in the first two stages results in proposed DQO's with accompanying specifications (constraints). In the third stage, an evaluation of potential designs is performed, leading to the selection of a design which is compatible with the constraints associated with the DQO's. The process is meant to be iterative among all stages (and among steps within a stage) if the proposed DQO's and corresponding constraints are found to be incompatible.

QAMS recognizes that its approach to DQO's is not the only one for all circumstances. We encourage the development of alternative approaches designed to achieve the same goals, and will be happy to provide support to EPA organizations attempting to apply the DQO concept to their particular situations.

SUMMARY OF THE THREE STAGES OF THE DQO PROCESS

STAGE I: DEFINE THE QUESTION OR DECISION

In this stage, the decision maker states his/her initial perceptions of what question should be addressed or decision should be made, what information is needed, why it is needed, how it will be used, and what the consequences will be if information of adequate quality is not available. It is expected that the decision maker's input at this point will be tentative, and expressed in non-quantitative terms. Initial estimates of the available time and resources for the data collection activity are stated.

STAGE II: CLARIFY AND THEN STATE PRECISELY THE INFORMATION NEEDED FOR THE QUESTION OR DECISION

In this stage, the senior staff (management and technical), with periodic involvement of the deciion maker, carefully examine the decision maker's Stage I statements. Senior staff then ask whether new environmental data are really needed to answer the question. If so, then the technical staff define precisely the domain or universe of inference (physical, chemical, temporal, and spatial elements and factors) for collecting the necessary environmental data. The staff then help the decision maker to understand and state in quantitative terms how good (certain) the decision maker requires the data to be. Quantitative statements, to the extent possible, of the data quality required (most frequently in terms of false positive and false negative error rates) are the important outputs of Stage II. The senior staff develop these quantitative statements for and with the decision maker after they have provided the decision maker with an intuitive feel for their implications.

STAGE III: DESIGN THE DATA COLLECTION PROGRAM

This stage is primarily the responsibility of the technical staff, but involves both the senior management and the decision maker to assure that the outputs of Stages I and II are understood by the technical design staff. The objective of Stage III is to develop data collection plans (numbers of samples, where to sample, type of laboratory analysis, type of data analysis, etc.) that will meet the quantitative criteria and constraints defined by the important outputs of Stage II. In Stage III, we evaluate all steps in the data collection process with associated errors, and selecting an optimal design that achieves the overall control of error as defined by the DQO, with the minimum cost. It is the prerogative of the decision maker to select the final design that provides the best balance between time and resources available for data collection on the one hand, and the level of uncertainty expected in the final results on the other.

17 April '84
Phil Robinson, Bill Coakley (Reg 2), Carl Koch (OPPE), Bryan Wood-Thomas (OPPE), Joe Breen, Tom Murray, Eileen Reilly-Wiedow, Ramona Trovato, Jay Glatz, David Kelly, Patricia Powers, Ben Hancker (IID), Carl Gaum (OWPE), Frank Prizner (Booz-Allen), Edie Sterrett, Marilyn McCall, ESSPI, Joan Blake, Matt Huston, Martha Otto, Ron Ramsey (MRI), Ed Hanley (Reg 2) Donald Cook

QAMS: "excited about DQOs" as a tool to address some EPA problems. Can provide tech and procedural support to establishing DQOs.

Gaum feels concept is too nebulous, needs more criteria for use
Ramsey says contractor defines in terms of time, money, milestones
Cook - acid rain research going from one specific type of region to larger,
testing for eg toxic fog.
Hanley Need to define if you're comparing to a standard or something else.
In Reg 2, make commitments to citizens re time by which will achieve X; DQO can assist in being prepared to let public know how far one is by that date.
Ramsey RfD (reference dose), establish detection limit needed and what, compare health- and concentration-based #s for TCL characteristic toxic leaching process in Nov. a "practical quantitation number" was defined. Any practical considerations in using multiples

⋮

Trovato How do you get from Stage II to Stage III? They're working on Computer assisted instruction, possibly self-paced.

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WORKGROUP DISTRIBUTION

GROUP A

B. Haneker
J. Blake
D. Kelly
B. Wood-Thomas
B. Moody
P. Powers
M. Otto
B. Coakley

GROUP B

C. Stroup
P. Robinson
C. Koch
F. Prizner
R. Trovato
D. Cook
M. Hantov

GROUP C

E. Hanlon
M. Frankenberry
E. Sterrett
M. McCall
R. Ramsey
A. Jover
C. Gaum

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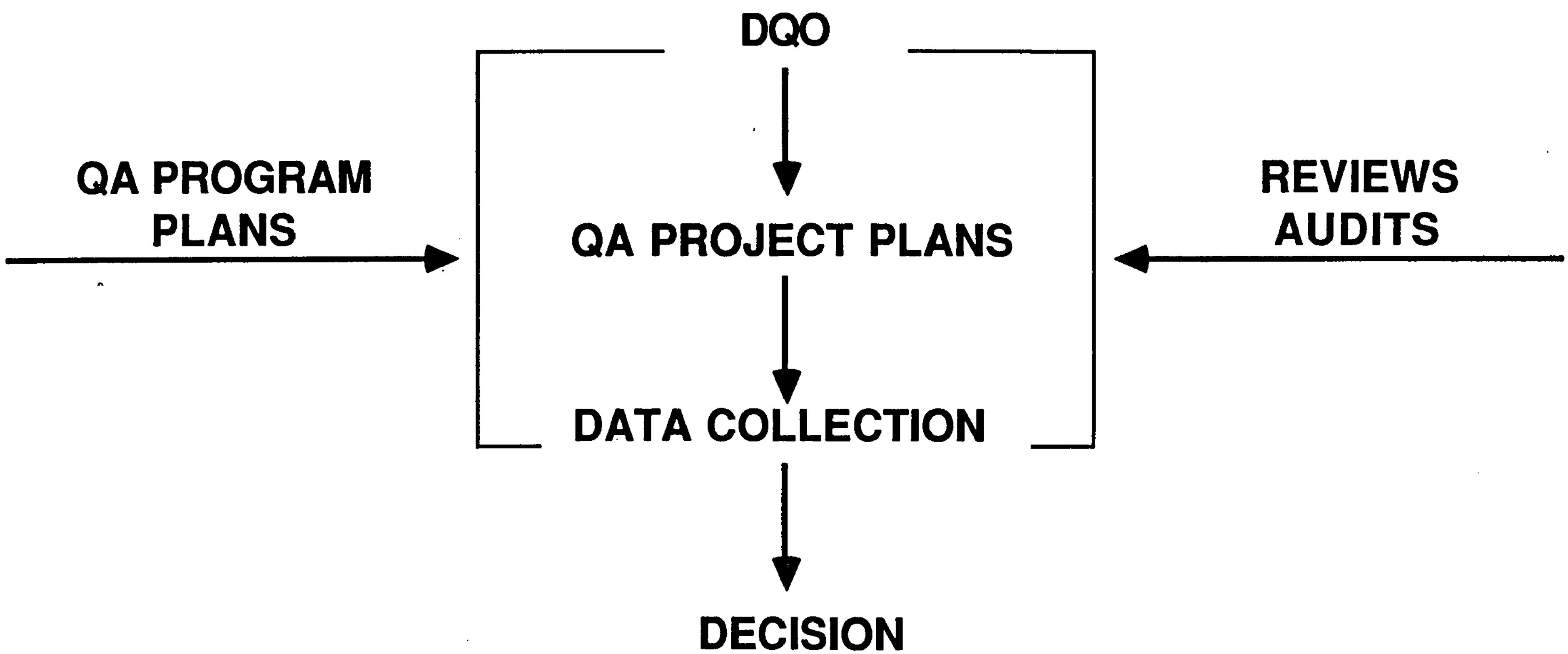
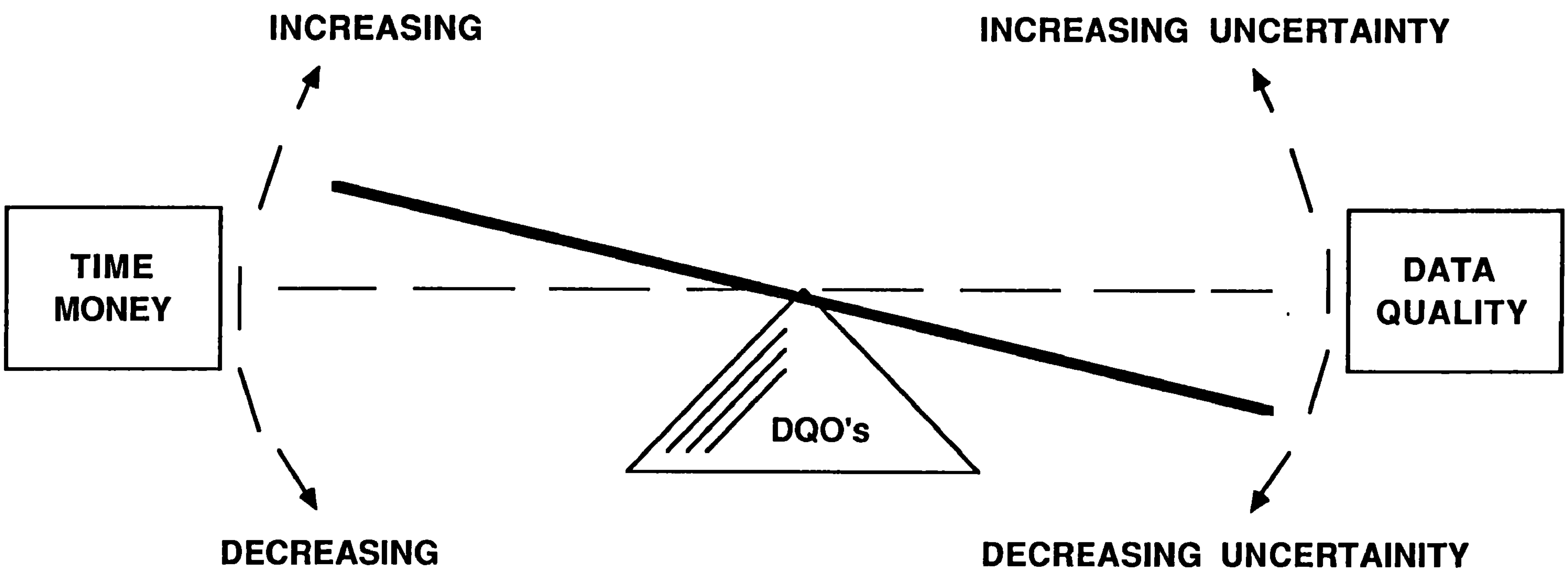
LECTURE 1

DATA QUALITY OBJECTIVES

QAMS QUALITY ASSURANCE PROGRAM



DQO'S STRIKE A BALANCE



DATA QUALITY OBJECTIVES

STATEMENTS OF THE LEVEL OF UNCERTAINTY A DECISION MAKER IS WILLING TO ACCEPT IN RESULTS DERIVED FROM ENVIRONMENTAL DATA

DATA QUALITY OBJECTIVES

I WOULD LIKE TO LIMIT THE CHANCE OF

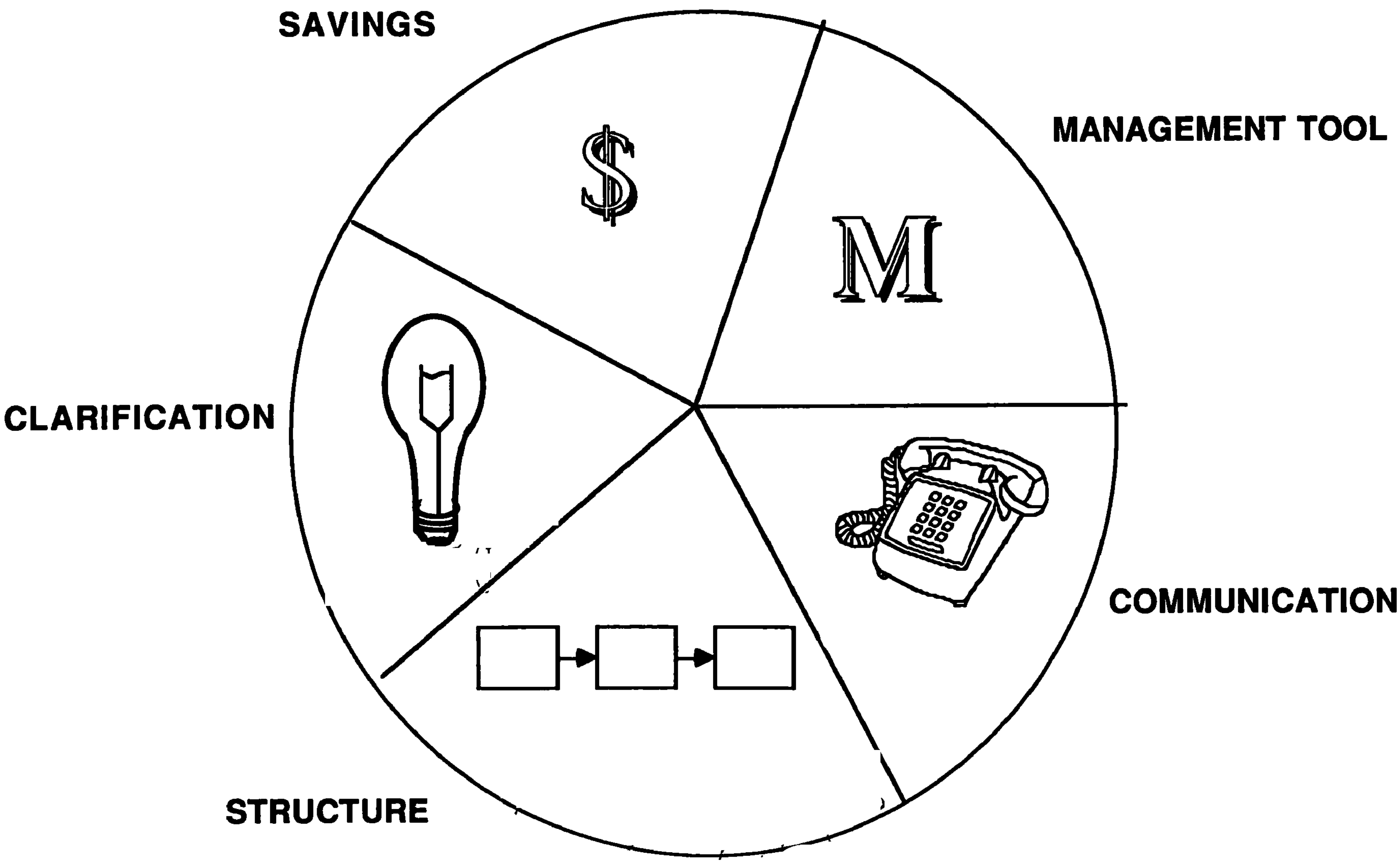
DATA LEADING TO AN INCORRECT CONCLUSION:

a) that a facility is out of compliance (when it's in)

or

b) that a facility is in compliance (when it's out)

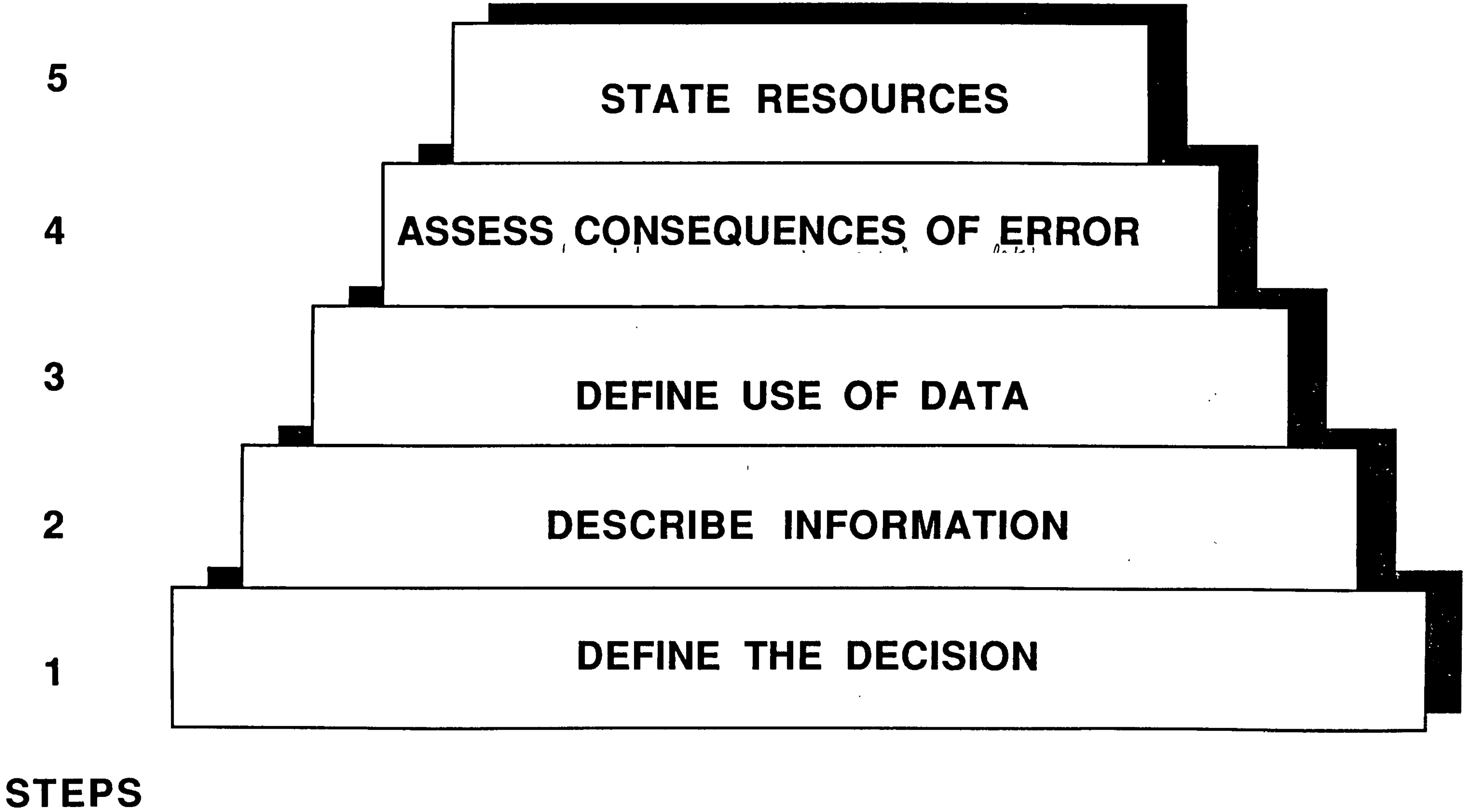
IMPORTANCE TO MANAGERS



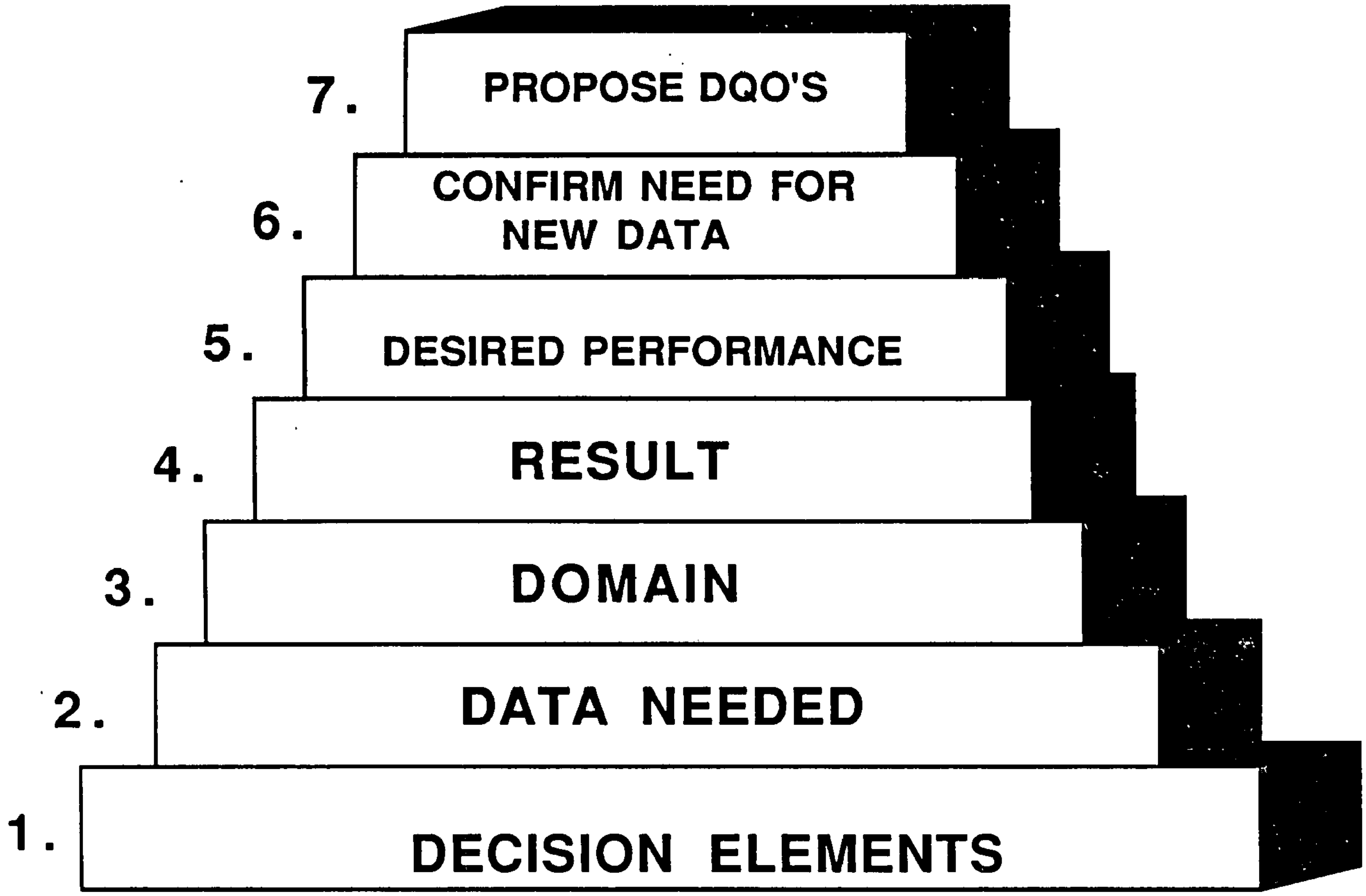
DQO PROCESS

STAGE	I	II	III
PURPOSE	DEFINE DECISION	ESTABLISH QUALITATIVE AND QUANTITATIVE CONSTRAINTS	DESIGN DATA COLLECTION PROGRAM TO MEET CONSTRAINTS
LEAD ROLE	DECISION MAKER	PROGRAM AND TECHNICAL STAFF	TECHNICAL STAFF

STAGE I


5
STATE RESOURCES
4
ASSESS CONSEQUENCES OF ERROR
3
DEFINE USE OF DATA
2
DESCRIBE INFORMATION
1
DEFINE THE DECISION
STEPS

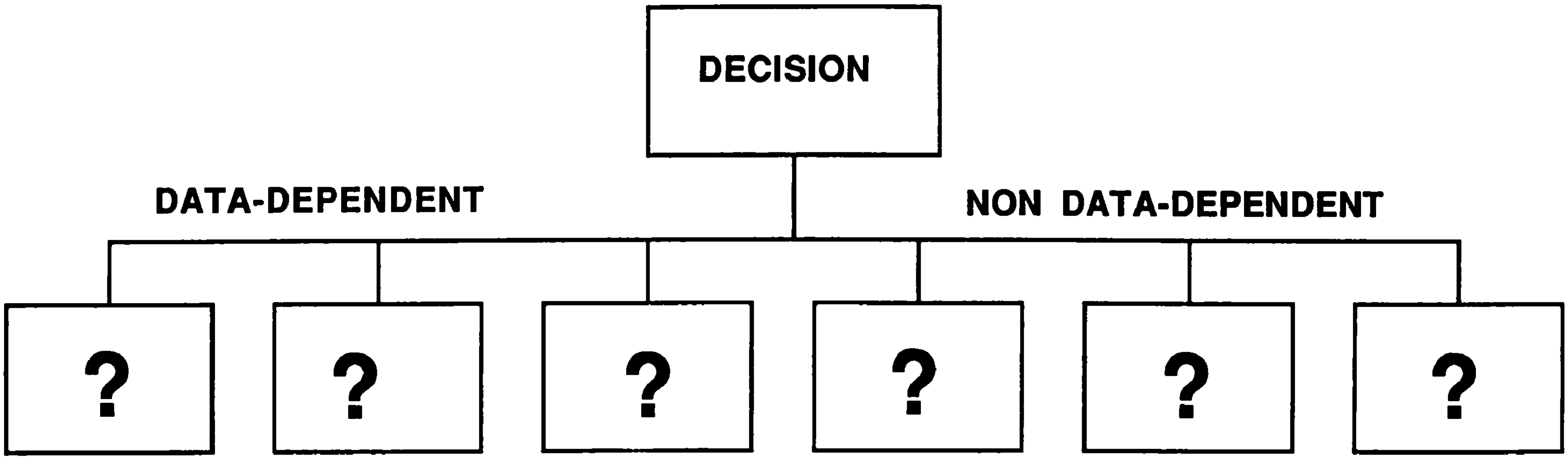
STAGE II



7. PROPOSE DQO'S
6. CONFIRM NEED FOR NEW DATA
5. DESIRED PERFORMANCE
4. RESULT
3. DOMAIN
2. DATA NEEDED
1. DECISION ELEMENTS

STAGE II

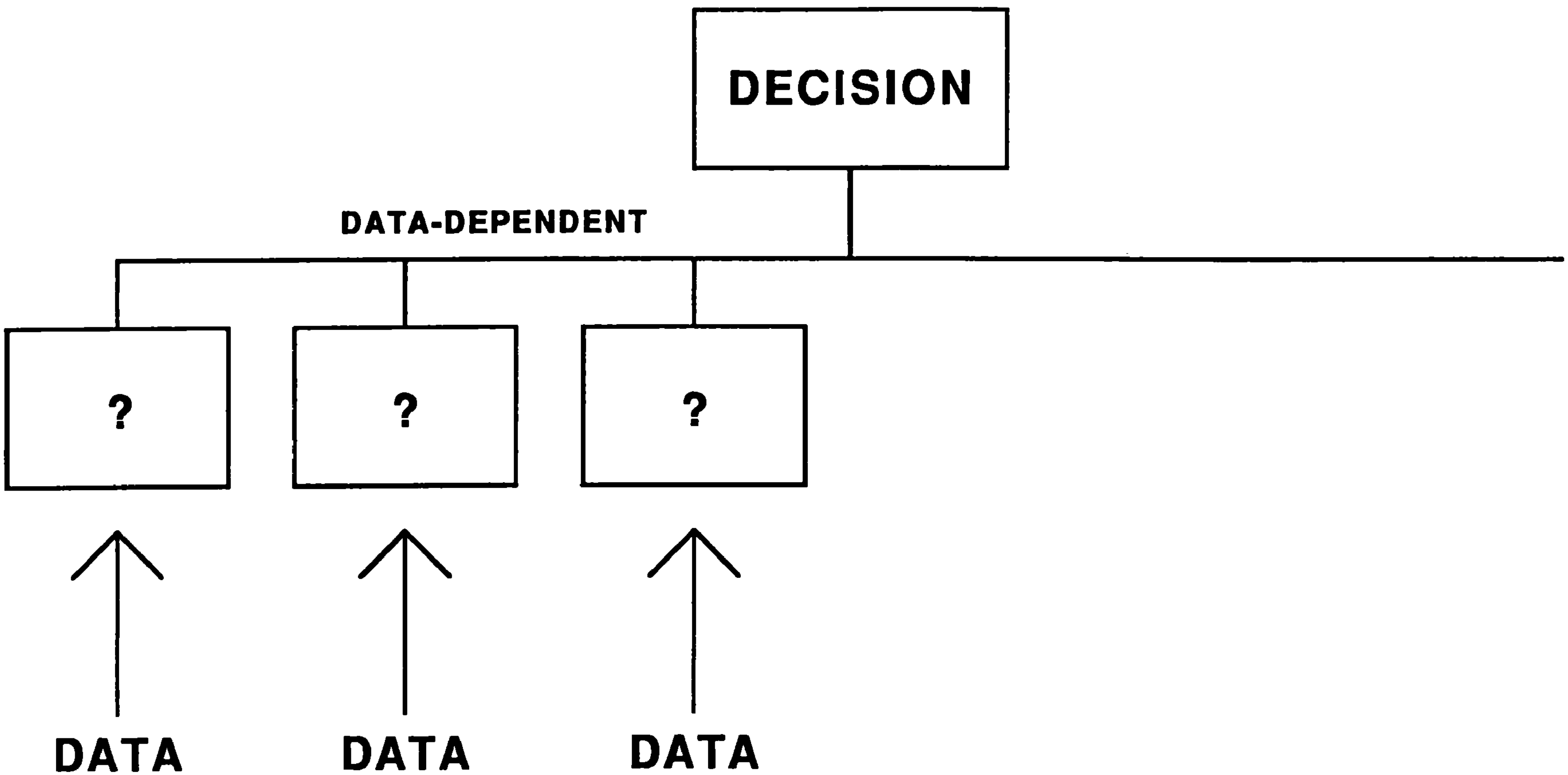
1. DECISION ELEMENTS



ELEMENTS

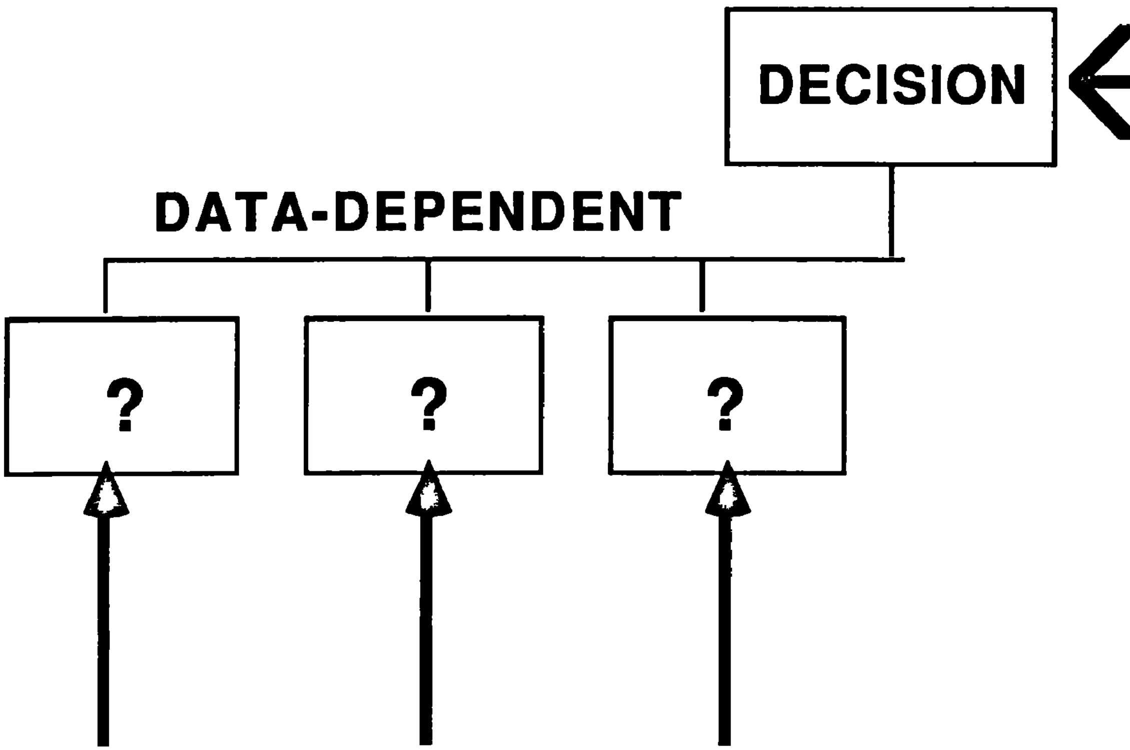
STAGE II

2. SPECIFY DATA



STAGE II

3. DEFINE DOMAIN

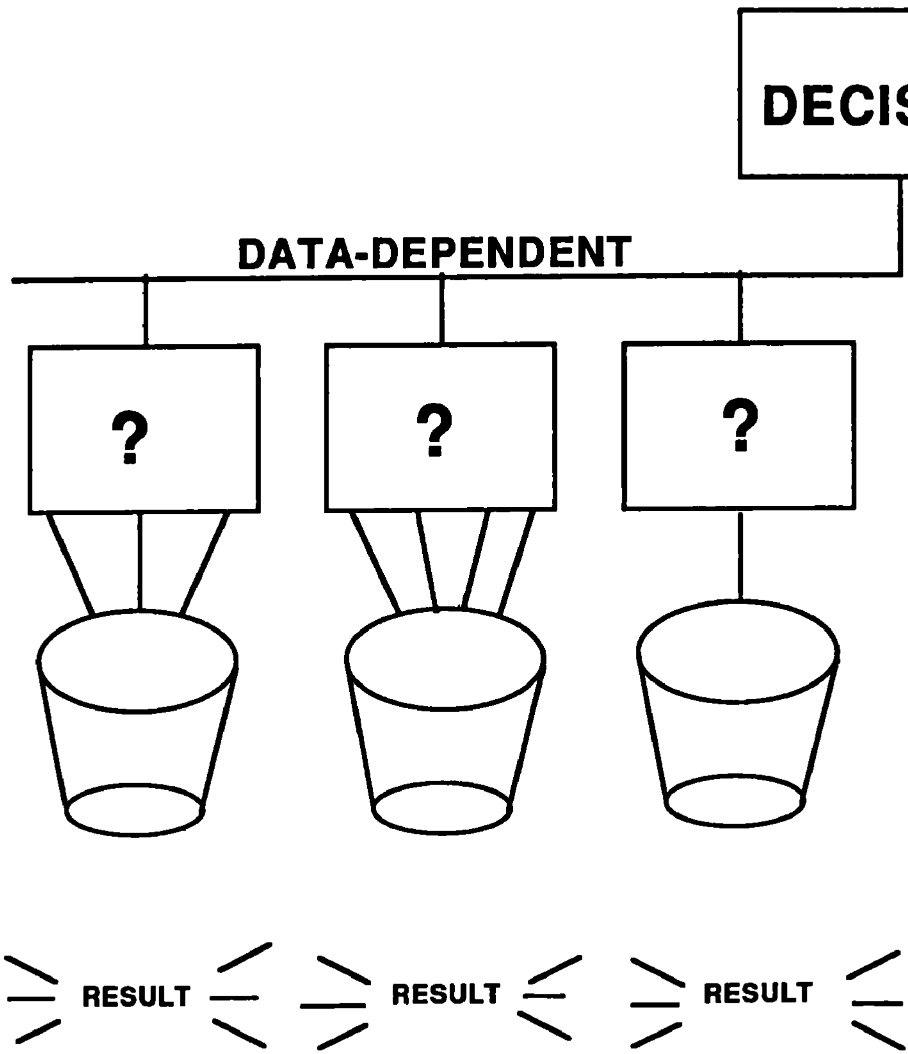


TO WHAT POPULATION WILL THE DECISION APPLY?

e.g. **FROM WHAT POPULATION SHOULD SAMPLES BE TAKEN?**

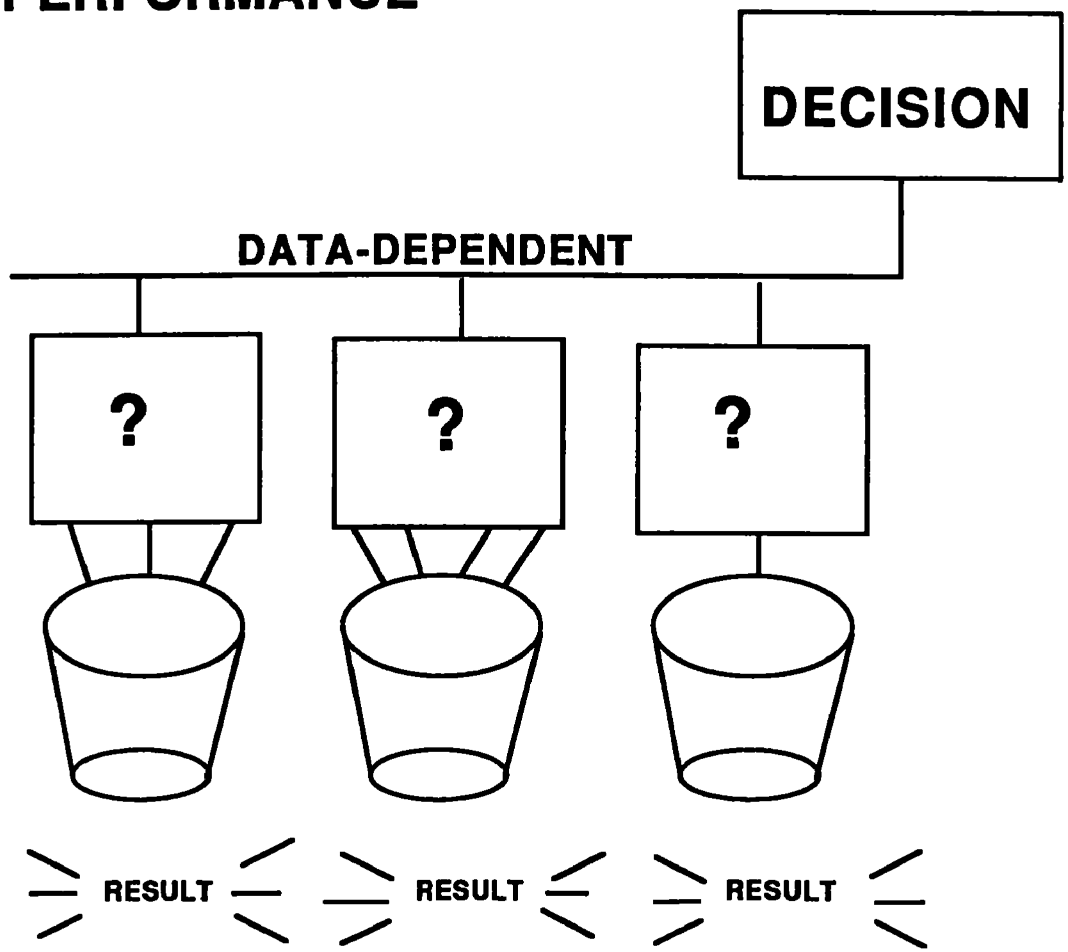
STAGE II

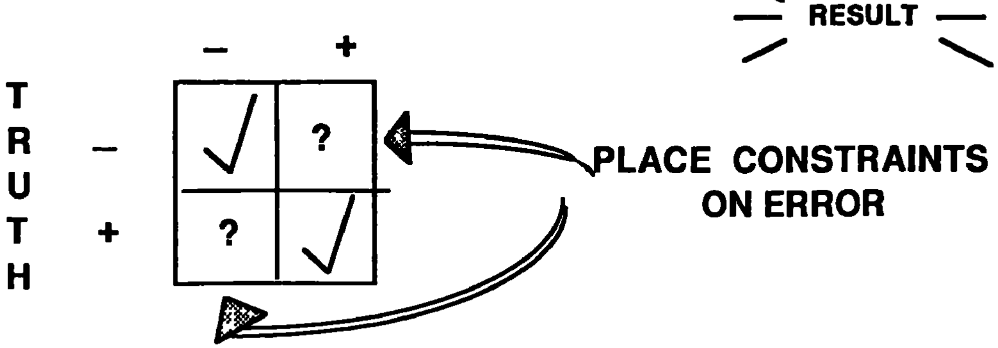
4. DEFINE RESULT



STAGE II

5. STATE DERIVED PERFORMANCE





STAGE II

6. DETERMINE NEED FOR NEW DATA

DOES ERROR IN RESULTS DERIVED

FROM EXISTING DATA MEET CONSTRAINTS?

STAGE II

7. PROPOSE DQO'S

* DECISION
* RESOURCE CONSTRAINTS
* ELEMENTS OF DECISION
  - Data Needed
  - Domain
  - Results
  - Limits on error in result

LECTURE 2

OBJECTIVES

1. WHAT ARE PERFORMANCE CRITERIA?
2. HOW ARE THEY DEVELOPED?

WHAT ARE PERFORMANCE CRITERIA?

* SPECIFICATIONS FOR A MONITORING PROGRAM
* DECISION ERRORS ATTRIBUTABLE TO DATA
* DESIRED LIMITS ON UNCERTAINTY

HOW ARE PERFORMANCE CRITERIA STATED?

- FALSE POSITIVES AND FALSE NEGATIVES
- CONFIDENCE INTERVALS
- POWER

COMPLIANCE DECISION

		TRUTH	
DECISION		IN	OUT
	IN	CORRECT	
	OUT		CORRECT

COMPLIANCE DECISION

DECISION	TRUTH: IN	TRUTH: OUT
IN	CORRECT	
OUT	FALSE POSITIVE	CORRECT

FALSE POSITIVE: Declaring non-compliance when permittee is in compliance

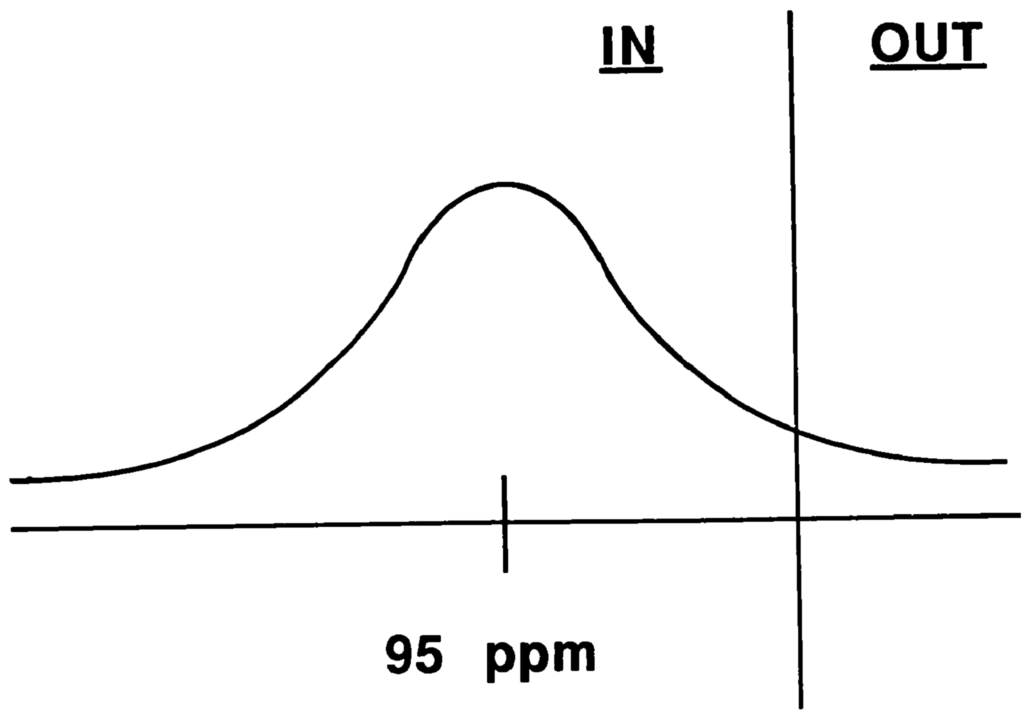
COMPLIANCE DECISION

DECISION	TRUTH: IN	TRUTH: OUT
IN	CORRECT	FALSE NEGATIVE
OUT		CORRECT

FALSE NEGATIVE: Declaring compliance when permittee is in non-compliance

COMPLIANCE MONITORING FOR COMPOUND X

CONTROL LEVEL: 95 ppm



COMPLIANCE MONITORING FOR COMPOUND X

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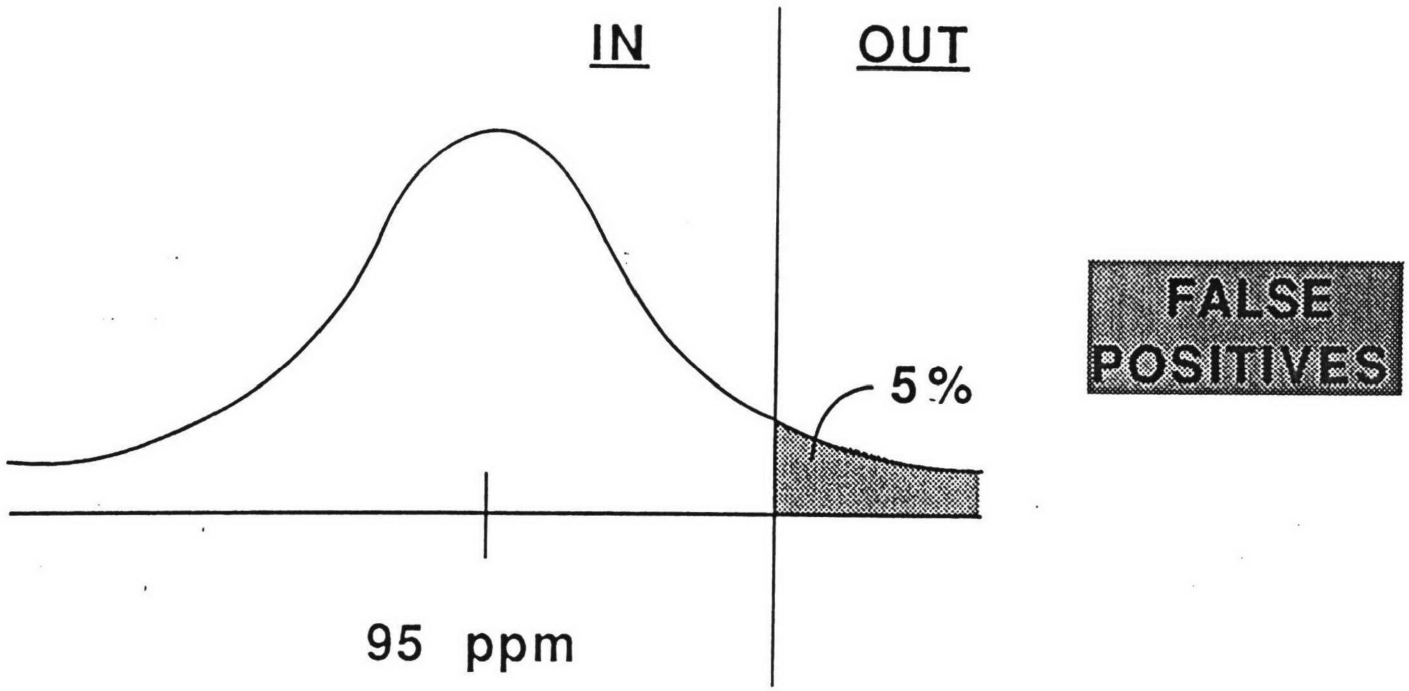
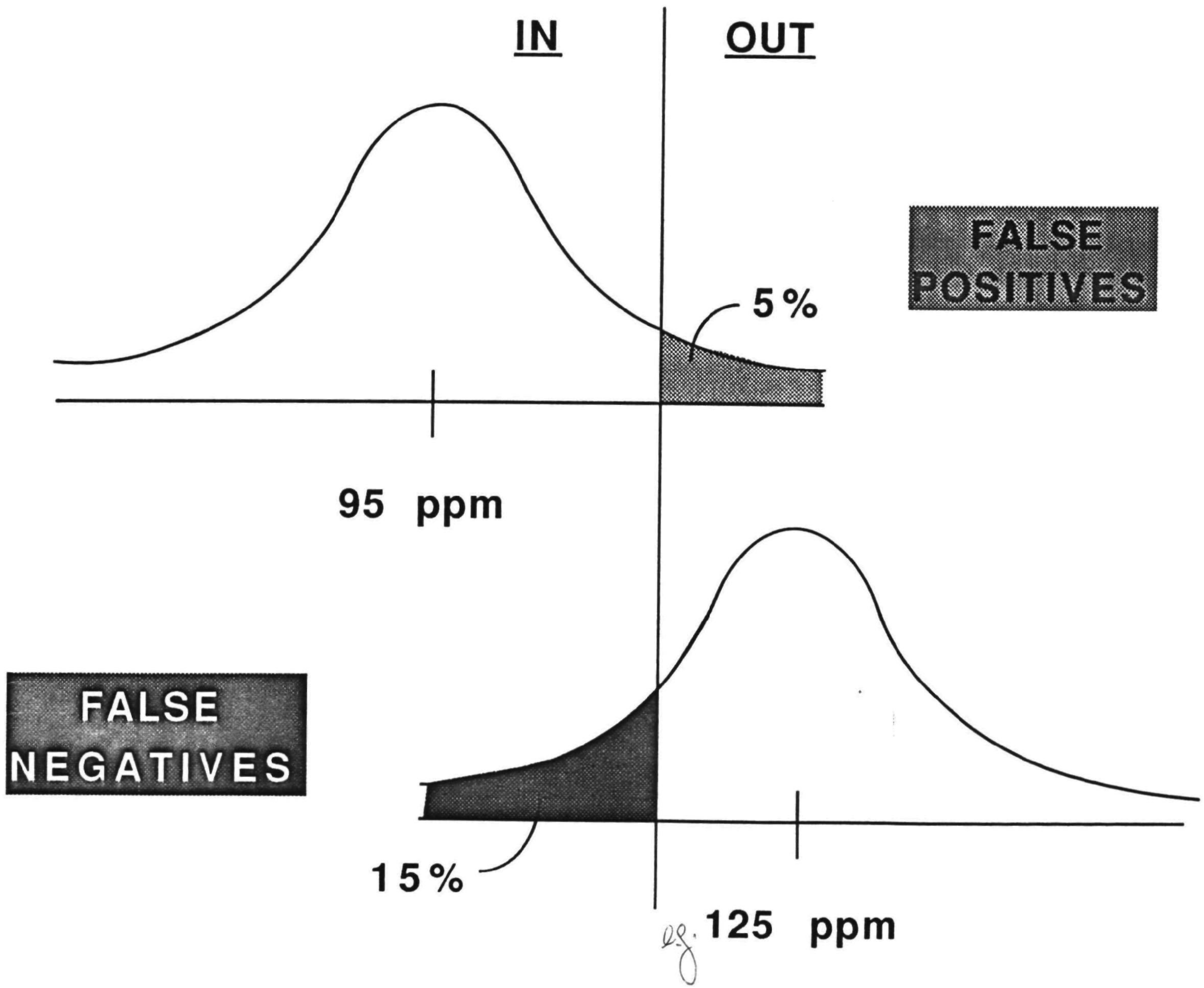


COMPLIANCE MONITORING FOR COMPOUND X

CONTROL LEVEL: 95 ppm



COMPLIANCE MONITORING FOR COMPOUND X

PERFORMANCE CRITERIA:

P[FALSE POSITIVE] $\leq$ .05 at 95 ppm

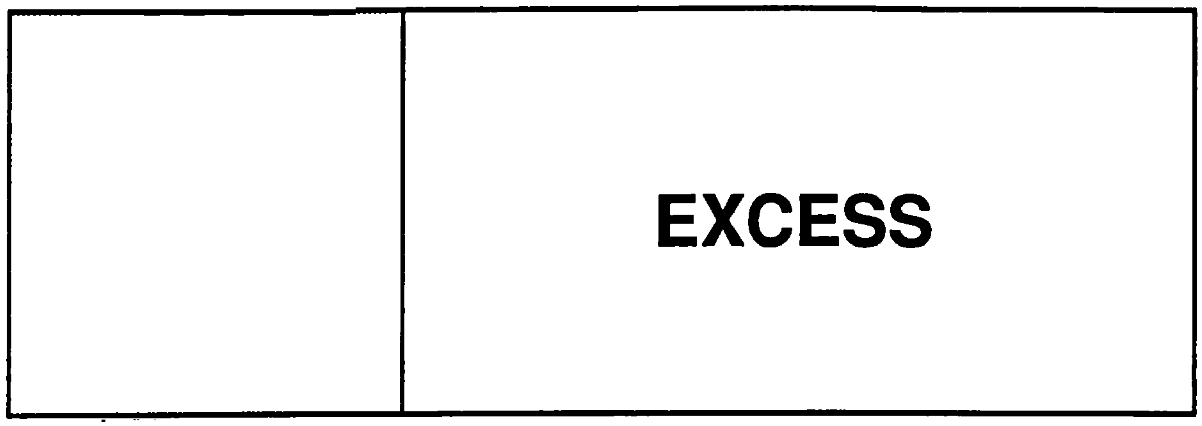
P[FALSE NEGATIVE] $\leq$ .01 at 2,000 ppm

P[FALSE NEGATIVE] $\leq$ .15 at 125 ppm

HOW ARE PERFORMANCE CRITERIA DEVELOPED?

PROCESS - DQO STAGES I AND II

EXAMPLE - MOBILE SOURCE I/M PROGRAM



TOTAL AUTO EMISSIONS

* PURPOSE OF I/M PROGRAM IS TO REDUCE EXCESS EXHAUST EMISSIONS.

STAGE I INFORMATION

DECISION: ARE HC AND CO EMISSIONS EXCESSIVE?

INPUTS: EMISSION DATA

CONSEQUENCES:

- Corrective Maintenance
- Retesting

STAGE I INFORMATION

CONSEQUENCES OF AN INCORRECT DECISION:

- Unnecessary Maintenance and Retesting
  with maybe loss of public support
- Missing an Auto with Excessive Exhaust Emissions
  if miss many - CO O_3 might still be out of control and state might have to institute other controls

STAGE II: STEP 1

IDENTIFY DECISION ELEMENTS:

- Are Exhaust Emissions Excessive for HC?
- Are Exhaust Emissions Excessive for CO?

If answer to either is yes decide "excessive"

STAGE II: STEP 2

for illustration, focus on HC

SPECIFY THE ENVIRONMENTAL DATA NEEDED:

- **Level of HC Emitted in Exhaust (ppm)**

STAGE II: STEP 3

SPECIFY THE "DOMAIN" -

SPATIAL AND TEMPORAL BOUNDS THAT DEFINE THE POPULATION OF INTEREST. for decision / for sampling

- **HC Emissions at Idle Speed**
- **All Cars in the Region** spatial
- **Annual or Semi-annual Tests** temporal

STAGE II: STEP 4

DEFINE THE RESULT -

A DATA SUMMARY FOR USE IN MAKING THE DECISION.

- Concentration of HC (ppm)
- Stable average or instantaneous concentration
- Result will be compared to a "Cut-point"

STAGE II: STEP 5

STATEMENT OF DESIRED PERFORMANCE

DEFINITIONS:

FALSE POSITIVE:

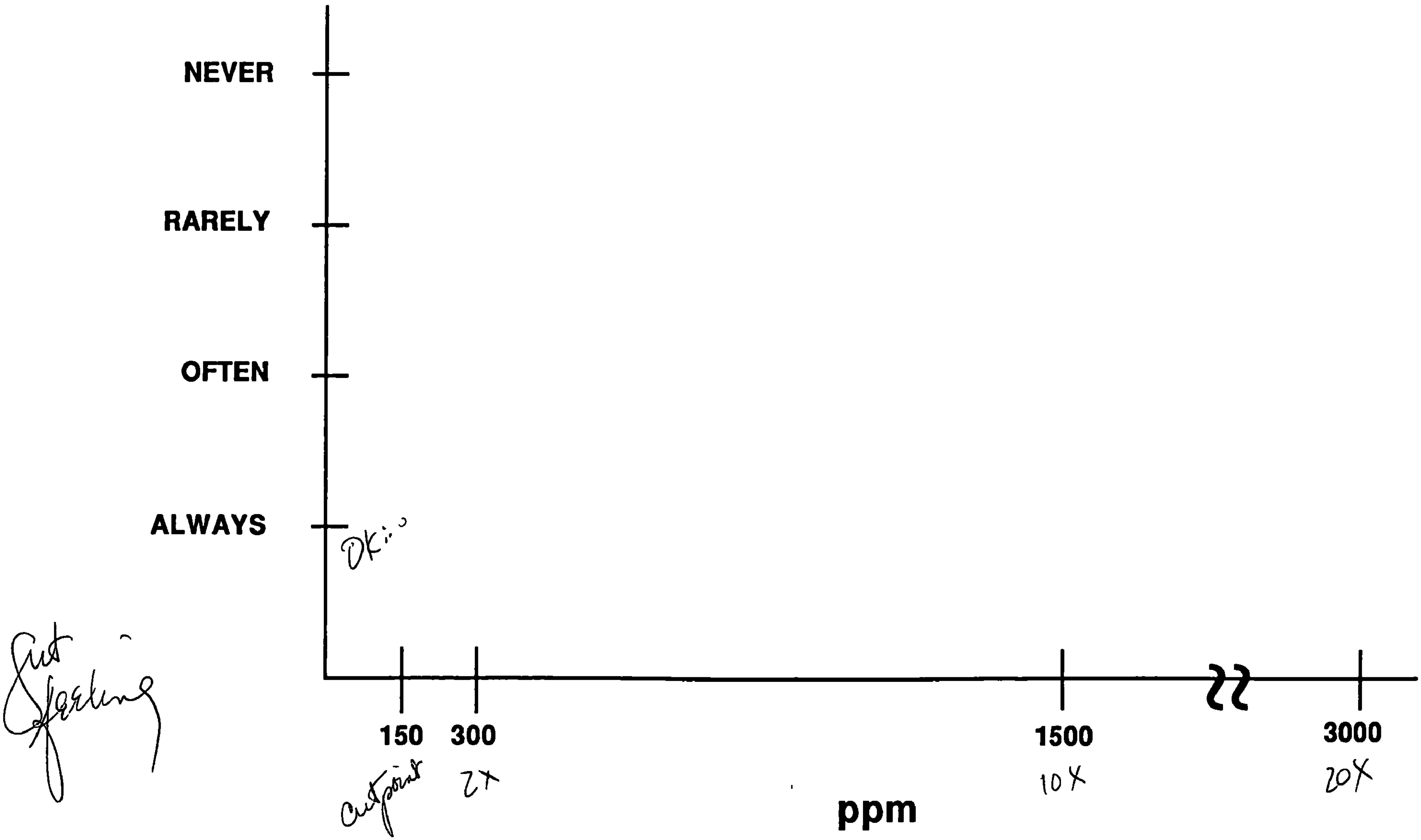
- **Finding that exhaust emissions are excessive, when they are not.**

FALSE NEGATIVE:

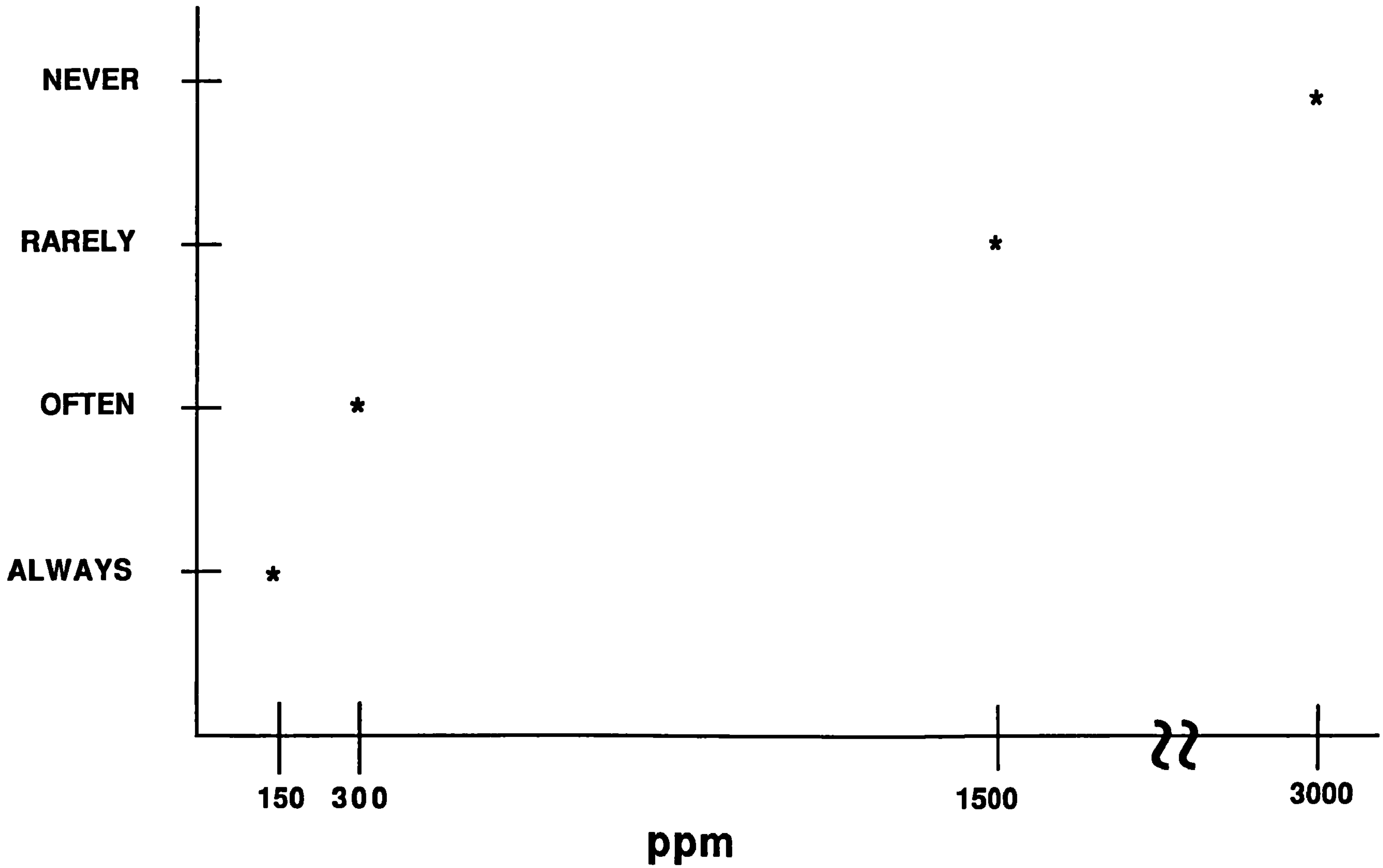
- **Finding that exhaust emissions are acceptable, when they are not.**

I/M found after testing that 150 ppm is cut point

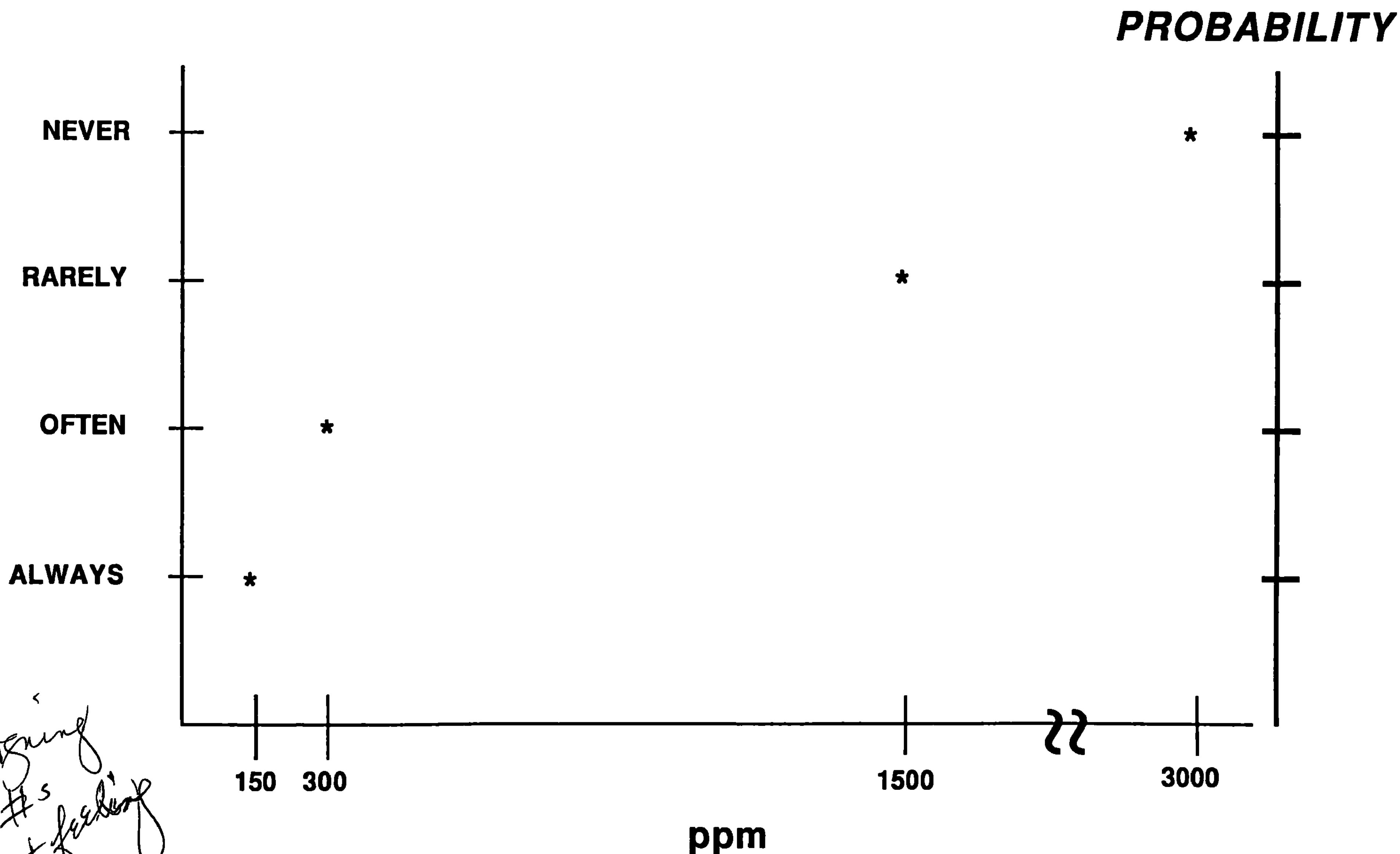
LIKELIHOOD OF PASSING EMISSIONS TEST



LIKELIHOOD OF PASSING EMISSIONS TEST

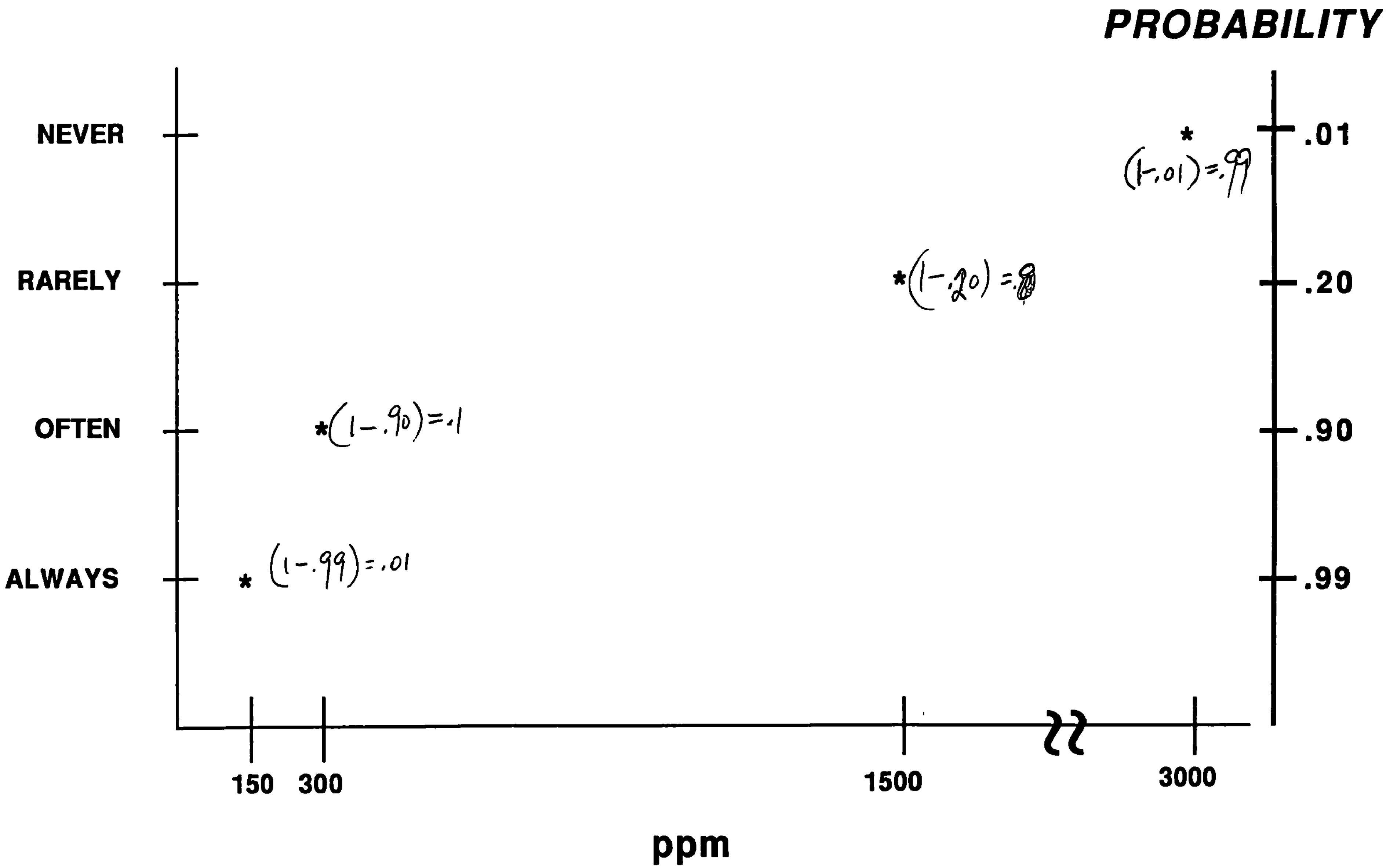


LIKELIHOOD OF PASSING EMISSIONS TEST



Assigning #s to gut feeling

LIKELIHOOD OF PASSING EMISSIONS TEST



STAGE II: STEP 5

STATEMENT OF DESIRED PERFORMANCE.

Desired Power of Emissions Test

Probability of Failing:

.01 at 150 ppm failing ⇒ false +ve

.10 at 300 ppm

.80 at 1500 ppm failing ⇒ true +ve

.99 at 3000 ppm

STAGE II: STEP 5

STATEMENT OF DESIRED PERFORMANCE.

P[FALSE POSITIVE] $\leq$ .01 at 150 ppm

P[FALSE NEGATIVE] $\leq$ .90 at 300 ppm

P[FALSE NEGATIVE] $\leq$ .20 at 1500 ppm

P[FALSE NEGATIVE] $\leq$ .01 at 3000 ppm

WORK SHEETS

DQO QUANTITATIVE WORKSHEET

AMBIENT AIR EXAMPLE

(A) A given area (usually defined by the political boundaries of a city) is classified by EPA as non-attainment with short term ambient air quality standards for Ozone if:

- on 2 or more days per calendar year,
- the maximum one hour average Ozone concentration measured on a given day is found to be greater than 0.12 ppm (40 CFR Part 50).

Continuous monitoring data are collected at fixed stations to determine hourly average ambient Ozone concentrations for each area. The results of this data collection activity are used to determine compliance (attainment) with ambient standards.

For this situation:

1) State what a false positive result would be:

____

____

2) State what a false negative result would be:

____

____

3) Why should EPA be concerned with false positive errors?

____

____

4) Why should EPA be concerned with false negative errors?

____

____

EXTRA: Which type of error would cause <u>you</u> greater concern?

SULFUR REDUCTION EXAMPLE

(B) A hypothetical group of coal-fired power plant companies in the Ohio River Valley have just agreed to install state-of-the-art scrubbers designed to significantly reduce sulfur emissions resulting from the use of locally mined high-sulfur coal. Congressmen and Governors in the New England area have asked the EPA Regional Administrator to collect data in the region so that, if a reduction occurs as a result of this action, it can be detected. The Governors from this region reached an unprecedented agreement: they agreed to split costs borne by Ohio residents and utility companies, if a reduction of greater than 20% in sulfur compounds associated with rain is detected in the New England area during the first year following installation of these scrubbers (which are currently scheduled to go on-line in Jan., 1988). EPA agreed to monitor sulfur deposition in the region in both 1987 (pre-scrubbers) and 1988 (post-scrubbers). This data will be available for EPA to determine if a $\geq$ 20% reduction can be documented when 1987 and 1988 sulfur deposition data are compared.

For this problem:

1) State what a false positive result would be:

____

____

2) State what a false negative result would be:

____

____

3) What type of error would Ohio taxpayers and utilities be most concerned with? Why?

____

____

4) Is this the same type of error that would be of concern to the New England residents? Why or why not?

____

____

5) How about environmental interest groups?

____

____

(C) **NON POINT SOURCE MITIGATION EXAMPLE**

As part of the Chesapeake Bay Program effort to control non-point source (NPS) run off of phosphorous (P) from farms into the Bay (including run-off into all major tributaries leading into the bay), EPA Region III has decided to conduct an evaluation of the relative efficacy of two potential NPS mitigation alternatives. Advocates of each method (M-1 and M-2) both claim that their method should yield substantial reduction in P loading from non-point agricultural sources into the Bay and its tributaries, based on limited data collected from the Great Lakes region and elsewhere. M-1 involves planting a 50' buffer strip with an effective scavenger crop. M-2 depends on use of low-till farming practices that require a much higher use of pesticides for weed and pest control.

To determine if M-1 will in fact result in a greater reduction in P runoff than the M-2, Region III is planning a field-test of both methods. The decision to be made from these field studies is whether M-1 is more effective than M-2, or if the methods are equally effective. The study will produce data that will be used to calculate the percent reduction in P for both methods under varying conditions. If the difference between % reduction resulting from M-1 versus M-2 is greater than 10% [e.g., is % red. M1- % red. M2 > 10%, or ≤ 10%?] (10% is the smallest difference considered by Regional Scientists to be meaningful), then EPA will conclude that M-1 should be adopted for use in the Chesapeake Bay Program. Otherwise EPA will recommend M-2 for use in this program.

1. State what a false positive would be in this case.

   ____

2. State what a false negative would be in this case.

   ____

   ____

3. Which type of error would be of greater concern, and why? (Hint: what are the consequences of each error situation?)

   ____

   ____

   ____

   ____

4. List three false negative scenarios where the consequences of error are of increasing magnitude due to the magnitude of difference missed: (Hint: what % change in P, if it occurred, would you want the study to be able to detect: always, most of the time, sometimes?)

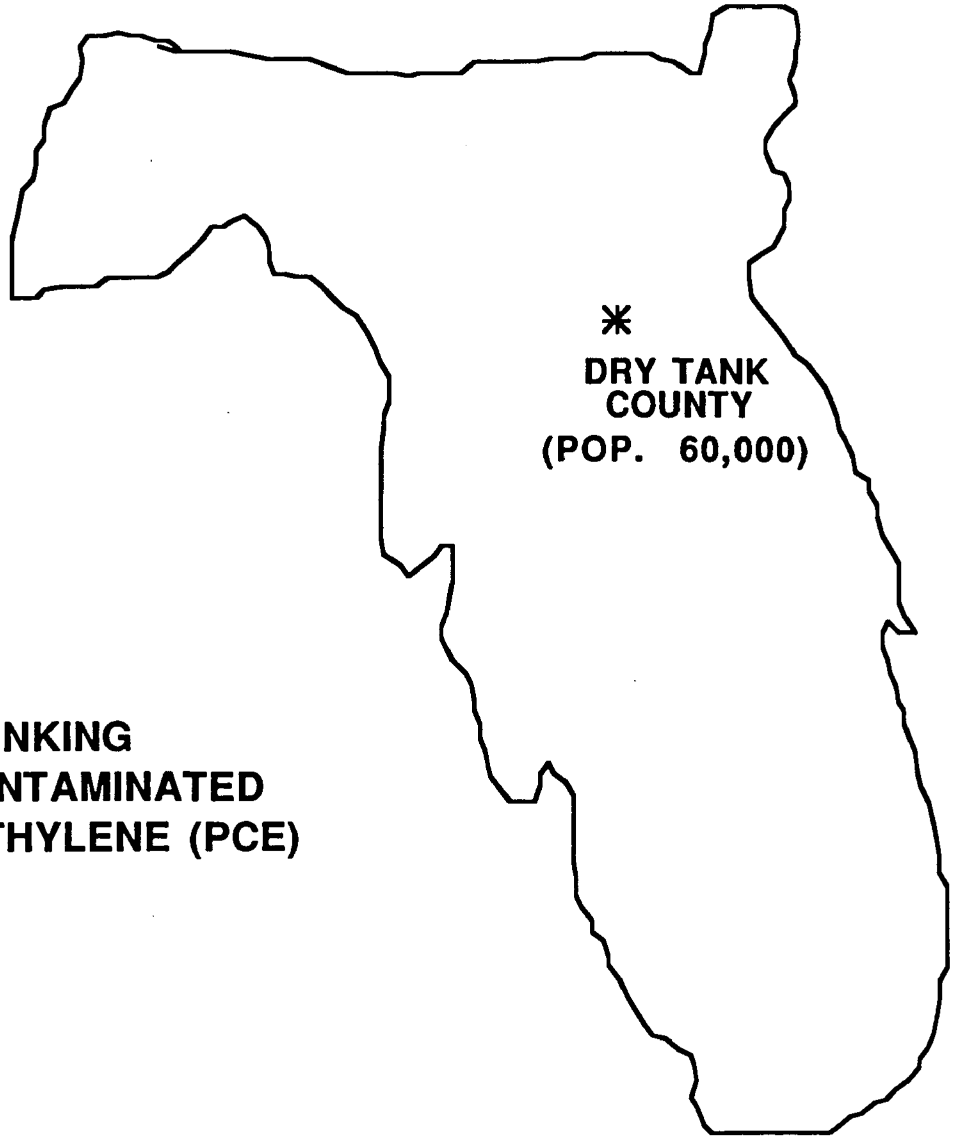
   ____

   ____

   ____

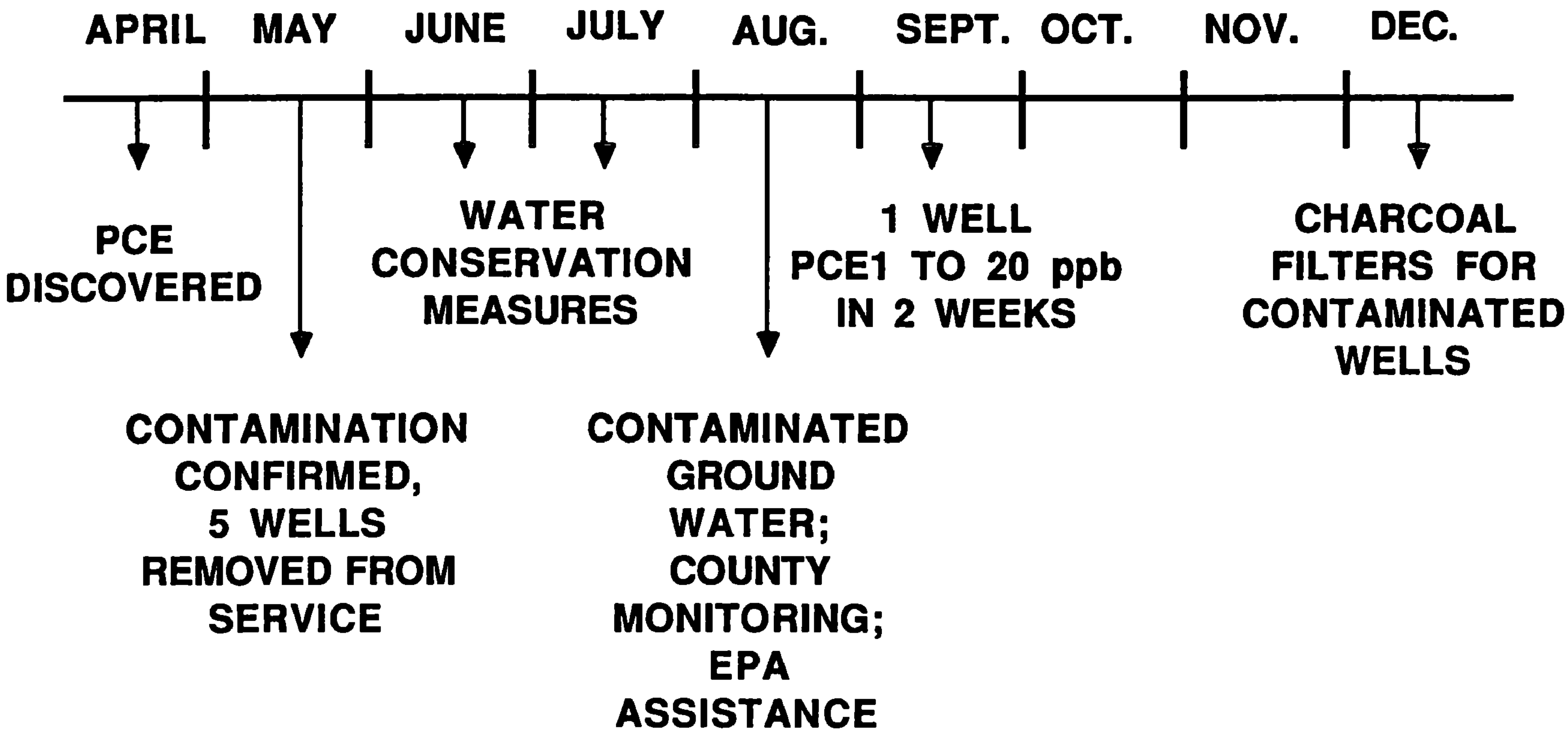
GROUP EXERCISE

PROBLEM

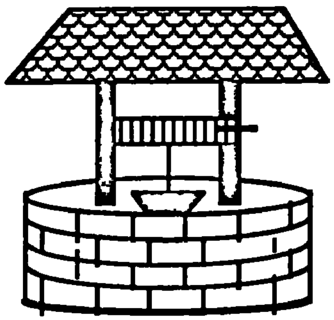


COUNTY'S SOLE DRINKING
WATER SOURCE CONTAMINATED
WITH PERCHLOROETHYLENE (PCE)

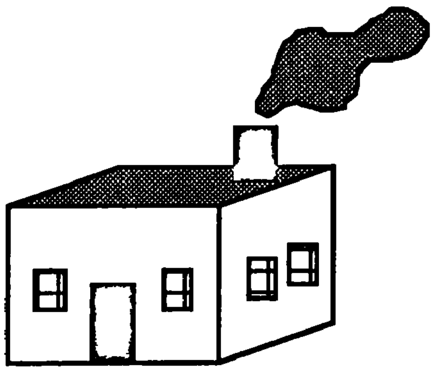
HISTORY OF CONTAMINATION PROBLEM



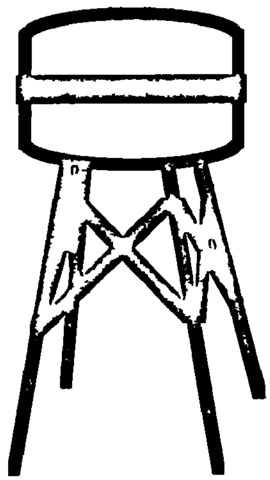
DRYTANK COUNTY WATER SUPPLY



- 31 WELLS
  INDIVIDUAL PUMPS/TREATMENT SYSTEM
  TOTAL CAPACITY: 72 MILLION GALLONS/DAY



- NO CENTRAL TREATMENT



- MINIMAL ABOVE GROUND STORAGE

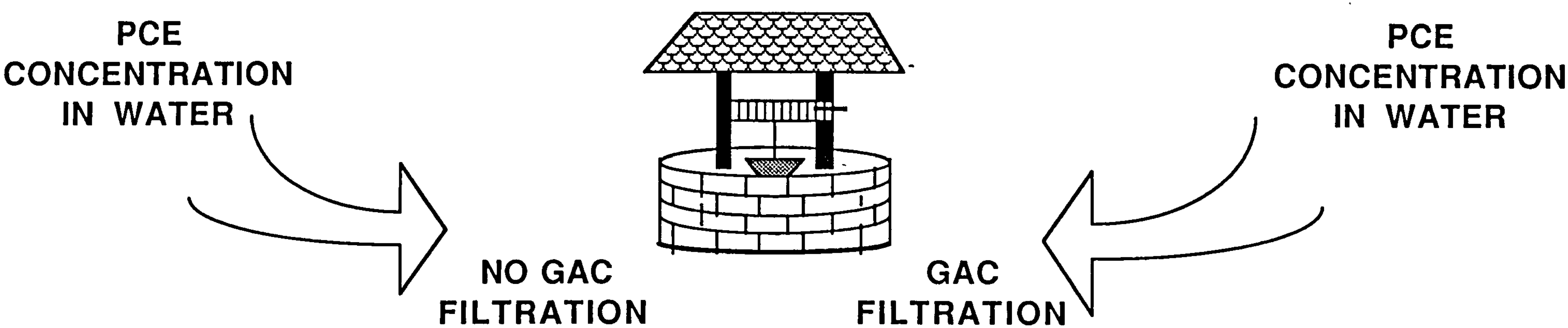
DECISIONS THAT REQUIRE MONITORING DATA

- WHETHER TO TAKE A GIVEN WELL OUT OF SERVICE.
- WHETHER A GIVEN WELL CAN BE RETURNED TO SERVICE AFTER INSTALLATION OF GAC COLUMNS.
- WHETHER A GIVEN WELL WITH GAC TREATMENT CAN REMAIN IN SERVICE.

CONSEQUENCES OF DECISIONS

- COST OF GAC TREATMENT AT EACH WELL HEAD
- MITIGATE LONG-TERM HEALTH EFFECTS FROM PCE EXPOSURE
- INABILITY TO MEET PEAK WATER DEMANDS IF MORE WELLS ARE REMOVED FROM SERVICE

DATA NEEDED FOR DECISION



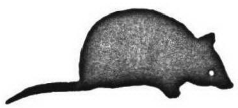
PCE STANDARDS

- NO EXISTING FEDERAL STANDARDS
- PROPOSED EPA HEALTH-BASED STANDARD IS ZERO (SUSPECTED CARCINOGEN)
- STATE DRINKING WATER STANDARD IS 3 ppb

HEALTH EFFECTS PCE

MOUSE

- LIVER CANCER: ORAL (GAVAGE) EXPOSURE
- RISK ASSESSMENT
  - 1 ppb - 1.5×10^{-6}
  - 10 ppb - 15.0×10^{-6}
  - 50 ppb - 75.0×10^{-6}



RAT

- LIVER CANCER: INHALATION EXPOSURE

HUMAN

- TRANSIENT LIVER DAMAGE
  SHORT TERM EXPOSURE (100ppm)

EPIDEMIOLOGIC DATA INCONCLUSIVE

PCE CONTAMINATION PROBLEM: SUMMARY FACT SHEET

PROBLEM:

- PCE (Tetrachloroethylene) contamination has been found in "Drytank Co", Florida ground water that supplies 100% of the drinking water in the this area.

PCE HEALTH EFFECTS:

- Health effects studies correlated with liver damage and predict cancers at concentrations as low as 1 ppb (EPA Risk Assessment 1 ppb= 1.5 x 10^{6})

COMMUNITY WATER SUPPLY:

- 31 wells in system, each provides about 2000 gal/min
- No central treatment, minimum above ground storage
- System serves 60 K people
- Aquifer is unconfined loose gravel and sand, rapid movement of ground water evidenced by sudden appearance of PCE in one well

ACTIONS TO DATE:

- 5 wells with PCE > 3 ppb found and removed from service
- Mandatory water conservation measures in summer (no watering gardens)
- Search for source(s) of PCE underway by State DER: results not yet available

REQUEST TO USEPA REG IV: INITIATION OF DOO PROCESS:

- Region to assist in design for monitoring program that will give Co and State officials data adequate for application of the 3 ppb Florida PCE standard.

STAGE I OUTPUT

DECISION: Data will be used to decide:

- Whether to take a given well out of service
    - Whether a given well can be returned to service after installation of GAC columns
    - Whether a given well with GAC treatment can remain in service

DATA NEEDS

- Concentration of PCE in water from each well prior to being pumped into main system (with or without GAC filtration)

POSSIBLE CONSEQUENCES OF DATA LEADING TO AN INCORRECT DECISION

° If a well is removed from service, when it really had < 3 ppb due to a false positive result:

  - unnecessary installation and maintenance of GAC filters, (initial cost: approx 80K/filter: 4 filters/well)

  - possible water shortages during peak demand periods

° If a well is left in service, when it was really > 3 ppb due to a false negative result:

  - unchecked potential health hazard,

  - community concern

° Dry Tank Co and State decision makers more concerned with falsely concluding a well is clean (especially as levels of PCE are increasingly greater than 3 ppb).

RESOURCE AND TIME CONSTRAINTS

° EPA informed that $1 mil/ year can be made available through State and Co funds
° Need EPA design within 2 months

ADDITIONAL COST INFORMATION

° Average cost per water sample for PCE analysis: $75.00/ sample using EPA Method 601 (Purge and Trap GC)

Workshop Tasks

The rest is up to you. Your task is to complete the following steps:

1) Define the domain of the decision. From what portion of the environment will data be collected?

They're shut 5 down, doesn't make sense to resample - already subject to filtration - no, only ordered, and still out of service. Since decisions must be made about each well, all must be sampled.

Options: Dry Tank County only
a wider area
DT wells
" other sources

What are the spatial and temporal boundaries associated with this portion of the environment (over what period of time and boundaries on space do you want to obtain estimates for use in the decision)? What portion of the environment is your decision going to be made for?

Spatial: 31 wells in D.T. County

Temporal: ≤ 2 wk monitoring interval, continuous → up to every 2 wks
need reasonable frequency to keep analytic results comparable lest pocket occur

Is it more effective to occasionally test the 5 now out of service pump down will cost too.

Only current decision to take out of service.
~~Is still providing supply.~~ (5 already out) begin monitoring after GAC column installation

2) Define the result to be derived from environmental data. This result should indicate the way in which environmental data will be used to draw the conclusions of interest. This amounts to answering the following questions:

What summary statistic will be calculated?

What is the number of wells w/ > 3 ppb? If EPA has a std and doesn't do something the public will get upset. Increase monitoring, install filters,

so say For each well, if detect at ≥ 3 ppb (iterative) monitoring will be performed more frequently

How many wells are still in service?

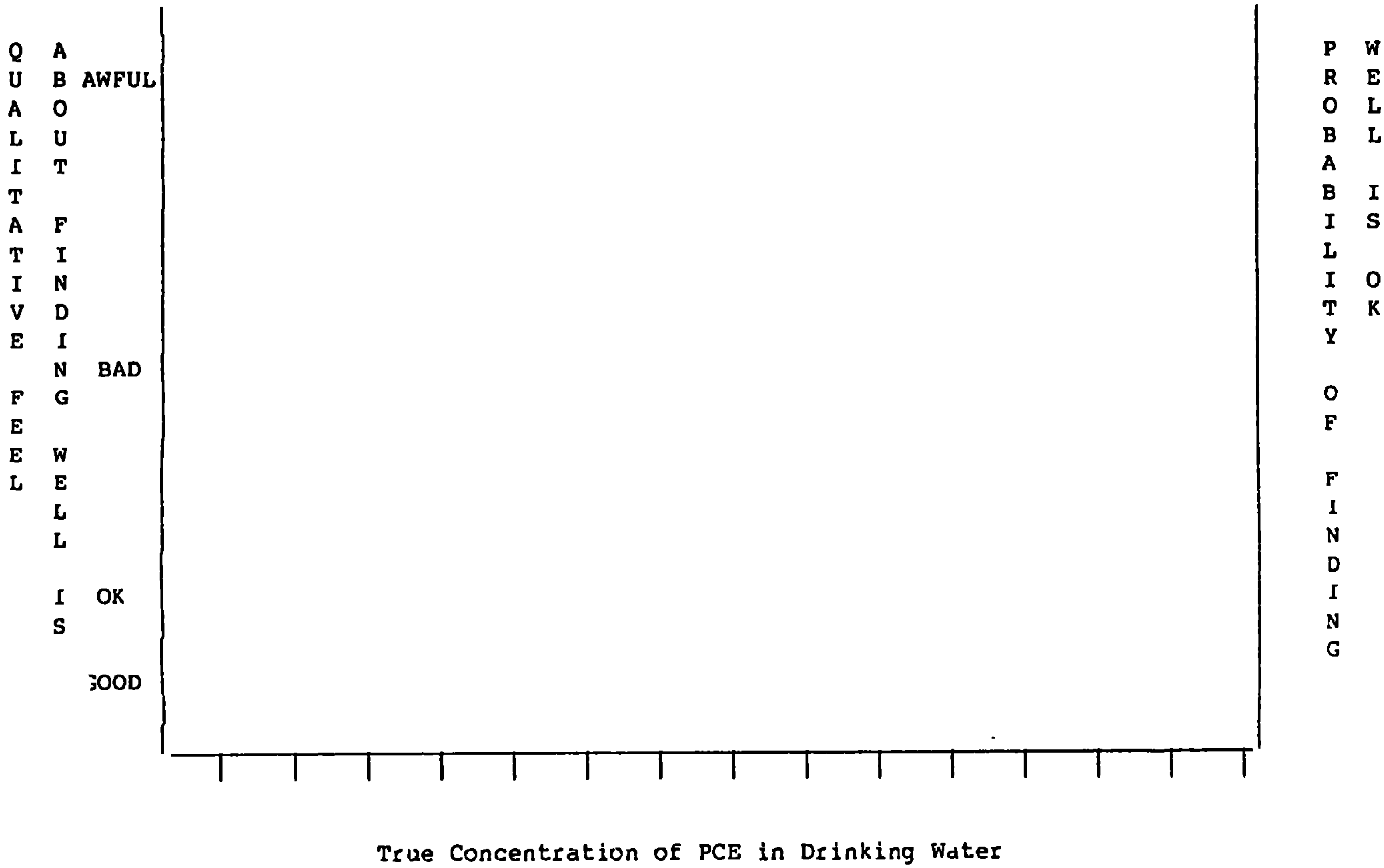
How will this be used? Will you compare it to some standard or other reference value? How will this comparison be made?

3) Go through the steps leading to specification of quantitative performance criteria:

   - Scenarios should be anticipated in which the new environmental data might lead to an incorrect result and thus cause the final decision about a well to be incorrect or questionable. To do this, look at the questions and identify what a false positive and a false negative result would be in relation to the Florida 3 ppb limit. Then list at least one additional false positive scenario and three additional false negative scenarios where the consequences of error are of increasing magnitude due to the magnitude of PCE concentrations missed or misrepresented (Hint: what level of PCE, if it occurred, would you want the monitoring program to detect accurately always, most of the time and sometimes).

   - Rank the above error situations based on the amount of concern that being wrong in different ways and by varying degrees would cause you if you were the decision maker. For example, concern over incorrect compliance decisions increases as the magnitude and frequency of non-compliance increases.

   - Assign a probability of occurrence that would be acceptable for each scenario, with the values corresponding to the level of concern associated with each. This statement should indicate the level of uncertainty that can be tolerated and the results still used in the decision making process. This statement represents a policy decision (by the decision maker) on the acceptable risk of being wrong in different ways. For your convenience, the following "desired power" curve might be used to develop performance statements.


QUALITATIVE FEEL ABOUT FINDING WELL IS
AWFUL
BAD
OK
GOOD
PROBABILITY OF FINDING WELL IS OK
True Concentration of PCE in Drinking Water

Example of an
ANSWER SHEET
(There is more than one Correct Answer)

DQO QUANTITATIVE WORKSHEET

AMBIENT AIR EXAMPLE

(A) A given area (usually defined by the political boundaries of a city) is classified by EPA as non-attainment with short term ambient air quality standards for Ozone if:

- on 2 or more days per calendar year,
- the maximum one hour average Ozone concentration measured on a given day is found to be greater than 0.12 ppm (40 CFR Part 50).

Continuous monitoring data are collected at fixed stations to determine hourly average ambient Ozone concentrations for each area. The results of this data collection activity are used to determine compliance (attainment) with ambient standards.

For this situation:

1) State what a false positive result would be:

Finding the max. 1-hour average O_3 at a station to be >0.12 ppm on 2 or more days, when really on one or more of those days the O_3 was ≤0.12 ppm.

2) State what a false negative result would be:

Finding a given result to be in attainment when on 2 or more days the O_3 was >0.12 ppm.

3) Why should EPA be concerned with false positive errors?

EPA is concerned about taking unwarranted actions possibly incurring costs on industry or on people operating cars when it was not needed to attain standards.

4) Why should EPA be concerned with false negative errors?

Unhealthy levels of O_3 could be present & go undetected by EPA — i.e., the purpose of monitoring is defeated. Depending on the magnitude of true O_3 levels that went undetected, this error could be serious.

EXTRA: Which type of error would cause you greater concern?

False negatives, on the basis that human health is the more important of the two — human health vs $

SULFUR REDUCTION EXAMPLE

(B) A hypothetical group of coal-fired power plant companies in the Ohio River Valley have just agreed to install state-of-the-art scrubbers designed to significantly reduce sulfur emissions resulting from the use of locally mined high-sulfur coal. Congressmen and Governors in the New England area have asked the EPA Regional Administrator to collect data in the region so that, if a reduction occurs as a result of this action, it can be detected. The Governors from this region reached an unprecedented agreement: they agreed to split costs borne by Ohio residents and utility companies, if a reduction of greater than 20% in sulfur compounds associated with rain is detected in the New England area during the first year following installation of these scrubbers (which are currently scheduled to go on-line in Jan., 1988). EPA agreed to monitor sulfur deposition in the region in both 1987 (pre-scrubbers) and 1988 (post-scrubbers). This data will be available for EPA to determine if a $\geq$ 20% reduction can be documented when 1987 and 1988 sulfur deposition data are compared.

For this problem:

1) State what a false positive result would be:

Finding that a > 20% reduction in S occurred, when in fact $\leq$ 20% reduction truly occurred.

2) State what a false negative result would be:

Finding that a $\leq$ 20% reduction in S occurred, when in fact > 20% reduction truly occurred.

3) What type of error would Ohio taxpayers and utilities be most concerned with? Why? Ohio is concerned with false (−) at 20% (i.e., missing a 20% reduction that had occurred), since this presumably means N.E. wouldn't split costs. Ohio may also not be concerned since one could conclude that this proves Ohio coal wasn't (isn't) to blame for N.E. acid deposition & they should continue to burn high S coal. In terms of a false (+), Ohio would be concerned because it links (falsely) Ohio coal to N.E. acid deposition.

4) Is this the same type of error that would be of concern to the New England residents? Why or why not? New England concerned with false (+) at 20%, since this means they would be paying for something (a S reduction) they are not getting; hence environ. deterioration will continue.

5) How about environmental interest groups? Both false (+) & false (−)'s. Env. grps want this "unprecedented" program to work since this should result in dec. acid rain. They are also interested in true levels of reduction related to use of scrubbers to determine what could be achieved with more wide spread programs of this type.

(C) **NON POINT SOURCE MITIGATION EXAMPLE**

As part of the Chesapeake Bay Program effort to control non-point source (NPS) run off of phosphorous (P) from farms into the Bay (including run-off into all major tributaries leading into the bay), EPA Region III has decided to conduct an evaluation of the relative efficacy of two potential NPS mitigation alternatives. Advocates of each method (M-1 and M-2) both claim that their method should yield substantial reduction in P loading from non-point agricultural sources into the Bay and its tributaries, based on limited data collected from the Great Lakes region and elsewhere. M-1 involves planting a 50' buffer strip with an effective scavenger crop. M-2 depends on use of low-till farming practices that require a much higher use of pesticides for weed and pest control.

To determine if M-1 will in fact result in a greater reduction in P runoff than the M-2, Region III is planning a field-test of both methods. The decision to be made from these field studies is whether M-1 is more effective than M-2, or if the methods are equally effective. The study will produce data that will be used to calculate the percent reduction in P for both methods under varying conditions. If the difference between % reduction resulting from M-1 versus M-2 is greater than 10% [e.g., is % red. M1- % red. M2 > 10%, or ≤ 10%?] (10% is the smallest difference considered by Regional Scientists to be meaningful), then EPA will conclude that M-1 should be adopted for use in the Chesapeake Bay Program. Otherwise EPA will recommend M-2 for use in this program.

% Red. M1 − % Red M2 ≤ 10
% Red M1 − % Red M2 > 10

1. State what a false positive would be in this case.

   Finding M-1 to yield a >10% reduction than M2, when in fact M1 ≤ 10% more effective.

2. State what a false negative would be in this case.

   Finding M1 to yield ≤10% more P reduction than M2, when in fact, M1 yielded >10% more P reduction than M2.

3. Which type of error would be of greater concern, and why? (Hint: what is the consequences of each error situation?)

   False (-): because this means M-2 would be used when M-1 was really the more effective method for reducing P, with M-2 having the potential to cause other env. problems associated with use of pesticides (eg., a real possibility of grd. H2O contamination exists)

4. List three false negative scenarios where the consequences of error are of increasing magnitude due to the magnitude of difference missed: (Hint: what % change in P, if it occurred, would you want the study to be able to detect: always, most of the time, sometimes?)

   Really M1 yields >10% P reduction than M2 -- find ≤10% difference
   " " " >25% " " " " -- " " "
   " " " >50% " " " " -- " " "

ANSWER SHEET

3) Transient liver damage in short term human exposures (100 ppm), and Acute Central Nervous System effects at 100 ppm pulmonary exposure,

4) Inconclusive epidemiological study correlating Dry Cleaning Workers with increased mortality due to colon cancer.

The rest is up to you. Your task is to complete the following steps:

1) Define the domain of the decision. From what portion of the environment will data be collected?

The volume of H_2O pumped from the aquifer into the drinking H_2O system from a given well sampled as water enters the County distribution system after receiving whatever treatment (e.g. chlorination) is at the given wellsite.

What are the spatial and temporal boundaries associated with this portion of the environment (over what period of time and boundaries on space do you want to obtain estimates for use in the decision)? What portion of the environment is your decision going to be made for?

TEMPORAL: Samples will be taken from a well on a given day and should represent the PCE concentration in the entire volume of H_2O pumped during the time period of interest. This time period is: 1 month for wells with no detectable PCE, 2 weeks for wells with <1ppb PCE detected and one week for wells with PCE detected at between 1-3ppb. The decision to remove a well from service will be made once >3ppb is detected. The time intervals may be changed if it is thought that samples miss the 3ppb mark too often.

2) Define the result to be derived from environmental data. This result should indicate the way in which environmental data will be used to draw the conclusions of interest. This amounts to answering the following questions:

What summary statistic will be calculated?

Mean [PCE] in samples collected on any day during a time period of interest, stated in ppb.

How will this be used? Will you compare it to some standard or other reference value? How will this comparison be made?

Mean [PCE] will be compared to 3ppb; if >3ppb the well will be removed from service.

3) Go through the steps leading to specification of quantitative performance criteria:

- Scenarios should be anticipated in which the new environmental data might lead to an incorrect result and thus cause the final decision about a well to be incorrect or questionable. To do this, look at the questions and identify what a false positive and a false negative result would be in relation to the Florida 3 ppb limit. Then list at least one additional false positive scenario and three additional false negative scenarios where the consequences of error are of increasing magnitude due to the magnitude of PCE concentrations missed or misrepresented (Hint: what level of PCE, if it occurred, would you want the monitoring program to detect accurately always, most of the time and sometimes).

false (+) : Finding [PCE] > 3 ppb, when [PCE] in water at that time was really ≤ 3 ppb.

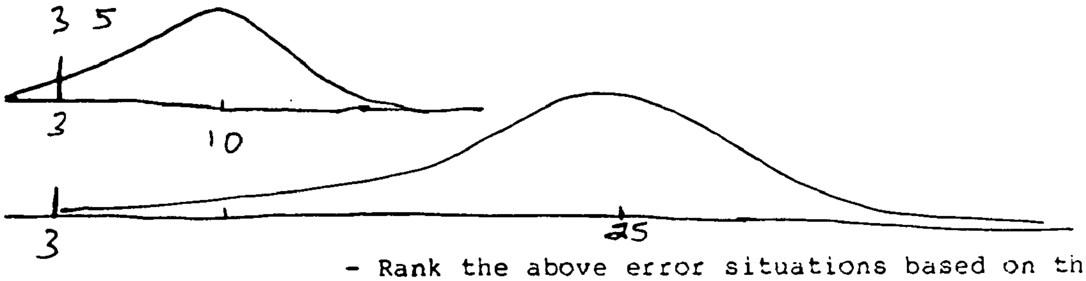
2nd false (+) scenario : Finding [PCE] > 3 ppb, when [PCE] in water at that time was really 1 ppb.

false (-) : Finding [PCE] ≤ 3 ppb, when really it is > 3 ppb (less conce.)

" " ≤ 3, " " " " ≥ 5 ppb

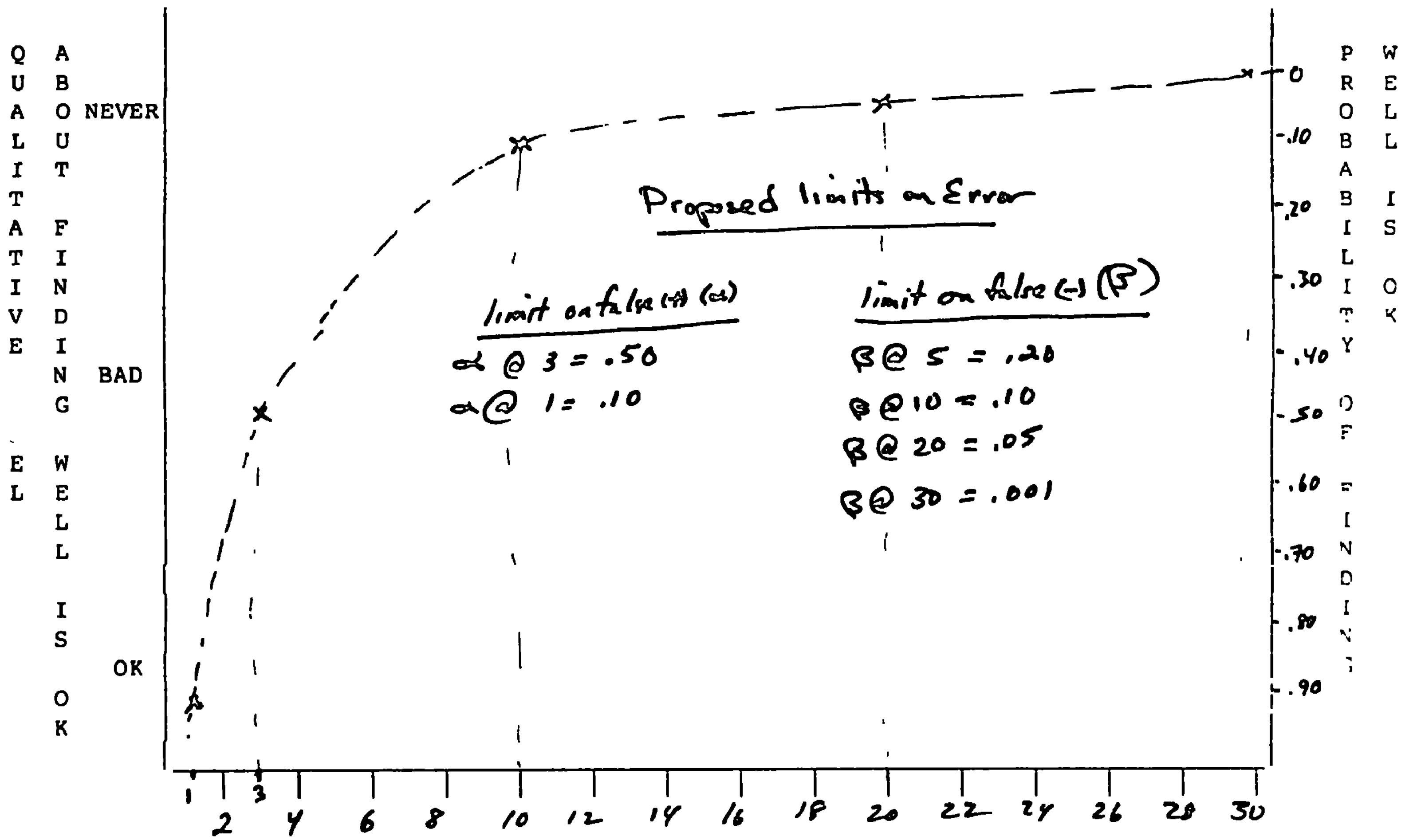
" " ≤ 3, " " " " ≥ 10

" " ≤ 3, " " " " ≥ 25 (greater concern)



- Rank the above error situations based on the amount of concern that being wrong in different ways and by varying degrees would cause you if you were the decision maker. For example, concern over incorrect compliance decisions increases as the magnitude and frequency of non-compliance increases.

- Assign a probability of occurrence that would be acceptable for each scenario, with the values corresponding to the level of concern associated with each. This statement should indicate the level of uncertainty that can be tolerated and the results still used in the decision making process. This statement represents a policy decision (by the decision maker) on the acceptable risk of being wrong in different ways. For your convenience, the following "desired power" curve might be used to develop performance statements.



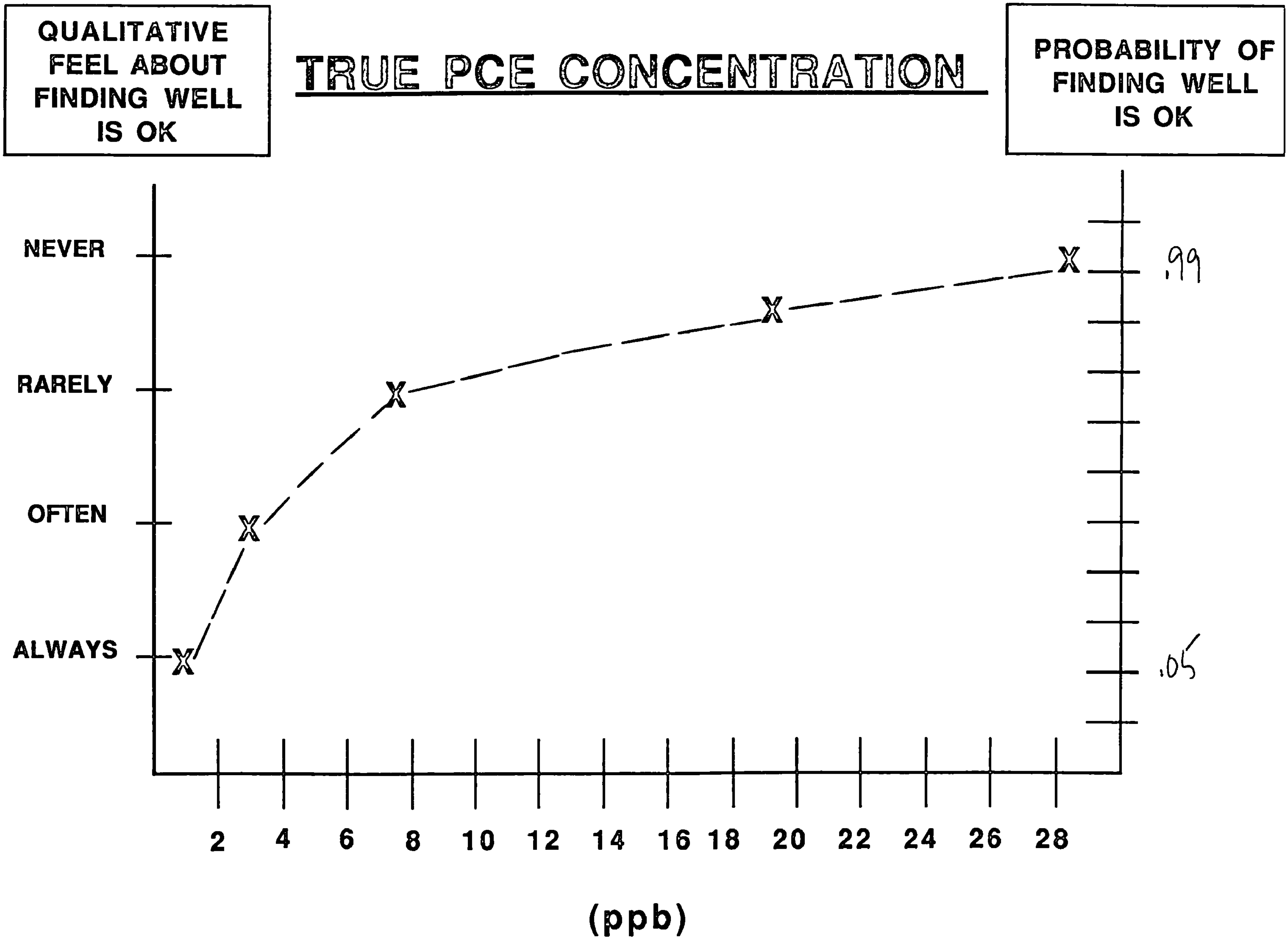
True Concentration of PCE in Drinking Water

Suppose

$P\{\text{false +ve}\} \leq 10\%$ at 1ppb

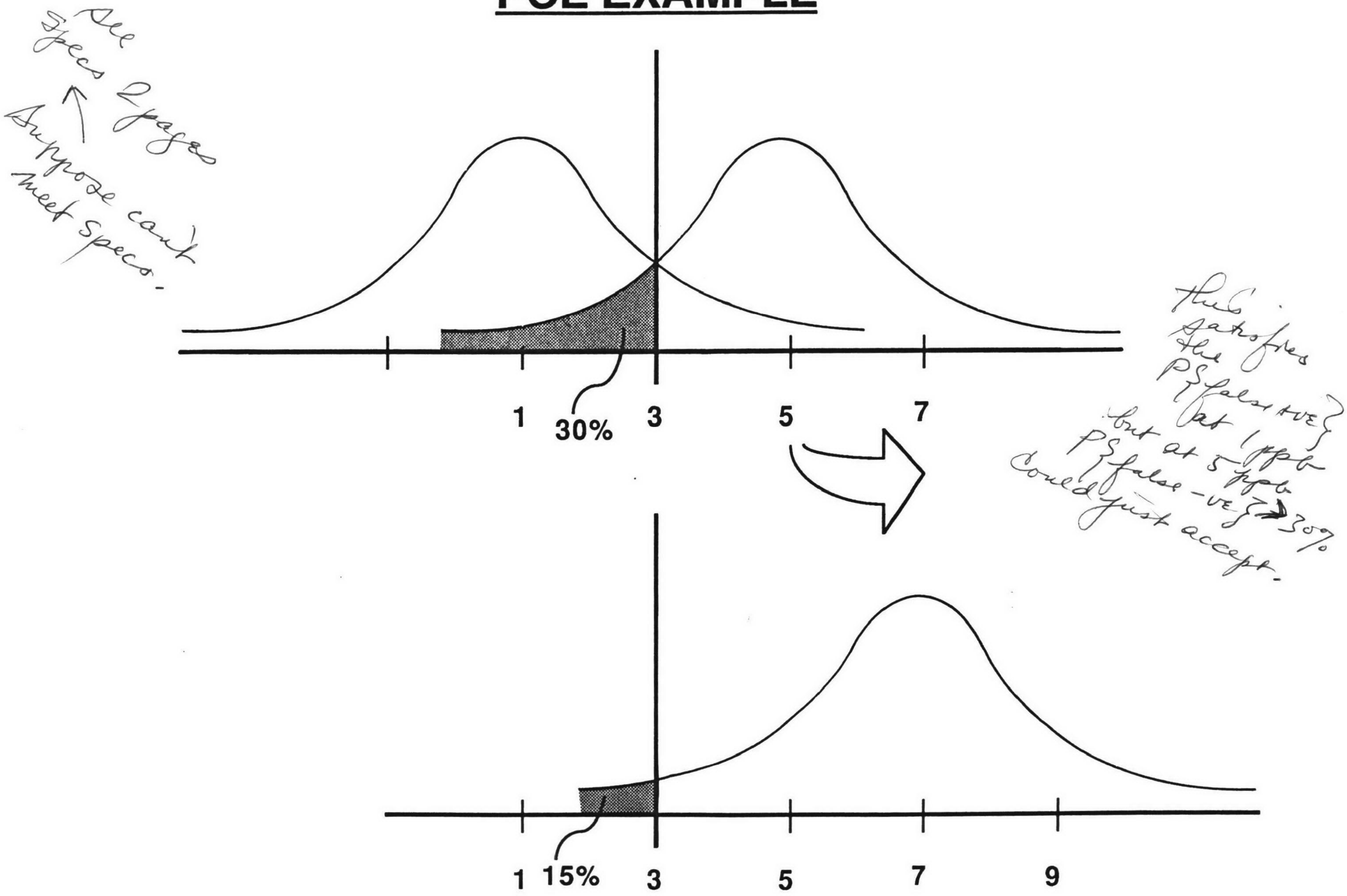
$P\{\text{false −ve}\} \leq 15\%$ at 5ppb

See Example 2 pages hence


QUALITATIVE FEEL ABOUT FINDING WELL IS OK
TRUE PCE CONCENTRATION
PROBABILITY OF FINDING WELL IS OK
NEVER
RARELY
OFTEN
ALWAYS
.99
.05
2
4
6
8
10
12
14
16
18
20
22
24
26
28
(ppb)

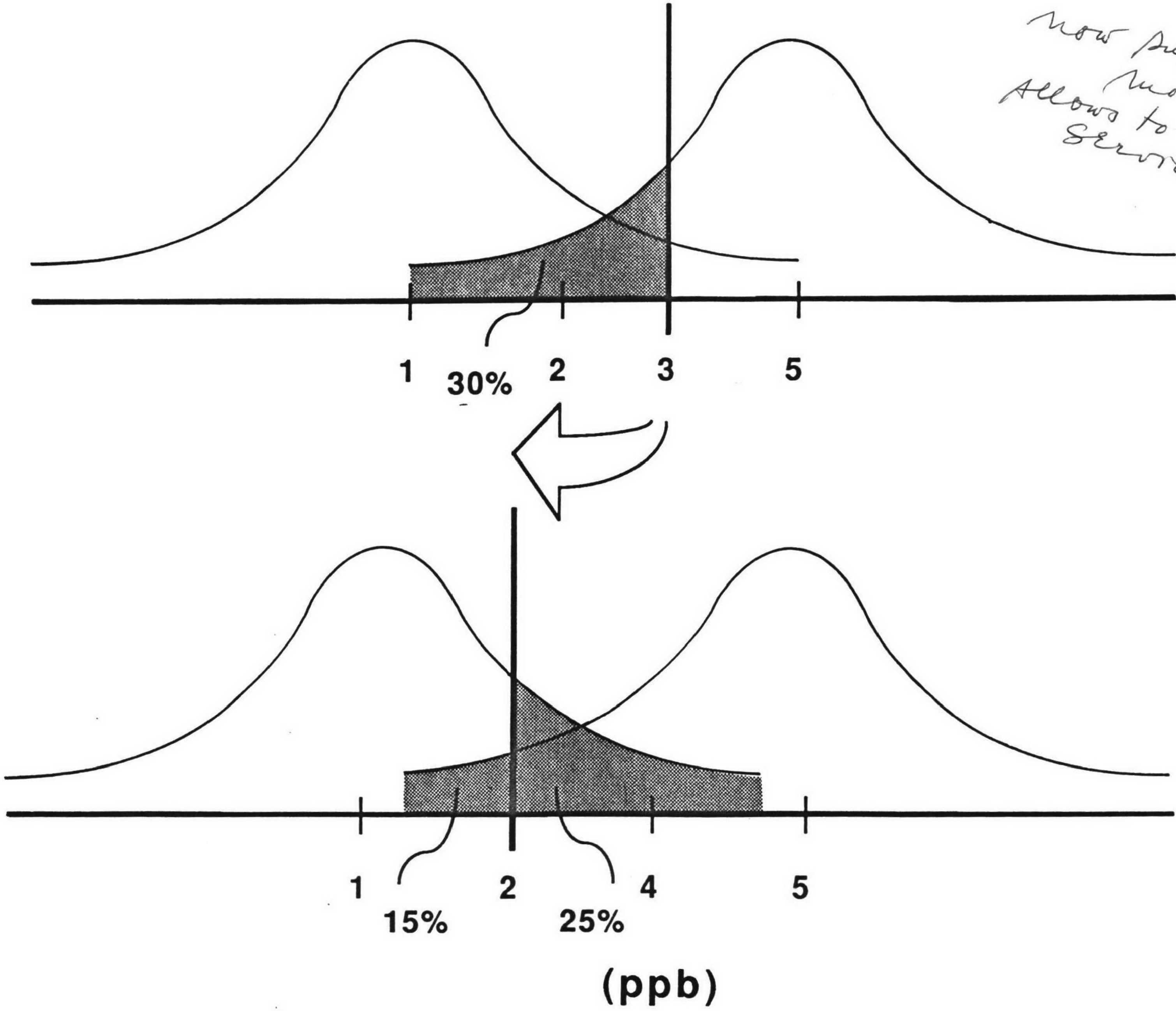
HOW ARE PERFORMANCE CRITERIA USED?

PCE EXAMPLE



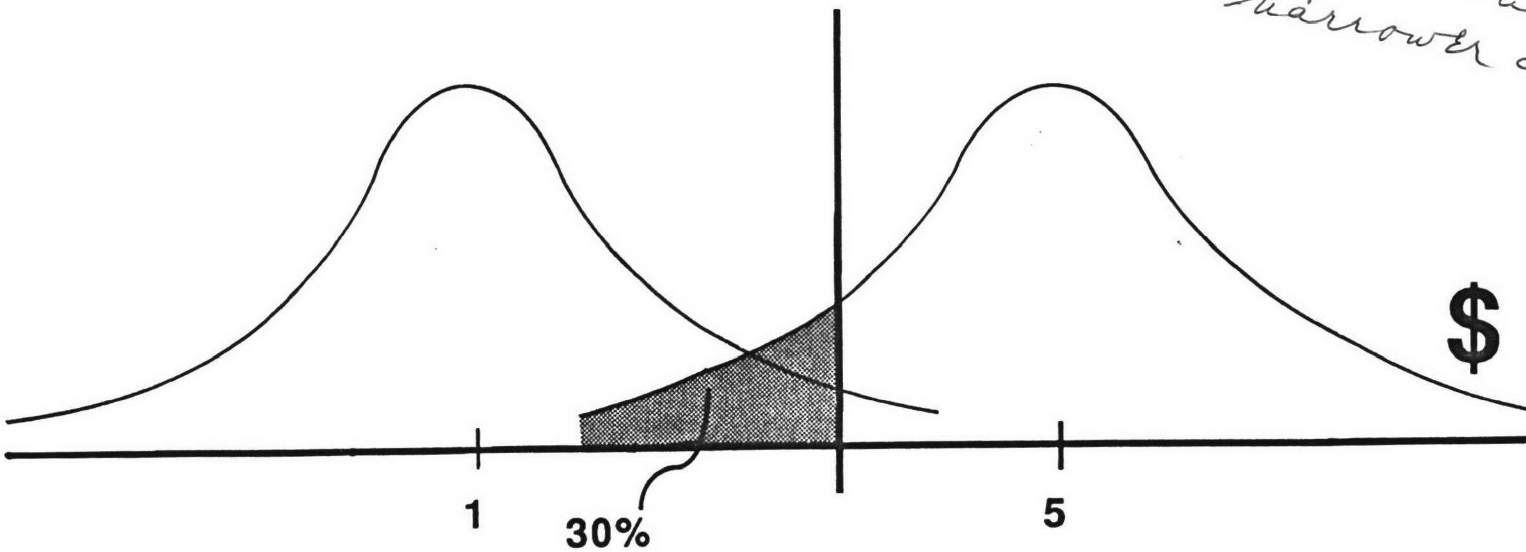
1
30%
3
5
7
1
15%
3
5
7
9
See Specs 2 pages
Suppose can't meet specs.
this satisfies the P{false +ve} at 1 ppb
but at 5 ppb P{false -ve} → 30%
Could just accept.

PCE EXAMPLE



now suppose move std to 2
Allows to keep some in service — but pay price of greater p of false +ve?

PCE EXAMPLE



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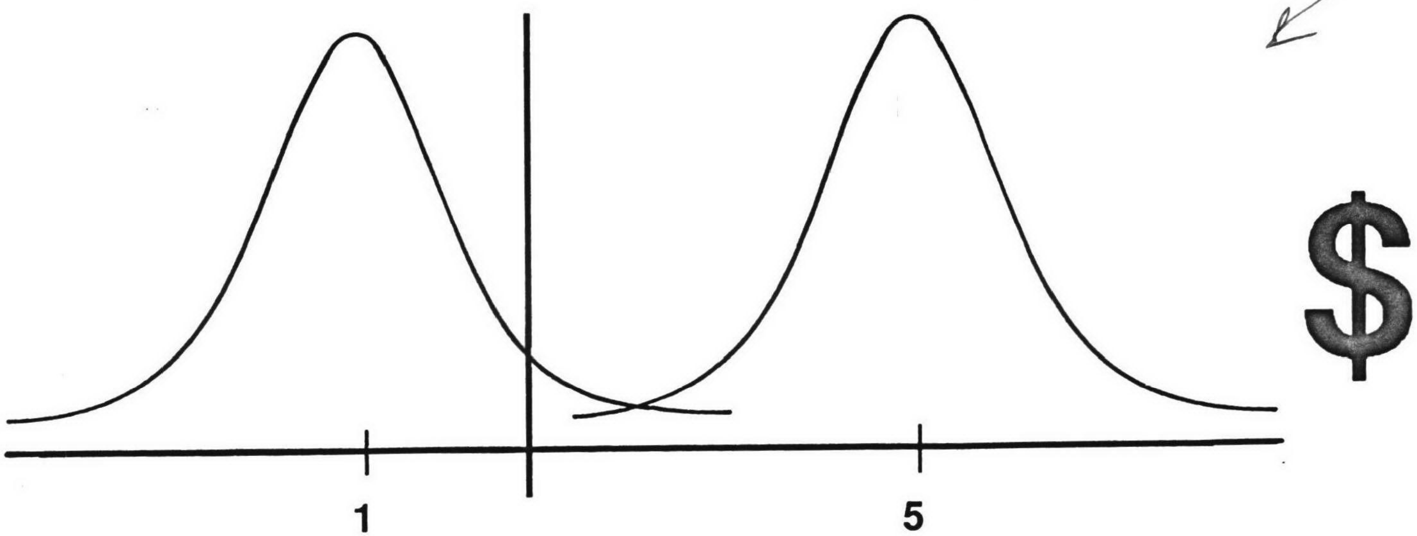

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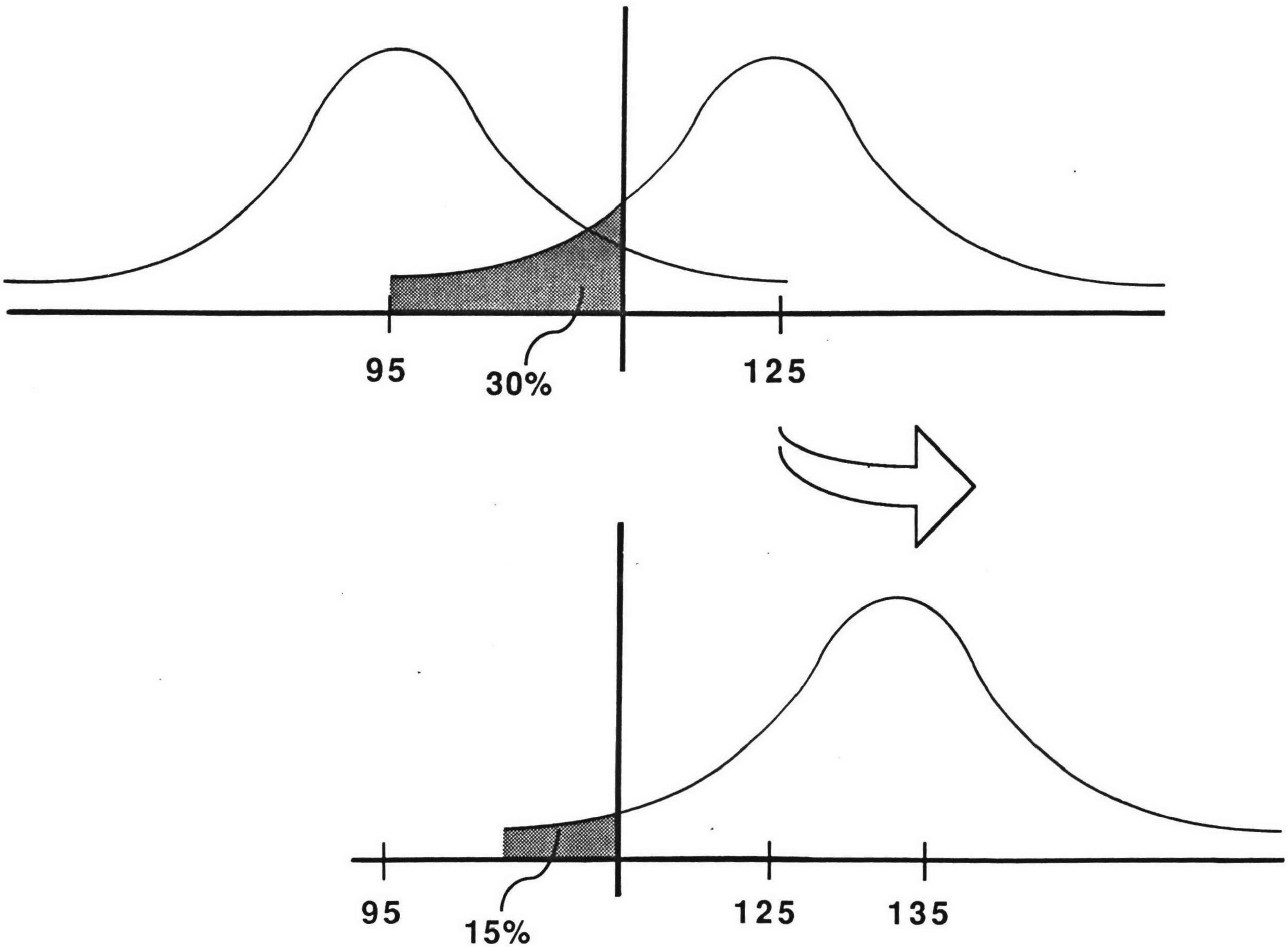

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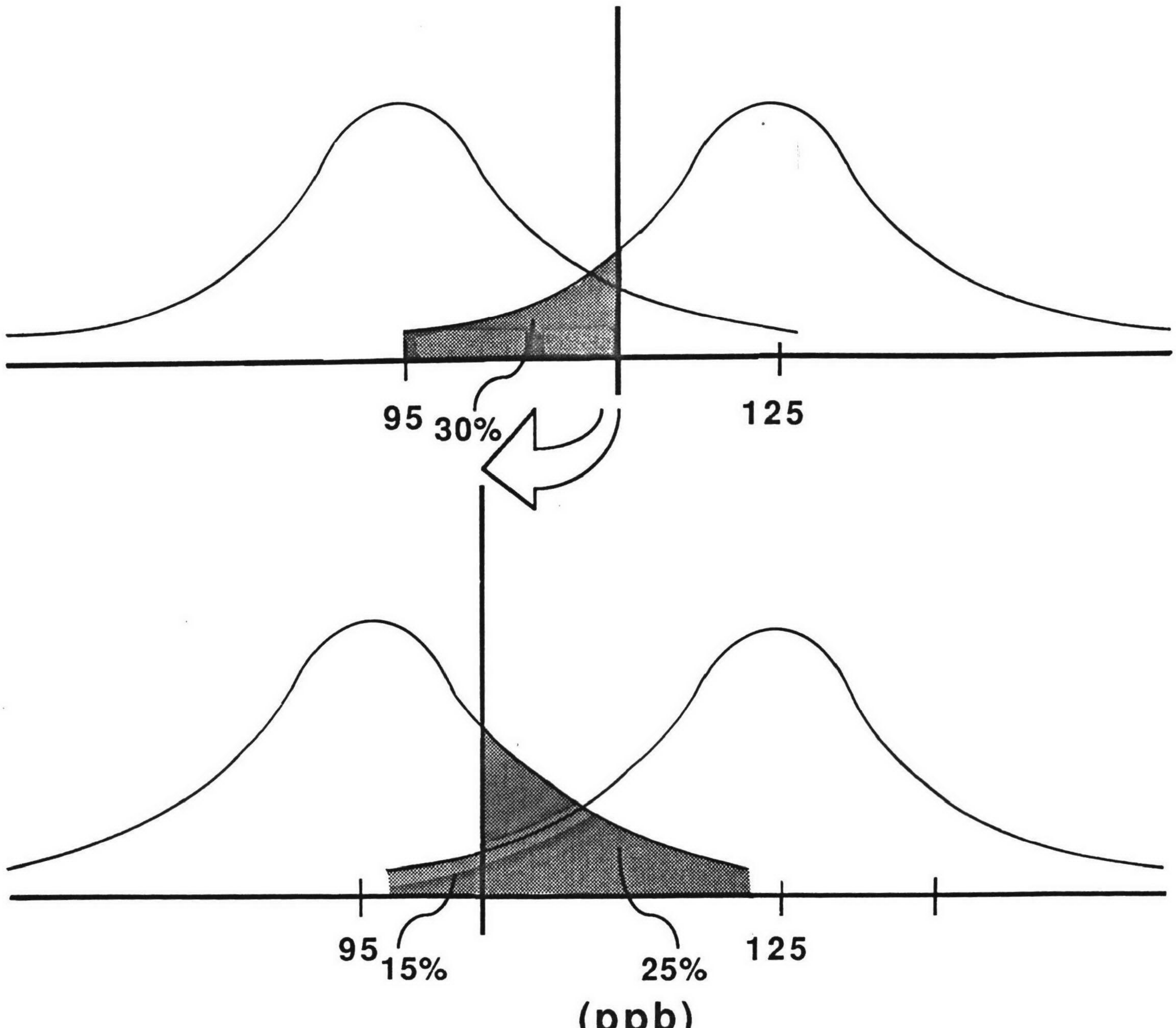

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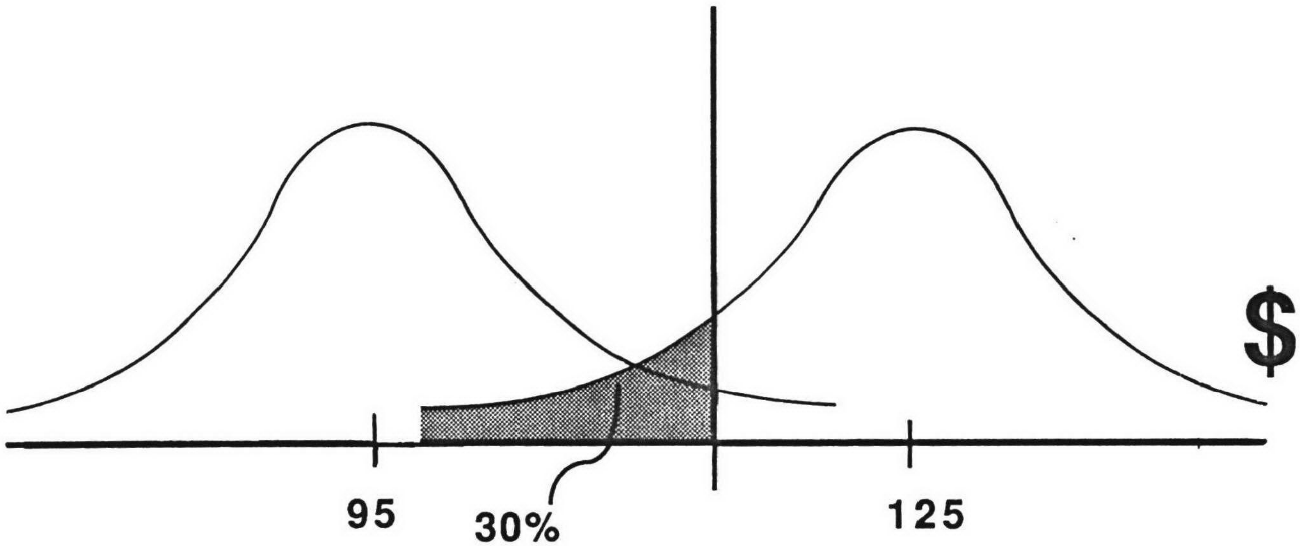

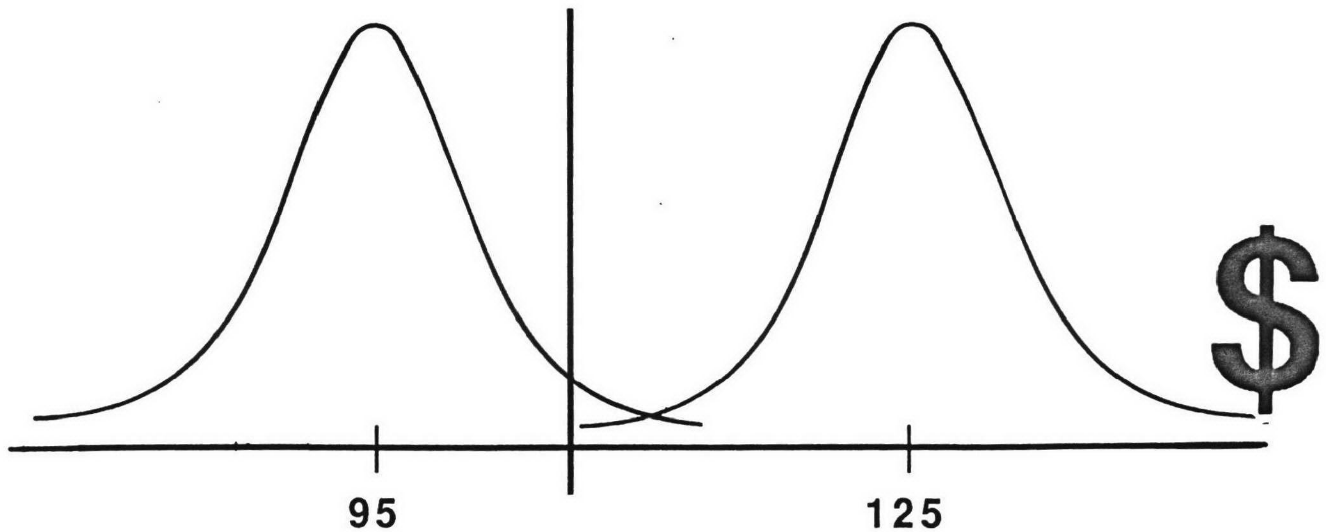

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
RESEARCH AND DEVELOPMENT

NOV 4 1986

SUBJECT: Draft Information Guide on Data Quality Objectives

FROM: Dean Neptune, Environmental Scientist
Quality Assurance Management Staff (RD-680)

TO: QA Management Meeting Participants

The attached draft Information Guide is an effort to summarize the essential elements of Stages I and II of the Data Quality Objectives (DQO) process. It is offered as a logical framework for addressing important issues that require attention in designing an effective data collection activity. This is not the only framework--others may be equally effective. QAMS is continuing to improve on this draft, as we gain more experience in working with the Agency on how best to present our ideas on DQO's.

Please contact me at 8-382-5763 with any questions or comments on this document.

Attachment

DRAFT

DEVELOPMENT OF DATA QUALITY OBJECTIVES

Description of Stages I and II

Quality Assurance Management Staff
July 16, 1986

TABLE OF CONTENTS

INTRODUCTION

Environmental data play a critical role in many EPA decisions. Because of the importance of environmental data to EPA, the process used to design data collection programs should place substantial emphasis on defining the regulatory objectives of the program, the decision that will be made with the data collected, and the possible consequences of the decision being incorrect. A design process that fails to explore these issues and focuses only on collecting the "best data possible" can result in serious problems, especially when the final responsiblity for defining "best data possible" is assumed by technical experts rather than EPA decision makers. Technical experts, presented with a pre-established budget, may identify the best sampling and analytical methods available and then determine the number of samples and measurements that can be afforded using these methods. While this approach may ensure that each individual measurement obtained is the best possible, it does not always ensure that adequate information is obtained for making a decision.

Before a data collection program can be initiated, EPA must frequently demonstrate (to regulated industries, the environmental community and to OMB) that its requirements for data are justified. Negotiations are often required to satisfy industry representatives that the data are in fact needed and to satisfy environmental groups that the monitoring requirements are sufficiently stringent. Although Agency accomplishments have shown that the process of designing programs to collect the "best data possible" can be successful, this approach is not scientifically rigorous and may fail to produce a scientific record that will support EPA's position. Furthermore, such a non-quantitative approach cannot be expected to uniformly result in data collection designs that will generate data of adequate quality for defensible decision making.

The Quality Assurance Management Staff (QAMS), in response to a requirement established by the Deputy Administrator in May, 1984, has proposed an approach to designing environmental data collection programs based on the development of Data Quality Objectives (DQO's). The DQO process does not use a pre-established budget as the sole constraint on the design of a data collection program. Rather, equal consideration is given to defining the quality of the product needed, i.e., the degree to which total error in the results derived from data must be controlled to achieve an acceptable level of confidence in a decision that will be made with the data. The DQO process provides a logical, objective, and quantitative framework for finding an appropriate balance between the time and resources that will be used to collect data and the quality of the data needed to make the decision. Therefore, data collection programs based on DQO's will be more likely to meet the needs of EPA decision makers in a cost effective manner.

One of the most important aspects of the DQO process is the involvement of decision makers. DQO's are developed using a top-down approach; the initial input and perspective of the decision maker is critical to the successful development of DQO's. QAMS recognizes that the role of the decision maker may vary to some degree among programs, from directly providing input and direction throughout the process, to reacting to or concurring with options presented by key senior staff. However, through their personal involvement, decision makers can ensure that the DQO process is used to properly design all significant data collection efforts. As the DQO process becomes a "way of life" in the Agency, it will provide a more effective system than currently available for ensuring that the quality of EPA data is compatible with the requirements of the decision making process.

The absence of a well-defined framework for obtaining the decision maker's input and for focusing the activities of senior program staff presents a significant obstacle to implementing the development of DQO's. QAMS has prepared the following discussion of the DQO process by building on the October, 1984 DQO guidance and experience gained in subsequent efforts to develop DQO's. This document presents a more detailed description of the DQO process than the initial guidance, focusing on the role and activities of the decision maker and the senior program staff. The discussion defines the stages and steps of the process and describes the information that is developed in each step. This document should be used to help familiarize decision makers and their senior staff with the DQO process and, more importantly, with their specific roles and responsibilities in that process.

OVERVIEW OF DQO'S AND THE DQO PROCESS

Data quality objectives (DQO's) are statements of the level of uncertainty that a decision maker is willing to accept in results derived from environmental data, when the results are going to be used in a regulatory or programmatic decision (e.g., deciding that a new regulation is needed, setting or revising a standard, or determining compliance). To be complete, these quantitative DQO's must be accompanied by clear statements of:

- the decision to be made;
- why environmental data are needed and how they will be used;
- time and resource constraints on data collection;
- descriptions of the environmental data to be collected;
- specifications regarding the domain of the decision; and
- the calculations, statistical or otherwise, that will be performed on the data in order to arrive at a result.

This document explains the information needed for each of the items above and suggests a step-by-step process by which all of the items may be prepared.

Developing DQO's should be the first step in initiating any significant environmental data collection program that will be conducted by or for the EPA. The DQO process helps to define the purposes for which environmental data will be used and sets guidelines for designing a data collection program that will meet the Agency's regulatory objectives. Once DQO's have been developed, and a design for the data collection activity expected to achieve these objectives has been selected, DQO's are used to define quality assurance (QA) and quality control (QC) programs that are specifically tailored to the data collection program being initiated. A "QA Project Plan" is prepared, documenting all of the activities needed to ensure that the data collection program will produce environmental data of the type and quality required to satisfy the DQO's. Without first developing DQO's, a QA program can only be used to document the quality of data obtained, rather than to ensure that the quality of data obtained will be sufficient to support an Agency decision.

The DQO process consists of three stages with several steps in each stage. The first two stages result in proposed DQO's with accompanying specifications and constraints for designing the data collection program. In the third stage, potential designs for the data collection program are evaluated. Stage III results in the selection of a design that is compatible with the constraints and is expected to meet the DQO's. The process is meant to be iterative between stages, if the proposed constraints from Stage I, the proposed DQO's from Stage II and the design alternatives analyzed in Stage III are found to be incompatible.

STAGE I: Define the Decision

This stage is the responsibility of the decision maker. The decision maker states an initial perception of what decision must be made, what information is needed, why and when it is needed, how it will be used, and what the consequences will be if the information of adequate quality is not available. Initial estimates of the time and resources that can reasonably be made available for the data collection activity are presented.

STAGE II: Clarify the Information Needed for the Decision

This stage is primarily the responsibility of the senior program staff with guidance and oversight from the decision maker and input from technical staff. The information from Stage I is carefully examined and discussed with the decision maker to ensure that senior program staff understand as many of the nuances of the program as possible. After this interactive process, senior program staff discuss each aspect of the initial problem, excercising their prerogative to reconsider key elements from a technical or policy standpoint. The outcome of their work, once explained and concurred upon by the decision maker, leads to the generation of specific guidance for designing the data collection program. The products of Stage II include proposed statements of the type and quality of environmental data required to support the decision, along with other technical constraints on the data collection activity that will place bounds on the search for an acceptable design in Stage III. These outputs are the proposed DQO's.

STAGE III: Design the Data Collection Program

This stage is primarily the responsibility of the technical staff but involves both the senior program staff and the decision maker to assure the outputs from Stages I and II are understood. The objective of Stage III is to develop data collection plans that will meet the criteria and constraints established in Stages I and II. All viable options should be presented to the decision maker. It is the prerogative of the decision maker to select the final design that provides the best balance between time and resources available for data collection and the level of uncertainty expected in the final results.

The following text lays out the steps that are performed in the first two stages of the DQO process. It is during these stages that proposed DQO's for a data collection activity are developed and stated in such a way that they can be used in Stage III. On close examination, the reader will discover that several of the steps can occur simultaneously, especially in Stage I. Furthermore, there are some situations in which the process does not have to include all steps. For example, when enforcement or compliance monitoring programs are being developed for regulations already in place, many of the steps described in Stage I may have already been completed. Also, when activities in either stage reveal that new environmental data are not needed to make the decision, the process can be stopped.

The process described in this document is not the only way to develop DQO's. However, QAMS is convinced that offices will find the DQO process described in the following pages to be a logical and efficient approach to initiating the design of an environmental data collection program and its associated QA/QC program. Programs that implement the steps addressed in Stages I and II will find that their data collection programs are able to satisfy the needs of decision makers in a cost effective manner.

DESCRIPTION OF STAGES I AND II

Initial Assumptions

Two assumptions are needed to justify initiating the DQO process. These assumptions will be tested at several points during the process:

1) There is a regulatory or program decision to be made, and environmental data will be required for the decision.

   "Regulatory and program decisions" are decisions to take an action, such as to:

   - determine whether a regulation is needed;
   - develop or revise a standard or regulation;
   - issue or revise a permit;
   - find a permittee in or out of compliance;
   - take enforcement action;
   - study a problem further;
   - determine program policy, direction or priorities;
   - implement a corrective action program.

   This decision will involve many different inputs, or "elements" (e.g., information on the environment, public health, process and control technology, economy, and social and legal issues).

2) The DQO process is being initiated because there is an expectation that existing environmental data will not provide the information required and that new environmental data will be needed for the decision.

STAGE I

The steps involved in Stage I are listed below. The adequate completion of Step 1 is essential to the success of all subsequent steps. The remaining steps of Stage I can be completed to a greater or lesser degree. However, the extent to which the decision maker can provide the information required in Steps 2-5 will directly affect the efficiency of the DQO process and the number of iterations required to complete Stage II.

STAGE I: Step 1. Describe the Decision

- The decision maker gives a preliminary description of the decision for which environmental data are thought to be needed.

- This step provides an initial explanation of why environmental information is needed.

- It is important for the decision maker to provide as much background as possible on the regulatory or programmatic context of the problem.

STAGE I: Step 2. Describe the Information Needed for the Decision

- The decision maker describes his or her initial thoughts on all of the inputs that will be considered in making the decision. This step is the first opportunity for defining the "elements" of the decision, and provides an initial description of what information the decision maker feels will be needed for the decision.

- The initial description of the information needed for the decision does not need to be technical; it may simply be an identification of some characteristics of the environment, geographic scope, economy, industrial technology, and other social and legal concerns that are related to the decision.

- This step allows the decision maker to address general questions that will guide the data collection activity. Examples of such questions are:

  Do we need data from the entire U.S. or only densely populated cities?,

  Do we need information on the health effects of a pollutant, or only data on ambient levels?,

  During what time period (season, time of day, etc.) must data be collected?,

  Do we need to monitor sources or ambient concentrations?,

  What regulations would provide EPA broadest authority?

The level of detail in answers to questions such as these will increase later in the process. The purpose here is to place initial bounds on the problem, as seen by the decision maker.

STAGE I: Step 3. Define the Use of the Environmental Data

- After describing all of the inputs to the decision, the decision maker should explain how environmental information will be used in the decision.

- The explanation may be effectively phrased as a series of "if, then" statements. For example, "If data indicate that the pollutant of interest is present in the environment at levels potentially harmful to human health, then a decision will be made to regulate its use, set ambient or source standards, or ban the use of the substance entirely."

- The decision maker should also state his or her initial impression of the importance of the environmental data for making the decision, relative to the other inputs (not dependent on environmental data).

- This step is the first opportunity for testing the initial assumption that environmental data will be needed for the decision.

  - To the extent that it is possible to define how environmental data will be used in the decision, and that such data seem to be to be a significant input to the decision making process, the assumption that environmental data are needed has been tentatively confirmed and the DQO process should continue.

  - If it proves difficult to define how environmental data would be used in the decision, and such data seem not to be a significant input, then it may be appropriate to conclude that new environmental data are not needed and the DQO process should be terminated at this point.

STAGE I: Step 4. Define the Consequences of an Incorrect Decision Attributable to Inadequate Environmental Data

- The decision maker should try to imagine how environmental data might lead to an incorrect decision, and what the conseqences of making an incorrect decision might be.

- The possible environmental, public health, and economic consequences of the following two situations should be considered:

  - deciding to take an action when environmental data have incorrectly indicated that a problem exists (a "false positive");

  - deciding not to take an action when environmental data have incorrectly indicated that a problem does not exist (a "false negative").

If it is clear at this point that false negatives would be of more concern than false positives, or vice versa, this should be stated; otherwise, simply stating the possible consequences of each is sufficient.

STAGE I: Step 5. Statement of Available Resources

- The decision maker should provide an initial estimate of the amount of time, number of FTE's, and level of extramural funds that can reasonably be made available for the data collection program. This estimate should be based upon the decision maker's experience with data collection activities of the general type under consideration and knowledge of budgetary constraints.

- At this early point in the process, the purpose of these resource estimates is to provide gross guidance and to propose some initial constraints on the resources available for the data collection activity. The decision maker will have an opportunity to make more specific time and resource decisions during Stage III of the DQO process, when design/cost alternatives are available. The estimates generated during Stage I should be considered subject to modification pending the results of Stage III, when the balance between desired data quality, time and resources is quantitatively assessed and the decision maker can readily grasp the trade-offs inherent in different proposed options.

STAGE II

To enter Stage II, the information generated by the decision maker during Stage I must now pass to the senior program staff. The Stage I outputs, at minimum, should include statements of: the decision to be made, the information needed for the decision, why data are needed, how data will be used, and what the constraints are on time and resources. After making sure they understand the input of the decision maker, the senior program staff do a more rigorous evaluation of all aspects of the problem, present their findings to the decision maker and then work with the decision maker to specify constraints and to develop proposed DQO's for the data collection activity.

In those situations where regulations are already in place and the need for compliance and enforcement monitoring is being defined, Stage I activities may have been completed and the DQO process might be entered at Stage II. The decision maker's involvement is still important, and will focus on interpreting the data needs specified implicitly or explicitly by the regulations and determining the level of uncertainty tolerable in enforcement and compliance data.

STAGE II: Step 1. Break Down the Decision into Decision Elements

- The senior program staff should identify all of the questions that need to be answered to make the decision. The list will include, but should go beyond, questions identified by the decision maker in Stage I.

Answers to these questions will be referred to as "elements" of the decision in the remainder of the document.

- Each of the elements of the decision should be classified in one of two categories:

  - elements that are dependent on environmental data;

  - elements that are not dependent on environmental data.

The senior program staff should now identify the "significant" elements among those that are dependent on environmental data. The activities above may reveal that certain of the data-dependent elements will have a negligible contribution to the decision as compared to other data- or non-data-dependent elements. A data-dependent element is "significant" if it appears to be required for the decision.

- This step provides another opportunity for testing the assumption that environmental data will be needed for the decision; it is the first opportunity for the program staff to formally and rigorously address the issue.

  - If it is possible to identify significant elements that depend on environmental data, then the assumption has been tentatively confirmed and the DQO process should continue.

  - If it proves difficult to identify significant elements that depend on environmental data, then it may be appropriate to conclude that environmental data are not needed and to consider terminating the DQO process.

- From this point on, the DQO process will only address significant elements of the decision that are dependent on environmental data.

STAGE II: Step 2. Specify the Environmental Data Needed

- Specify the data that will be needed for each significant data-dependent element (i.e., the data needed to answer each question that requires data). The data should be specified in terms of the variables (e.g., specific pollutant(s)) for which quantitative estimates are desired and the matrix or medium in which they will be measured.

STAGE II: Step 3. Define the Domain of the Decision

- Define the "domain" to which the decision will apply. The domain is that portion of the environment or physical system, delineated by spatial and temporal boundaries, from which samples will be collected and to which the decision will apply. The domain typically consists of, and is restricted to, a particular medium (soil, air, etc.) or group of objects (people, factories, storage tanks, etc.) about which information is collected in order to arrive at some decision. If the decision will apply to a different or larger domain than that being considered in the study design, the decision will have to be qualified, since the degree to which the results will be representative of the larger domain is not quantifiable.

- Although it is recognized that this will be a first attempt at defining the domain of the decision, the definition should be as detailed as possible. The definition of the domain should contain the following information:

  - the definition must incorporate all of the important characteristics that distinguish the areas, time periods, or groups of objects that are part of the domain from those that are not;

  - the definition must specify the largest unit (area, time period, or group of objects) that the data will be used to represent and to which the decision will apply;

  - the definition must specify the smallest unit (area, time period, or object/group of objects) for which a separate decision might be made;

  - the definition must specify parts of the domain (e.g., distinct sub-areas, time intervals, or subgroups of objects) that are of special interest or importance in making the decision.

STAGE II: Step 4. Define the Result to Be Derived from the Environmental Data

- Define the result that will be derived through calculations or operations performed with the environmental data:

  - the result consists of analyzed environmental data used in making the decision;

  - the result will constitute an answer to the environmental question first posed in Stage I, Step 3 and formally stated in Stage II, Step 1.

- The definition of the result should include the following items:

  - the statistic(s) that will be used to summarize the data (e.g., mean, range, maximum);

  - for compliance and enforcement programs, the standard, "action level", or other value to which the summary statistic will be compared;

- for trends monitoring and research programs, the reference value (if any) to which the summary statistic will be compared (e.g., baseline values for detecting trends, background or control values for detecting environmental effects, or ambient concentrations of a pollutant that might be of concern);

- if possible, a statement of rationale for the mathematical or statistical procedures that will be used to derive the result.

- Increasing the level of detail with which the result is defined will improve the efficiency of later work in Stage III.

STAGE II: Step 5. Statement of the Desired Performance

- The collection of environmental data always involves some error. Error is an inherent characteristic of any sampling design, methods used for sample collection or sample analysis and statistics employed for raw data interpretation. With these potential sources of error in mind, the senior program staff works with the decision maker to establish limits on the total error that can be accepted in the results of the data collection program, in order to be able to use these results in the decision making process. This effort will build on the Stage I, Step 4 description of potential effects of data errors on the decision by establishing the acceptable probability of such effects and the level of concern they would cause the decision maker in making the decision.

- This step is referred to as establishing the desired performance of the data collection program. Performance, as the term is used here, refers to the likelihood (probability) that the data collected will correctly and accurately reflect the environmental characteristics being measured. Each design will have its own level of performance. The measure of performance appropriate to most monitoring programs is the probability of false positives (finding that a problem exists when in fact it does not) and false negatives (finding that a problem does not exist when in fact it does). The frequency with which false positives and false negatives occur will be a function of the total uncertainty associated with the result, based on the error contributed by both the analytical and sampling portions of the design.

  For example, if data are collected to determine compliance with some discharge standard, the combined error associated with sampling of the discharge from the facility (which varies in concentration in time and space), and analyses of the substance in the laboratory (using a method with imprecision and bias), may contribute to an incorrect compliance determination. The data may indicate that the facility is in compliance, when it is really out, or that the facility is out of compliance, when it is really in compliance. If enough is known about the variability of the discharge, a monitoring program can be designed that will limit the likelihood of both false positives and false negatives to acceptable levels.

- The following activities will lead to the specification of desired performance.

  - The program staff should describe situations for each data-dependent element in which the error associated with the environmental data collected might result in a false positive or a false negative. The same degree of control on uncertainty may not be required (or achievable) for all of the elements.

  - Working with the decision maker, the senior program staff should rank these situations according to the relative level of concern that the actual occurrence of each would cause.

  - The magnitude of concern over each false positive and false negative situation should be considered in ranking how important each situation is to the decision maker in making the decision. While subjective to a certain degree, concern is related to the potential effects of being in error. For example, if data are collected to determine if a standard has been exceeded and both the seriousness of the health effect and size of the population affected go up with increasing concentration of the regulated substance, the amount of concern over false negatives would increase as the magnitude of the potential exceedence increases.

- After the relative rankings have been established, the probability of occurrence that would be acceptable for each situation should be expressed quantitatively. Stating the desired performance in quantitative probability terms is important in order to establish a goal for designing the data collection program and to compare the performance of potential alternative designs. It should be stressed that values assigned at this time may need to be adjusted if no design can be found that controls false positives and false negatives to the desired levels under the existing constraints. If this happens, the decison maker may consider the option of increasing resources, or accepting greater chances of being in error than originally desired.

  - It will be helpful to start with the two situations that would cause the greatest and the least concern, and then "work to the middle." In other words, start by identifying the situation that you feel should never occur (such as not detecting a life-threatening level of a substance if it is there), and assign an acceptable probability which reflects your level of concern over this situation, such as 1 in 10^6 (one chance in a million). Next, identify situations that would cause very little concern if you miss them (minor, infrequent exceedences of low magnitude) and assign acceptable probabilites to these situations (e.g., 1 chance in 10 might be acceptable, depending on the consequences of missing a level just above the standard). Then proceed to assign acceptable probabilities to all of the other situations, checking to make sure that the assigned probabilities are consistent with the order in which the situations were ranked.

- The probability statements for each situation should then be combined into a formal statement of the levels of uncertainty that can be tolerated in the result (a separate statement should be developed for each significant data-dependent element). This formal statement might take the form of a table which contains a listing of possible situations (false positives and false negatives), along with the acceptable probability associated with each. Whatever form the formal statement takes, the information should be sufficient to allow design experts in Stage III to understand the level of uncertainty that can be tolerated in the result to be derived from data. Results with a higher level of uncertainty may not be of sufficient quality to support the decision to be made.

STAGE II: Step 6. Determine the Need for NEW Environmental Data

- Determine whether there are any existing environmental data that could provide some of the information needed for the data-dependent element. For example, the following questions could help begin the search for existing data: Are data available on the appropriate variables in the media of interest (identified in Stage II, Step 2)? Were the available data taken from the locations of interest? Were the available data taken during the season, or time period of interest? In summary, do the available data adequately represent the domain of the decision?

- Using the performance criteria developed in Step 5 above, determine quantitatively whether the existing environmental data will be sufficient for the decision.

    - This should be done if QC data are available to assess the level of uncertainty associated with the existing data. If QC data do exist, one must determine whether the level of uncertainty in the results derived from existing data is within acceptable bounds. If an extensive quantitative analysis is required to determine adequacy, then this should be an early step performed by technical staff in Stage III.

- Identify all of the new environmental data that will be needed in order to provide information not provided by the existing data.

STAGE II: Step 7. Summary of Stage II Outputs: Statement of the Proposed DQO's

- The purpose of this step is to ensure that sufficient documentation of the results of Stages I and II is produced and provided to the technical design experts who will be responsible for the bulk of Stage III activities. This summary is, in the most complete sense, the proposed Data Quality Objectives for the data collection activity. It should contain all of the quantitative information required by technical design experts to unambiguously proceed with developing and evaluating alternative designs. Each of these designs should reflect the quality of data specified by the decision maker to answer each data dependent question.

- The summary should include final statements by the senior program staff, approved by the decision maker, which include:

  - A clear statement of the decision to be made.

  - Initial estimates of the time, FTE's and dollar resources that can reasonably be made available for the data collection effort.

  - A description of the new environmental data to be collected for each significant data dependent element stated in terms of the variables that will be measured and the medium from which samples will be collected.

  - The domain of the decision including: parts of the domain of particular interest to the decision maker and data user(s); the smallest part of the domain for which a separate result will be calculated; and the largest unit (area, time period, or group of objects) which the data will be used to represent and to which the decision will apply.

  - The way in which the result for each data dependent element will be stated, including the statistic(s) that will be used to summarize the data, any standards, reference values or action levels to which the statistic will be compared, and a statement of the rationale for and specifics of the mathematical and/or statistical procedures that will be used to derive the result.

  - A statement of the desired performance for each data dependent element, which specifies in as much detail as possible acceptable probabilities associated with false positive and false negative situations of varying degrees of magnitude. This statement should indicate the level of uncertainty which can be tolerated to use the result in the decision making process.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D C 20460

OFFICE OF
RESEARCH AND DEVELOPMENT

SUBJECT: Individual Office Institutionalization of Data Quality Objectives

FROM: Vaun A. Newill, Assistant Administrator for Research and Development (RD-672)

Milton Russell, Assistant Administrator for Policy, Planning, and Evaluation (PM-219)

TO: See Addressees Below

The Deputy Administrator's memorandum states his intentions that individual Offices begin to institutionalize Data Quality Objectives (DQO's) for all significant environmental data collection activities. Recently, we met with your program office Assistant Administrators, the Administrator and Deputy Administrator to discuss the Deputy Administrator's memorandum. In this meeting, we concluded that we discuss with each of you the next steps in implementing the DQO process.

We see these steps as follows:

- Introduce you and your senior program staff to:
  - the DQO process,
  - DQO's as an important management tool,
  - the value of DQO's to your program,
  - the importance of your senior management's direct involvement and attention in developing your DQO, and
  - answer questions that arise regarding the DQO process and its application.
- Exchange views on how we may best implement the Deputy Administrator's request for DQO institutionalization.
- Review candidate environmental data collection selections for your office so that we may agree on a final selection.

- o Identify lead individuals within each of your offices to:
    - be the decision maker in DQO development, and
    - coordinate information flow to you.

  This individual should be a senior line manager responsible for recommending to you alternative policies and designs for carrying out the data collection effort.

- o Identify each of our expectations of what a successful DQO application will be and how success may be assessed.

We would like these lead individuals to define a set of interim outputs and to establish scheduled dates for completing your DQO. A key element in achieving the Deputy Administrator's request is that we agree to a mechanism for following DQO implementation progress and surfacing problems as they arise for resolution.

We look forward to working with you on this ambitious and valuable effort. We will be working with your office to arrange a date for this important meeting.

Attachment (Barnes Memo, 11/14/86)

Addressees:
Rebecca Hanmer, DAA, OW (WH-556)
Jack W. McGraw, DAA, OSWER (WH-562A)
Don R. Clay, DAA, OAR (ANR-443)
Victor J. Kimm, DAA, OPTS (TS-788)
Stanley L. Laskowski, DRA, Region III

cc: Thomas L. Adams, AA, OECM (LE-133)
Robert S. Cahill, AA, ORO (A-101)
David P. Ryan, Acting Comptroller (PM-225)
Sheldon Meyers, Director, ORP (ANR-458C)
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Stanley Blacker, Director, QAMS (RD-680)
John Warren, OPPE-SPB (PM-223)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D C 20460

NOV 14 1986

OFFICE OF
THE ADMINISTRATOR

MEMORANDUM

SUBJECT: Agency Institutionalization of Data Quality Objectives

TO: See Below

The process of developing and implementing Data Quality Objectives (DQO's) has been underway in EPA since the Deputy Administrator's DQO policy memorandum to the AAs was issued in May 1984. The DQO's, one of the key elements of the Agency's quality assurance program, are explicit statements of the quality of data needed to support a regulatory decision. As you know, the DQO process is a key tool in making our extensive data collection activities cost effective, but I believe that progress in the institutionalization of the DQO process can be improved.

The value and benefits that can result from following the three-stage DQO process are real and worth extra attention from senior managers. Accordingly, I am:

- asking the Assistant Administrator for Research and Development (the Agency lead for quality assurance) and the Assistant Administrator for Policy, Planning and Evaluation to work with each program office Assistant Administrator to:
  - assure that each program office understands what the DQO process is and its utility,
  - reach agreement with each appropriate National Program Office and Region prior to data collection on developing DQO's for their proposed major data collection activities (see attachment), and
  - develop a reasonable schedule for preparing DQO's for each major data collection activity;
- requesting that an appropriate staff person in each AA's (or RA's) office be assigned the responsibility for working with ORD, OPPE, and the program to assure that DQO's are prepared; and

- requesting that the AAs for ORD and OPPE periodically discuss the status with each program AA on developing their individual DQO's, and for ORD to report each quarter to me in writing on individual DQO progress.

The staffs of ORD and OPPE will be available to provide technical assistance in understanding what should go on in each step of the DQO process, but the development of the required DQO's will remain the responsibility of the program office. From time to time, I will ask that each program office report on progress or problems in the biweekly ATS meetings. Prior to the actual commitment of resources for establishing major field data collection operations, I feel it would be valuable if the DQO team (ORD, OPPE and the responsible program office) brief the AAs for ORD and OPPE on the developed DQO's.

The DQO concept is not new. It is simply the institutionalization of sound management planning. I am convinced that DQO's should provide benefits both in cost-savings and improved data quality. The steps that I have outlined here for these selected environmental data collection activities should facilitate the institutionalization of DQO's for all ongoing and future significant data collection activities. I am looking forward to following your progress on this ambitious and valuable effort.

Jim Barnes
A. James Barnes
Deputy Administrator

Attachment

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Lawrence J. Jensen, AA, OW (WH-556)
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cc: Francis S. Blake, General Counsel (LE-130)
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Partial Listing of Major Agency Environmental Data Collection Programs

- Next Candidates for DQO's

  - Office of Air and Radiation

    * Radon (Indoors)† [ORP]
    * Air Toxics [OAQPS]

  - Office of Solid Waste and Emergency Response

    * RI/FS (Superfund) [OERR]
    * Ground Water Monitoring at Owner/Operator Facilities [OSW]
    * Leaking Underground Storage (Exempt) Tank† [OUST]

  - Office of Pesticides and Toxic Substances

    * Pesticides in Drinking Water [OPP/ODW/ORD]

  - Office of Water

    * Pesticides in Drinking Water [ODW/OPP/ORD]
    * NPDES Organic Chemical Industries [OWEP]
    * Basic Surface Water Monitoring [OWRS]

  - Regions

    * Chesapeake Bay Study [Region III]

  - Office of Research and Development††

- How the above candidate projects were selected:

  - Major Agency data collection activity ($, time, FTE's)
  - At or near the beginning of the project planning phase
  - Represent each of the program offices and significant environmental data collection projects

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†DQO implementation underway through joint agreement among Program, ORD, and OPPE.

††Because of the research nature of data collection activities conducted by ORD, ORD is on an active parallel track in implementing DQO's.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C 20460

NOV 14 1986

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MEMORANDUM

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 24 1984

OFFICE OF
THE ADMINISTRATOR

MEMORANDUM

SUBJECT: Data Quality Objectives

FROM: Alvin L. Alm
Deputy Administrator

TO: Assistant Administrators

On April 3, 1984, EPA Order 5360.1, "Policy and Program Requirements to Implement the Quality Assurance Program" was issued. In my accompanying memorandum of April 17, I identified two major steps that have to be taken in order to assure the reliability of environmental measurements. One of these steps requires a data user to specify the quality of data he or she needs. In the Order, each National Program Manager is responsible for establishing data quality acceptance criteria (i.e., data quality objectives) for all of their projects [4b(2)].

Defining data quality objectives will not be easy. They need to be defined during the planning stage of any data collection activity. Otherwise, too little quality assurance will cause data to be of insufficient quality, or too much quality assurance will result in unnecessary costs. Your personal involvement in defining data quality objectives is needed in order to obtain the important policy perspective on how that data needs to be used in the regulatory process. I request that you be an active participant during the stages where policy guidance will be crucial. I have attached a brief statement describing data quality objectives in more detail.

The Quality Assurance Management Staff (QAMS) has been working with key individuals from the Air, Water, Toxics, Superfund, and Research Offices to develop example data quality objectives. These examples should be completed by July 1984 and will provide a "blueprint" for developing data quality objectives for each new and existing data collection activity. As a result of this effort, several of the offices will have individuals quite knowledgeable about how to define data quality objectives.

While we are awaiting completion of the example data quality objectives, I request that your staff work with QAMS to develop a listing in priority order of those significant ongoing data collection activities for which data quality objectives need to be defined. One basis for establishing priorities should be the priority list in "Agency Operating Guidance--FY 1985-1986." Many of these items depend on analysis of environmental data. Once the examples are completed and all of us have a clear understanding of what is required, I request that your staff work with QAMS to prepare by September 1984 a schedule for developing data quality objectives for each of your significant ongoing environmental data collection activities. Beginning in September 1984, data quality objectives should be an integral part of each significant new data collection activity.

Quality assurance is an important mechanism for ensuring that all EPA decisions can be supported by a sound data base. Data quality objectives are a key element in that mechanism. Your personal assistance in this undertaking is desired.

Attachment

bcc: AA/ORD RF
ORD PENDING FILE
OMSQA CHRON FILE
QAMS CHRON FILE
AUTHOR FILE
AX (3 COPIES)

Prepared by: RD-680/S.Blacker/rar/3100WSM/382-5763/05-09-84/
S.Blacker Disl #2

QAMS STATEMENT ON DATA QUALITY OBJECTIVES

Using EPA Order 5360.1, "Policy and Program Requirements to Implement the Mandatory Quality Assurance Program," the Quality Assurance Management Staff (QAMS) of ORD will require, as a necessary element in preparing quality assurance (QA) project plans for each major data collection effort, that data quality objectives (DQO) be established. The responsibility for developing data quality objectives will reside with primary data users; these are, in most cases, the headquarters offices responsible for administering EPA programs. QAMS will depend on data quality objectives as the tool to ensure that programs have clearly defined before the fact the level of QA that must be included in data collection efforts.

What are data quality objectives?

Data quality objectives are descriptors of the quality of data needed to support a specific environmental decision or action. Quantitative and qualitative descriptors of data quality must be considered in order to determine whether data are appropriate for a particular application. The person or organization that will use the data must decide what quality of data is needed for the specific application intended.

Data quality objectives are target values for data quality and are not necessarily criteria for the acceptance or rejection of data. If data quality objectives are not met, it is still the responsibility of the data user to consider the limitations of the data and determine whether they may be used for the intended purpose.

What if data quality objectives are not developed?

Methods and procedures may be selected for a project without consideration of data quality objectives. In some cases when DQO's are not used, data quality will exceed that required causing more resources to be spent than necessary. In other cases, data quality may be less than that required and may be useless if the information needed to characterize data quality was not obtained. DQO's are a starting point for cost-effective project design.

What are the responsibilities of QAMS and the Program Offices?

QAMS will develop guidance on data quality objectives with the help of the Program and Regional offices. The guidance will explain what data quality objectives are and will discuss the types of descriptors available for the various data applications. The guidance will include examples showing how DQO's are developed for different media and programs. QAMS will also develop guidance that specifies the technical materials that Program Offices need to provide to the organizations responsible for data collection.

Employing this guidance, Program Offices will be responsible for establishing data quality objectives for each of their major monitoring programs. This will require a careful consideration of what data are needed for each major program, why the data are needed, and how the data will be used. Program Offices will also be responsible for preparing the technical guidance required by data collectors to produce data meeting the established data quality objectives.

QAMS will perform program plan reviews and management audits to assure that Program Offices establish and use data quality objectives. QAMS will not evaluate the intended use of the data or the appropriateness of the established data quality objectives. QAMS will determine only whether data quality objectives have been established, whether data collection programs have been designed so the necessary descriptors of data quality will be collected, and whether the data and associated descriptors of quality have been collected in a manner consistent with the data quality objectives.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 17 1984

OFFICE OF
THE ADMINISTRATOR

MEMORANDUM

SUBJECT: EPA Order 5360.1, "Policy and Program Requirements to Implement the Quality Assurance Program"

FROM: Alvin L. Alm
Deputy Administrator

TO: Addressees

One of my major goals is to ensure that all decisions by EPA can be supported by a sound data base. An important step toward achieving this objective is to require that quality assurance become an integral part of all data collection activities. Quality assurance is the total integrated program for assuring the reliability of environmental measurements and consists of multiple steps undertaken to ensure that all acquired data are suitable for the user's intended purpose. Two of the major steps are: the user must first specify the quality of data he needs; then the degree of quality control necessary to assure that the resultant data satisfies his specifications must be determined. Central to this process is assuring that the data is of known quality. The quality of data is known when all components associated with its derivation are thoroughly documented, such documentation being verifiable and defensible.

In order to establish quality assurance solidly in all data collection activities, the important step of issuing this order on quality assurance is being taken. The implementation of the elements in this order will require dedication and hard work by the Quality Assurance Management and Special Studies Staff, by quality assurance officers throughout the Agency, and by senior management. This order identifies the goals, objectives, and general responsibilities of each program area. To carry out the order, specific policy and technical guidance materials need to be prepared. I will be following that progress.

The attached order reflects my commitment to the Agency's QA program and to the promotion of good science in all EPA monitoring and measurement activities. Therefore, I expect that each of you work cooperatively to ensure that the appropriate level of quality assurance is embedded in all data collection undertaken by or for the Agency.

Attachment

POLICY AND PROGRAM REQUIREMENTS TO IMPLEMENT THE MANDATORY QUALITY ASSURANCE PROGRAM

1. PURPOSE. This Order establishes policy and program requirements for the conduct of quality assurance (QA) for all environmentally related measurements performed by or for this Agency.

2. BACKGROUND. Agency policy requires participation in a centrally managed QA program by all EPA organizational units supporting environmentally related measurements. Under Delegation of Authority 1-41, "Mandatory Quality Assurance Program" (dated 4/1/81), the Office of Research and Development (ORD) is the focal point in the Agency for quality assurance policy and is responsible for developing QA requirements and overseeing Agencywide implementation of the QA program. ORD established the Quality Assurance Management and Special Studies Staff (QAMSS) to serve as the central management authority for this program. The QAMSS activities involve the development of policies and procedures; co-ordination for and direction of the implementation of the Agency QA program; and review, evaluation, and audit of program activities involving environmental monitoring and other types of data generation.

The Agency QA program embraces many functions including: establishing QA policy and guidelines for development of program and project operational plans; establishing criteria and guidelines for assessing data quality; serving as a QA information focal point; auditing to ascertain effectiveness of QA implementation; and identifying and developing QA training programs.

3. GOALS AND POLICY. The primary goal of the QA program is to ensure that all environmentally related measurements supported by the EPA produce data of known quality. The quality of data is known when all components associated with its derivation are thoroughly documented, such documentation being verifiable and defensible. It shall be the policy of all EPA organizational units to ensure that data representing environmentally related measurements are of known quality. Decisions by management rest on the quality of environmental data; therefore, program managers shall be responsible for: 1) specifying the quality of the data required from environmentally related measurements and 2) providing sufficient resources to assure that an adequate level of QA is performed. All routine or planned projects or tasks involving environmentally related measurements shall be undertaken with an adequate QA project plan that specifies data quality goals acceptable to the data user and assigns responsibility for achieving these goals.

In discharging its responsibility for implementing the Agency-mandated Quality Assurance Program, the ORD/QAMSS will strive for consensus by submitting for review proposed policies and procedures to affected program offices and regions. Responsibility for adjudication of unresolved issues, with respect to the above and QAMSS conducted audits, will be at the lowest level of authority consistent with the scope of the issues. The QAMSS will refer issues which remain unresolved at lower levels of authority to the AA/ORD for decision, after consultation with the appropriate AA or RA.

The following activities are basic to the implementation of the QA program:

a. Preparation and annual update of a QA program plan based on guidelines established by QAMSS.

b. Development of a QA project plan for all projects and tasks involving environmentally related measurements in accordance with guidelines established by QAMSS.

c. Assuring implementation of QA for all contracts and financial assistance involving environmentally related measurements, as specified in applicable EPA regulations, including subcontracts and subagreements.

d. Conducting audits (system, performance evaluations, data quality, bench, etc.) on a scheduled basis of organizational units and projects involving environmentally related measurements.

e. Developing and adopting technical guidelines for estimating data quality in terms of precision (variability), bias (accuracy), representativeness, completeness and comparability, as appropriate, and incorporating data quality requirements in all projects and tasks involving environmentally related measurements.

f. Establishing achievable data quality limits for methods cited in regulations based on results of methods evaluations arising from the methods standardization process, e.g., ASTM Standard D2777-77.

g. Implementation of corrective actions, based on audit results, and for incorporating this process into the management accountability system.

h. Provision for appropriate training based on perceived needs, for all levels of QA management, to assure that QA responsibilities and requirements are understood at every stage of project implementation.

4. RESPONSIBILITIES.

a. In conformity with the oversight responsibility for the mandatory QA program, the AA/ORD shall:

(1) Establish Agency policies and procedures for implementing the mandatory QA program.

(2) Provide guidance for determining precision, bias, representativeness, completeness, and comparability of data.

(3) Review QA Program Plans from Agency components involved in environmentally related measurements.

(4) Conduct QA audits of all organizational units supporting environmentally related measurements based on established audit criteria and procedures.

(5) Recommend corrective actions, based on audit results, for inclusion in the management accountability system.

(6) Establish achievable data quality limits for methods provided by ORD for citation in regulations, based on results of methods evaluations arising from the methods standardization process, e.g., ASTM Standard D2777-77, to help project officers define data quality goals.

(7) Serve as the Agency QA information focal point.

(8) Develop generic training programs, based on perceived needs, for all levels of management to assure that QA responsibilities and requirements are understood at every stage of project implementation.

(9) Ensure that all ORD investigations involving data collection are covered by an acceptable QA plan with resources adequate to accomplish program objectives.

(10) Ensure that deficiencies highlighted in review of ORD program plans or in audits of ORD components are appropriately addressed.

b. In accordance with policies and procedures established by AA/ORD, National Program Managers shall:

(1) Ensure that QA is an identifiable activity with associated resources adequate to accomplish program goals in the development and execution of all projects and tasks, both intramural and extramural, involving environmentally related measurements.

(2) Ensure that appropriate QA criteria are included in operating guidance.

(3) Establish data quality acceptance criteria for all projects and tasks conducted by the program office.

(4) Ensure that an adequate degree of auditing is performed to determine compliance with QA requirements.

(5) Ensure that deficiencies highlighted in audits are appropriately addressed.

(6) Ensure that all projects and tasks involving environmentally related measurements are covered by an acceptable QA project plan and that the plan is implemented.

(7) Identify program-specific QA training needs and provide for the required QA training.

c. In accordance with policies and procedures established by AA/ORD, Regional Administrators shall:

(1) Ensure that QA is an identifiable activity with associated resources adequate to accomplish program and regional goals in the development and execution of all projects and tasks involving environmentally related measurements, both intramural and extramural.

(2) Ensure that QA guidelines are specified for estimating data quality in terms of precision, bias, representativeness, completeness, and comparability, for all environmentally related measurements which meet the operating guidance established by the program offices.

(3) Establish data quality acceptance criteria for all projects and tasks initiated by the Region.

(4) Ensure that all projects and tasks involving environmentally related measurements are covered by an acceptable QA project plan and that the plan is implemented.

(5) Ensure that an adequate degree of auditing is performed to determine compliance with QA requirements.

(6) Ensure that deficiencies highlighted in audits are corrected expeditiously.

(7) Identify program-specific QA training needs and provide for the required QA training.

d. The AA for Administration shall establish a mechanism for incorporating QA in the Agency's planning and budgeting cycle.

5. DEFINITIONS. The following terms have special meanings in relation to this Order.

(a) Documentation. The use of documentary evidence; a written record furnishing information that a procedure has been performed. When applied to environmentally related measurements it includes all calculations related to sampling design; all steps in the chain of custody, where appropriate; and all notes and raw data generated in the sampling, analysis, or data validation process.

(b) Defensible. The ability to withstand any reasonable challenge related to veracity or truthfulness.

(c) Environmentally Related Measurement. Any laboratory or field data gathering activity or investigation involving the determination of chemical, physical, or biological factors related to the environment.

The following are representative examples of environmentally related measurements. Data collection or investigation of chemical, physical, or biological factors for determination of:

(1) pollutant concentrations from sources, in the ambient environment, or pollutant transport and fate;

(2) response of organisms to pollutants;

(3) the effects of pollutants on human health and on the environment;

(4) risk/benefit analysis;

(5) environmental or economic impact.

(6) the environmental impact of cultural and natural processes;

(7) pollutant levels, exposure levels, etc., used in modeling.

(d) Organizational Unit. Any administrative entity (national program office, regional office, ORD or NEIC laboratory) which engages in environmentally related measurements.

(e) Project. An organized undertaking or specified unit of investigation involving environmentally related measurements.

(f) Quality Assurance. The total integrated program for assuring the reliability of monitoring and measurement data.

(g) Verifiable. The ability to prove or substantiate any claim or result related to the documented record.

6. ADDITIONAL REFERENCE. This Order will be amplified by a detailed implementation plan.

Seymour D. Greenstone, Acting

Howard M. Messner
Assistant Administrator
Office of Administration and Resources Management